

Office of the National Coordinator for Health IT Governance RFI
Establishing a Governance Mechanism for the Nationwide Health Information Network
HIT Policy Committee (HITPC) Comments

General Comments:

The ultimate test of governance is to enable trust and the flow of information such that data follows the patients across any organizational or technology boundaries, enabling them and their caregiver(s) to make the appropriate decisions.

Nationwide governance is needed to reduce the cost of exchange, and eliminate the need for redundant local or otherwise limited governance. However, because the technology is still nascent, governance should not restrict innovation and should be responsive to the evolution of processes of exchange.

The HITPC recommends that governance seek to achieve a balance, recognizing that there is not yet a mature health information exchange marketplace where market checks and balances could limit anti-competitive behavior, so some intervention to protect the public interest is required. In the early stages, it is possible that one or more players establishes a dominance which is counter to the public interest, and it could be difficult to correct the situation because changing vendors and systems can be costly and complicated for end users. On the other hand, health information exchange is not a utility that requires strong regulation.

Business models are still evolving. The HITPC recommends that ONC develop more information on market forces and monitor the HIE connectivity space to ensure that consumer interests are protected.

Establishing a Governance Mechanism

Question 1: Would these categories comprehensively reflect the types of CTEs needed to govern the nationwide health information network? If not, what other categories should we consider?

Question Context: The question solicits input on the CTE categories ONC has proposed: Safeguards, Interoperability, and Business Practices.

Yes, these three categories are valid.

However, the HITPC is concerned that there is a level missing in general. Many of the CTEs are expressed at the level of an accreditation or certification criteria. The HITPC recommends that the governance process should first focus on establishing and defining the policy objectives in and across each category. There should subsequently be a process for identifying the detailed accreditation/certification criteria that would achieve the policy objective, and which would then be validated by an accreditation or certifying body. The policy objectives are likely to change only slowly over time whereas the associated standards, implementation guidance and accreditation and certification criteria will be subject to more rapid change. The rule should describe a specific process for developing, maintaining and revising accreditation and certification criteria associated with the policy level CTEs, which may be different from validation of other CTEs.

The HITPC notes that the applicability for Safeguard and Business Practice CTEs is broad across multiple categories and types of exchange, but the applicability of Interoperability CTEs is focused on the business and clinical purpose for which the Interoperability CTE is intended. In addition, for Interoperability CTEs, there is a tradeoff between ensuring interoperability and being open to innovation and change. Accordingly, we recommend that most Safeguard and Business Practice CTEs be applicable broadly to NVEs. Interoperability CTEs should be applied to NVEs where relevant to their HIE model, and can be applied on a modular basis. Certification to an Interoperability CTE should not constrain the ability of the NVE to use other

standards and implementation guidance, including “**Emergence**” phase standards and implementation guidance, to meet the policy objectives defined by the Interoperability CTE.

The HITPC requests that ONC provide more detail on the modules that might be certifiable.

The HITPC believes that the proposed CTEs are sufficient for creating a governance structure for the nationwide health information network. As outlined in response to **Question 56**, the HITPC believes that a process for addressing grievances should be included in governance.

The HITPC does not believe that it would be appropriate or necessary for federal imposition or participation in the daily deliberations of each CTE.

Establishing a Governance Mechanism

Question 2: What kind of governance approach would best produce a trusted, secure, and interoperable electronic exchange nationwide?

Question Context: Are there other approaches to governance that ONC should consider for the achieving the policy aim of trusted, secure and interoperable electronic exchange?

(In formulating a response, the HITPC thought it appropriate to group Question 2 along with Questions 4 and 7): The HITPC believes that it’s important to first define success criteria. The objective of such criteria would be to identify an approach that includes but is not limited to : is cost effective in establishing interoperability and trusted exchange; is participative and accepted by a broad range of stakeholders (including consumers); raises the level of standards and interoperability maturity in the healthcare system and the associated level of real-world interoperability within and among NVEs; is sufficiently flexible to allow

for dynamic changes in the market and in technologies; and helps states fulfill their responsibilities for their citizens without having to create structures of their own. A voluntary approach would be sufficient if, as the HITPC expects, other incentives are tied to them by other public or private entities, e.g. if Federal agencies make validation a condition of exchanging with them, or if companies make validation a condition in their business contracts.

The HITPC also reaffirms the nine principles of sound governance that were accepted by the HITPC in December 2010, and which are mentioned in the RFI Preamble (p. 23).

The HITPC believes that a governance approach with validation and certification processes similar to those followed for electronic health record certification would create trusted, secure and in <http://blogpro.com/wp-content/uploads/2007/06/windowslivewriterenterposttitlehere-b6a9clip-image0027.jpg> interoperable electronic exchange nationwide.

As noted in response to question 56, establishing an overarching policy for grievances as well as transparent and consistent accreditation and validation policies followed by all CTEs and NVEs operating in every state and territory will facilitate interoperability and encourage exchange.

The HITPC recommends that ONC identify other potential incentives, such as Meaningful Use.

Establishing a Governance Mechanism

Question 3: How urgent is the need for a nationwide governance approach for electronic health information exchange? Conversely, please indicate if you believe that it is untimely for a nationwide approach to be developed and why.

Question Context: Why is it important for ONC to exercise its statutory authority to establish a governance mechanism now?

There is a need for a rational nationwide governance framework. Absence of nationwide governance has not prevented the establishment of health information exchange, but the disparate efforts to create local, regional and statewide governance approaches has increased the cost and burdens substantially. In addition, the fragmentation of governance methods and approaches has increased the time, cost, and complexity of exchange-to-exchange governance. The framework should be lightweight initially, leveraging the federal government's coordination function and convening role - facilitating dialogue and deliberation, while not limiting opportunities in the marketplace, including innovation in how to share health data.

The HITPC believes that there is an urgent need for a clear and robust governance structure to encourage participation in health information exchange nationwide.

Establishing a Governance Mechanism

Question 4: Would a voluntary validation approach as described above sufficiently achieve this goal? If not, why?

Question Context: As part of the governance mechanism, ONC is considering to include a validation process where entities that facilitate electronic exchange would, voluntarily, demonstrate compliance with the CTEs.

See response to Question 2.

Establishing a Governance Mechanism

Question 5: Would establishing a national validation process as described above effectively relieve any burden on the States to regulate local and regional health information exchange markets?

Question Context:

Yes, see answers to questions 2, 3, 4, and 7.

The HITPC believes that for states that have established their own validations processes for health information exchange, establishing a national validation process that offers clear and rigorous privacy, interoperability, and business requirements may allow them to discontinue these activities and therefore alleviate states' burden.

However, for states with stringent privacy and security requirements, it is likely they will feel a continued need for additional policies and regulation in addition to those included in the proposed governance RFI.

Establishing a Governance Mechanism

Question 6: How could we ensure alignment between the governance mechanism and existing State governance approaches?

Question Context:

Acceptance and alignment with State governance approaches should be a success criterion as noted in the answer to questions 2, 3, 4 and 7. In addition, existing and future grants have voluntary and other policy levers to encourage alignment with the national framework.

The HITPC recommends that ONC provide guidance to State legislatures on the direction of governance planning as early as possible, and follow up with additional guidance/information/education as appropriate in advance of the final rule.

The HITPC believes that clear and rigorous privacy, interoperability, and business CTE requirements will encourage support from public and private sectors as well as patient communities that will encourage states to align their own governance approaches with national standards.

The benefits will be particularly striking for interstate exchange. States pursuing interstate exchange will have a natural incentive to follow national guidance, reducing the need to develop specific policies or navigate conflicting state approaches.

The HITPC also believes that federal support for states transitioning to national governance—including assistance in conducting gap analysis to identify differences between state policies and national governance--will encourage states to align their policies with those of the proposed governance structure.

Establishing a Governance Mechanism

Question 7: What other approaches to exercising our authority to establish a governance mechanism for the nationwide health information network should we consider?

Question Context:

See response to Question 2.

Actors and Associated Responsibilities

Question 8: We solicit feedback on the appropriateness of ONC's role in coordinating the governance mechanism and whether certain responsibilities might be better delegated to, and/or fulfilled by, the private sector.

Question Context:

The HITPC agrees that ONC has a critical role to play in coordinating NWHIN governance. Specifically in:

- Endorsing and adopting CTEs and publishing guidance
- Facilitating input from/to the HIT Policy and Standards Committees on: revisions to CTEs, creating new CTEs, and retirement of CTEs
- Selection and oversight processes for an accreditation body
- Overall oversight of all entities and processes established as part of the governance mechanism.

The HITPC further believes that while ONC should ultimately oversee the process for selecting and overseeing an accreditation body, that the day-to-day validation and oversight of NVEs should fall to private sector entities (validation bodies) overseen by the accreditation body.

The HITPC recommends that ONC should play an arbiter role for any disputes that may arise between actors (accreditation body, validation bodies and NVEs), to reconcile disputes and ensure that the intent of the CTEs are followed in practice. The HITPC recommends that the dispute resolution process should be spelled out in the rule.

The HITPC recommends that ONC produce operationally defined descriptions of CTEs and be responsible for updating and clarifying those definitions over time

The HITPC recommends that other private entities may have a significant role to play in the adoption and use of standards and implementation specifications to support interoperability related to CTEs. The HITPC believes that entities currently playing roles in the certification of EHRs for Meaningful Use could also play a role in certification for governance. Also, as noted in reply to question #1, there would need to be accreditation bodies for the policy-oriented CTEs.

The HITPC recommends ONC add detail on the process of sanctions for NVEs' "bad actors" and violations where there are no existing legal remedies.

Actors and Associated Responsibilities

Question 9: Would a voluntary validation process be effective for ensuring that entities engaged in facilitating electronic exchange continue to comply with adopted CTEs? If not, what other validation processes could be leveraged for validating conformance with adopted CTEs? If you identify existing processes, please explain the focus of each and its scope.

Question Context:

The HITPC felt it was important to clarify the intent of this question as it was not clear what was intended by a "voluntary validation" process. The HITPC assumed that a "voluntary validation process" implies that it is voluntary (not required) for entities to adopt CTEs when exchanging PHI with other entities. The HITPC believes that a voluntary approach to validation will only work if there are sufficient incentives to encourage widespread participation, e.g. a requirement by Federal agencies that exchange partners be NVEs, incorporation of NVE status into MU requirements, safe harbors, financial incentives.

The HITPC has two recommendations:

Recommendation #1. Adoption of CTEs should be voluntary, and not required for all entities that desire to share PHI with other entities. HIOs and HISPs may elect to do this because it can generate more business. Individual providers may require HIOs/HISPs as a condition of doing business with them.

Recommendation #2. For entities (HIOs, HISPs, etc.) that wish to be recognized as NVEs, adoption and compliance with CTEs should be mandatory. Rationale. A voluntary process for obtaining validation would not be sufficient for entities to be recognized as compliant with federally determined CTEs. A voluntary process does not adequately support a trust framework to assure NVEs that other NVEs will conform to the safeguard, interoperability and business process CTEs. Further, without tight conformance to standards, the cost of participation would increase.

The HITPC recommends that the validation process likely would be a combination of certification, accreditation and self-attestation (further articulated in the subsequent question) and that a self-policing mechanism would be ineffective.

Actors and Associated Responsibilities

Question 10: Should the validation method vary by CTE? Which methods would be most effective for ensuring compliance with the CTEs? (Before answering this question it may be useful to first review the CTEs we are considering to adopt, see section “VI. Conditions for Trusted Exchange.”)

Question Context:

Yes. The HITPC further suggests that validation methods be mutable over time, allowing for changes in methodology to accommodate changes to CTEs

As a principle, the HITPC recommends that a certification process would generally be most appropriate for CTEs that focus on standards and specifications (“technical CTEs”), while accreditation processes should be adopted for policy and process CTEs. Accreditation for policy and process CTEs could be initially done through self-attestation. However, ONC should consider a more formal accreditation process (including audits and site visits), especially with respect to CTEs that don’t carry with them civil/monetary penalty implications/penalties or for which there are no other formal compliance processes (i.e., don’t invoke state of federal law such as HIPAA) Also, ONC might accept accreditation by other bodies, such as the Joint Commission or EHNAC.

The HITPC recommends rigorous validation to the extent applicable, necessary and possible, i.e. including but not limited to conformance testing for certification and site visits for accreditation The committee also believes that NVEs’ clients should be able to report them through a complaint process if the clients find the NVEs are not adhering to the CTEs.

Actors and Associated Responsibilities

Question 11: What successful validation models or approaches exist in other industries that could be used as a model for our purposes in this context?

Question Context:

The HITPC recommends that ONC consider a number of validation models from other industries and health care that may be models for NVE validation. Including the following:

- International Organization for Standardization (ISO) has some relevant experience with standards development and validation that could be examined .
- Payment Card Industry (PCI) supports a security standard validation process that has several similarities; including description of conditions for trusted exchange for payment transactions and objects (banks, individuals) involved in those transactions.
- TRUSTe and other website trust networks have a certification process to review website’s privacy policy and validate that websites adhere to TRUSTe’s privacy program requirements.

- ACORD – Supports a set of data standards for exchanging information on non-health care policies. The organization writes standards and has a certification process as a requirement to join ACORD. ACORD certifies people as well as entities to support exchange of information about property, reinsurance, etc.
- Within health care :
 - SureScripts certification
 - CLIA accreditation
 - EHNAC certification

Actors and Associated Responsibilities

Question 12: What would be the potential impact of this accreditation/validation body model on electronic health information exchange, in particular, on the volume and efficiency of exchange in local health care markets and provider confidence? What is the best way to maximize the benefit while minimizing the burden on providers or other actors in the market?

Question Context:

Comments:

Entities Eligible for Validation

Question 13: Should there be an eligibility criterion that requires an entity to have a valid purpose (e.g., treatment) for exchanging health information? If so, what would constitute a “valid” purpose for exchange?

Question Context:

No. The HITPC recommends that an entity need not be required to have a “valid purpose” for exchanging health information. However, there may be value in requiring a public statement of their purposes - which would invoke FTC jurisdiction - for all NVEs.

Rationale: It is hard to imagine a definition that is effective here that would anticipate all appropriate uses/purposes. Constraining exchange by listing a set of predetermined purposes could prevent exchange even for valid reasons. Also, having a “valid purpose” would likely not deter inappropriate exchange (for reasons that are “not valid”). It is more important that NVE state their intended purposes, and comply with federal and state law.

Entities Eligible for Validation

Question 14: Should there be an eligibility criterion that requires an entity to have prior electronic exchange experience or a certain number of participants it serves?

Question Context:

The HITPC does not believe that prior experience or volume of participants should be a criterion. Anything that would attend to these two criteria should be covered by other criteria. If the NVE is able to pass all other certification/accreditation criteria, then that should be sufficient.

Entities Eligible for Validation

Question 15: Are there other eligibility criteria that we should also consider?

Question Context:

The HITPC does not recommend that other eligibility criteria be considered.

There was no appropriate place for the following comment: the HITPC recommends that ONC carefully consider the following proposed eligibility criteria and reconsider it:

“Have not had civil monetary penalties, criminal penalties, or damages imposed, or have been enjoined for a HIPAA violation within two years prior to seeking validation”.

Eligibility criteria regarding HIPAA violation needs to be carefully considered and might be very problematic. Institutions may have policies in place to prevent inappropriate use, though still have “bad actors” within those institutions that violate those policies. Instead, ONC should consider criteria that require NVEs to create and enforce policies for “bad actors” within their own institutions. The HITPC is concerned that if this is not considered, entities that have been enjoined for a HIPAA violation, even if they put policies and processes in place to address the violation, would not be able to participate in the nationwide health information network in perpetuity.

The HITPC believes that several approaches may be appropriate for addressing this concern. If an NVE is in significant violation of HIPAA to the extent of being fined by the Federal Government, a two year ban might be reasonable. However, because of concern of the impact on patients whose data depends on that single entity, other enforcement options might be considered to enable the entity to keep functioning, e.g. having trustees assume management during the ban period.

The HITPC recommends that ONC review the language “enjoined for a HIPAA violation” in the NVE exclusion criteria and possibly replacing it with the language developed by the HITPC to describe circumstances when providers who have violated HIPAA should be excluded from participating in meaningful use.

Entities Eligible for Validation

Question 16: Should eligibility be limited to entities that are tax-exempt under section 501(c)(3) of the IRC? If yes, please explain why.

Question Context:

No. The HITPC does not recommend that eligibility be limited to tax-exempt entities. It should be broader, and open to entities that meet CTEs that would deem them suitable for exchange.

Stakeholders

Question 17: What is the optimum role for stakeholders, including consumers, in governance of the nationwide health information network? What mechanisms would most effectively implement that role?

Question Context:

The HITPC recommends that the following be considered in governance of the nationwide health information network:

A process should be created to settle matters or grievances that cannot be settled (for whatever reason) by NVEs or those entities that certify and/or accredit them. Stakeholders in this case may have an important role to play in dispute resolution.

Stakeholders should play a role in reviewing, updating, creating new and retiring old CTEs

The majority of nationwide health information network governance representatives should have experience managing, operating or governing HIE activities or initiatives to ensure there governance processes are overseen by individuals/entities with adequate and directly relevant experience.

Consumers have a very important perspective that needs to be considered and included in governance, but stakeholder engagement needs to be broader and include others.

The HITPC recommends that the Accrediting Body, the Validation Bodies, and NVEs be encouraged to have consumers represented in their own governance.

Monitoring and Transparent Oversight

Question 18: What are the most appropriate monitoring and oversight methods to include as part of the governance mechanism for the nationwide health information network? Why?

Question Context:

Appropriate monitoring and enforcement methods would rest on “robust validation” (accreditation and certification) in addition to the duties of regulating agencies such as OCR and FTC. Accreditation could include monitoring of self-attestation. The self-attestation processes should be spelled out in the rule. If accreditation by another body, such as the Joint Commission or EHNAC, is accepted, that body would have oversight of its own accreditation. ONC would retain overall oversight. Because disputes may arise between NVEs, or between other exchange parties, or between an NVE and a validation body, dispute resolution mechanisms will be critical to ensure accountability. The HITPC recommends that such mechanisms be included in the governance rule, but did not take a position on how much granularity there should be.

Monitoring and Transparent Oversight

Question 19: What other approaches might ONC consider for addressing violations of compliance with CTEs?

Question Context:

The validation bodies could have powers to impose remediation. There would need to be a process for (1) filing a validation complaint, (2) adjudicating that complaint, (3) a time period for the entity to respond to the proposed remediation, (4) a process to appeal the remediation. The ultimate ‘remediation’ would be to remove an NVE’s accreditation status, so there would need to be (5) a process to remove the NVE status from the entity if necessary. OCR and FTC would have authority in their domains. ONC should consider examples from other sectors, such as finance.

Monitoring and Transparent Oversight

Question 20: What limits, if any, would need to be in place in order to ensure that services and/or activities performed by NVEs for which no validation is available are not misrepresented as being part of an NVE’s validation? Should NVEs be required to make some type of public disclosure or associate some type of labeling with the validated services or activities they support?

Question Context:

The validation “sticker” (in whatever form) should clearly but simply indicate what the entity is validated for, possibly stated as a functional capacity rather than more granular elements (which could be incorporated into the validation criteria). NVEs should be required to clearly and publicly display their validation status, perhaps with expiration date prominently featured.

Monitoring and Transparent Oversight

Question 21: How long should validation status be effective?

Question Context:

Validation status should be maintained for 2 years to start. The accreditation rule should specify circumstances requiring either a notification from the entity (e.g. major changes like chapter 11 or acquisition by another company) or other trigger to re-validation, (e.g. changes to elements within the governance mechanism like CTEs/standards or a significant change within the NVE such as bringing up a new vendor system). Timeline could change as validation criteria stabilize.

Safeguard CTEs

Question 22: Are there HIPAA Security Rule implementation specifications that should not be required of entities that facilitate electronic exchange? If so, which ones and why?

Question Context: In reference to CTE [S-1]: An NVE must comply with sections 164.308, 164.310, 164.312, and 164.316 of title 45 of the Code of Federal Regulations as if it were a covered entity, and must treat all implementation specifications included within sections 164.308, 164.310, and 164.312 as “required.”

Safeguard CTEs

Question 23: Are there other security frameworks or guidance that we should consider for this CTE? Should we look to leverage NISTIR 7497 Security Architecture Design Process for Health Information Exchanges¹? If so, please also include information on how this framework would be validated.

Question Context: In reference to CTE [S-1]: An NVE must comply with sections 164.308, 164.310, 164.312, and 164.316 of title 45 of the Code of Federal Regulations as if it were a covered entity, and must treat all implementation specifications included within sections 164.308, 164.310, and 164.312 as “required.”

¹ (2010) NIST. “Security Architecture Design Process for Health Information Exchanges (HIEs).” Available at: <http://csrc.nist.gov/publications/nistir/ir7497/nistir-7497.pdf>

Safeguard CTEs

Question 24: What is the most appropriate level of assurance that an NVE should look to achieve in directly authenticating and authorizing a party for which it facilitates electronic exchange?

Question Context: In reference to CTE [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.

[The HITPC notes that this CTE is titled authentication but actually covers both authentication and identity proofing]

Consistent with previous recommendations of the HIT Policy Committee, NVEs should have a high degree of assurance in authenticating parties for which it facilitates electronic exchange. DEVEN: not necessarily a NIST framework with specific requirements.

NVEs that allow for individuals to access information directly from the NVE must authenticate individuals.

The HITPC believes that NVEs should be responsible for authenticating and authorizing entities they serve at an organizational level, allowing organizations to authorize and authenticate their own users.

In regards to NVE to NVE communication, the HITPC recognizes that NVEs may have differing standards for authentication due to the nature of services they provide, but it will be important to minimize differences in authentication requirements among NVEs.

All standards and requirements for authentication and authorization should be transparent and should not produce undue burdens on other NVEs or be disruptive to basic exchange services.

The HITPC believes ONC should focus on mitigating/limiting differences among NVE certification standards/requirements to enhance exchange. The Committee did not recommend a specific level of assurance (e.g. NIST level 3) or specific approach to authenticating individuals. (See questions 25 and 26)

Safeguard CTEs

Question 25: Would an indirect approach to satisfy this CTE reduce the potential trust that an NVE could provide? More specifically, should we consider proposing specific requirements that would need to be met in order for indirect authentication and authorization processes to be implemented consistently across NVEs?

Question Context: In reference to CTE [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.

See Q. 24.

The HITPC believes that NVEs should be responsible for authenticating and authorizing entities they serve at an organizational level, allowing organizations to authorizing and authenticate their own users.

The HITPC does not find it appropriate to establish specific requirements for indirect authentication and authorization processes for NVEs. Authentication and authorization processes will be dependent upon the unique services provided by each NVE and their clients, influenced by market and regulatory forces. NVEs should be transparent regarding authentication requirements.

Safeguard CTEs

Question 26: With respect to this CTE as well as others (particularly the Safeguards CTEs), should we consider applying the “flow down” concept in more cases? That is, should we impose requirements on NVEs to enforce upon the parties for which they facilitate electronic exchange, to ensure greater consistency and/or compliance with the requirements specified in some CTEs?

Question Context: In reference to CTE [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.

The CTEs should allow for authentication of participating (provider) entities, and leave to each entity the responsibility of authenticating individual users (consistent with previous HIT Policy Committee recommendations for entity-level digital certificates).

NVEs may (but should not be required to) set additional policies for individual user authentication, such as requiring more than user name and password for remote access (previous HIT Policy Committee recommendation).

The HITPC believes that NVEs should be responsible for authenticating and authorizing entities they serve at an organizational level, allowing organizations to authorize and authenticate their own users.

Safeguard CTEs

Question 27: In accommodating various meaningful choice approaches (e.g., opt-in, opt-out, or some combination of the two), what would be the operational challenges for each approach? What types of criteria could we use for validating meaningful choice under each approach? Considering some States have already established certain “choice” policies, how could we ensure consistency in implementing this CTE?

Question Context: In reference to CTE [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.

The HITPC recommends that NVEs follow the same criteria for meaningful choice (“meaningful consent”²) that the HITPC previously recommended. As noted in the RFI, consent is meaningful when it:

- Allows the individual advanced knowledge/time to make a decision;
- Is not compelled, or is not used for discriminatory purposes;
- Provides full transparency and education;
- Is commensurate with the circumstances; and
- Must be consistent with reasonable patient expectations for privacy, health, and safety; and must be revocable.

Consistency in approach—opt-in or opt-out—is not as important as meeting these specific criteria, which could also be used for validation purposes. An NVE is required to apply consent with respect to the data sharing it performs or facilitates; consequently, some variation in policy among NVEs is acceptable (and may be necessary in order to accommodate different community norms).

The HITPC believes that many NVEs will not act as providers, or those otherwise tasked with obtaining and monitoring meaningful choice directly from patients. Unless NVEs are providers already required to obtain consent from patients, NVEs working to facilitate directed exchange should not be required to obtain consent. Requiring NVEs to ensure meaningful consent was obtained would create a significant operational barrier for most NVEs.

NVEs should be transparent and provide notice as to how data accessed will be used. Accordingly, patients can offer meaningful opt-in or opt-out consent to providers served by a particular NVE.

The HITPC did not reach consensus on whether all NVEs should be required to offer meaningful choice for all circumstances. The Committee believes that further discussion is needed about policies for different use case scenarios, linked to the concept of modules for validation, and also on the applicability of consent obtained by one organization to uses by the receiving organization. (See [Question 33](#))

² For the purposes of the HITPC’s responses, meaningful “choice” and meaningful “consent” are terms that have the same meaning. We have used the word “consent” more often in our response because we believe it is more understandable to the public necessary in order to accommodate different community norms).

Safeguard CTEs

Question 28: Under what circumstances and in what manner should individual choice be required for other electronic exchange purposes?

Question Context: In reference to CTE [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IHI may be exchanged by the NVE.

The HITPC has not yet considered whether individual consent should be required for other electronic exchange purposes, beyond what the HIPAA Privacy Rule currently requires.

The HITPC agrees that consent (beyond what might already be required by law) should not be required when an NVE is facilitating secure, directed exchange. However, when the decision regarding whether or not to share health information is no longer in control of the provider (or the provider's OHCA), the patient should have meaningful consent about whether or not his/her information is collected, used, or disclosed by the NVE. Examples of NVEs that should provide meaningful consent include centralized databases, federated models where the NVE controls data sharing decisions, or NVEs that aggregate data from multiple sources. When the NVE model is one where consent should be required, patients should have meaningful consent even if the purpose for exchange is for treatment.

The HITPC recommended that ONC provide guidance on other exchange scenarios, including but not limited to directed query and exchange within an OCHA.

Safeguard CTEs

Question 29: Should an additional “meaningful choice” Safeguards CTE be considered to address electronic exchange scenarios (e.g., distributed query) that do not take place following Interoperability CTE I-1?

Question Context: In reference to CTE [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IHI may be exchanged by the NVE.

See Q. 27 and 28.

Safeguard CTEs

Question 30: The process of giving patients a meaningful choice may be delegated to providers or other users of NVE services (as opposed to the patient receiving the choice from the NVE directly). In such instances, how would the provision of meaningful choice be validated?

Question Context: In reference to CTE [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.

The HITPC has observed that the relationship between the patient and his or her health care provider is the foundation for trust in health information exchange, particularly with respect to protecting the confidentiality of personal health information. For this reason, we believe that providers should, in most cases, have some responsibility for discussing patient choice with respect to the NVE. Nevertheless, NVEs should also play a role in educating the community about the NVE, its purposes, and its practices, and the NVE should give providers resources to help educate their patients so that meaningful choice is possible. With respect to documentation of consent (when such documentation is needed), in circumstances where providers are responsible for educating patients and documenting consent, meaningful consent can be validated through an attestation from providers.

Safeguard CTEs

Question 31: Should there be exceptions to this CTE? If so, please describe these exceptions.

Question Context: In reference to CTE [S-4]: An NVE must only exchange encrypted IIHI.

The HITPC supports the position that NVEs must ensure that data in motion is encrypted but concludes that Condition [S-4] is redundant of other requirements. The Security Rule already contains an addressable specification requiring encryption of data in transit, as appropriate. This addressable specification—which CTE [S-1] would make “required”—along with the Security Rule’s emphasis on risk management adequately cover the issue of encryption. The HITPC recommends that this CTE be deleted.

An NVE must exchange IIHI in an encrypted manner or through an encrypted channel, with the sole exception being when the NVE is exchanging IIHI within a physically secure setting such as within a data center.

Micky wants transparent about data exchange that could be outside purview of HIPAA.

The HITPC recommends that S-4 be removed as its objectives are already covered by S-1

Safeguard CTEs

Question 32: Are there specific uses or actions about which we should consider explicitly requiring an NVE to be transparent?

Question Context: In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

The HITPC believes that all NVEs should be transparent and provide notice as to how data--whether identifiable or de-identified-- will be used. See additional comments in response to **Question 34**. NVEs will be expected to adhere to HIPAA regulations and be transparent with regards to data exchange outside the purview of HIPAA.

In particular those NVEs not directly using or facilitating data exchange for treatment and healthcare services to patients should have well defined categories of their uses of exchange data.

The HITPC believes NVEs should not have to disclose each client, but rather the classes of clients with whom they share data. NVEs should also make note of when they obtain new classes of clients/modify how they share data.

Safeguard CTEs

Question 33: Would an NVE be able to accurately disclose all of the activities it may need to include in its notice? Should some type of summarization be permitted?

Question Context: In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

NVEs should provide a layered notice: a short, 1-2 page summary of actual information sharing policies and activities, with an opportunity for interested individuals or NVE participants to obtain more specific details (such as through website links or a contact who can answer specific questions). This summary notice should cover categories of information sharing (vs. each and every specific instance of data use and disclosure). ONC should do further work with stakeholders to determine standardized categories and terminology for information uses by NVEs. [Note: this is consistent with recent FTC recommendations on consumer privacy, which call for privacy notices to be “clearer, shorter, and more standardized to enable better comprehension and comparison of privacy practices.”]

It is important that the notice be written not only in plain English but also at the reading level of the average patient seen by the health center/provider and presented in compliance with applicable laws with respect to language and disability.

The HITPC believes that NVEs should disclose classes of uses, including public health and population health. The Committee also believes it is important to educate patients about the valuable uses of de-identified data, and about the legal right of provider organizations that receive data to use it as they wish for treatment, payment, and operations.

The HITPC believes that all NVEs should be transparent and provide notice as to how data accessed will be used.

NVEs should be permitted to provide categorical use case descriptions in its notices. Requiring NVEs to provide notice on every specific activity would create a significant burden.

Safeguard CTEs

Question 34: What is the anticipated cost and administrative burden for providing such notice?

Question Context: In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

Providing notice will not be burdensome or costly if NVEs are provided with a model notice or guidelines outlining specific and well-defined categories/types of data practices to be reported in data notices.

In the absence of clear and well-defined guidelines the cost and burden will be high due to legal and compliance efforts.

Safeguard CTEs

Question 35: Should this CTE require that an NVE disclose its activities related to de-identified and aggregated data?

Question Context: In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

The notice should also include uses and disclosures of de-identified data, per the Policy Committee's previous recommendations.

The HITPC believes that all NVEs should be transparent and provide notice about how data will be used. As stated in answer to **Question 34**, uses of de-identified information should be disclosed in the NVEs public notice of data practices along with the commitment not to re-identify the data.

Safeguard CTEs

Question 36: Should this CTE require that an NVE just post its notice on a website or should it be required to broadly disseminate the notice to the health care providers and others to which it provides electronic exchange services?

Question Context: In reference to CTE [S-5]: An NVE must make publicly available a notice of its data practices describing why IIHI is collected, how it is used, and to whom and for what reason it is disclosed.

NVEs should be required to make their notices available to all participants in the NVE. NVEs should also post notices and any updates to the notices on the NVE's

website(s). NVEs should also make available website notices for NVE participants to share with their patients.

The rule making process should not be used to determine the detailed specifics of what notice is appropriate. Perhaps FTC guidance on privacy notices is a reasonable alternative.

The notice should be broadly disseminated.

An additional comment from a workgroup member recommended an automated mechanism so that when patients don't authorize specific categories of uses for their data; exchange of data does not occur.

Safeguard CTEs

Question 37: What impact, if any, would this CTE have on various evolving business models? Would the additional trust gained from this CTE outweigh the potential impact on these models?

Question Context: In reference to CTE [S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.

The HITPC believes that the proposed Condition S-6 would have a chilling effect on many existing and emerging business models including for quality improvement, public health and research.

Instead of prohibiting the use or disclosure of de-identified information, the HITPC recommends that NVEs be permitted to disclose de-identified information only:

- As permitted under business associate agreements (BAAs) the NVE holds with its customers.
- When uses of de-identified information are disclosed in the NVEs public notice of data practices along with the commitment not to re-identify the data.
- When de-identified information meets the HIPAA de-identification standards.
- When the NVE prohibits any downstream recipients from re-identifying patient information.

This approach is consistent with the recommendations made by the FTC in the recently released report, “Protecting Consumer Privacy in an Era of Rapid Change” <http://www.ftc.gov/opa/2012/03/privacyframework.shtm>

No. There are many commercial purposes that involve de-identified data that are appropriate. The HITPC supports CTE S-5, which would require NVEs to post a privacy policy that would disclose such activities.

The HITPC recommends this be clarified as to whether it would encompass only data that is exchanged through the NwHIN under governance or all the data which an entity holds. The boundaries need to be understood. The HITPC is concerned that it would be difficult to implement if providers are NVEs. If an NVE

is a provider and takes in data, it becomes part of its record. It would be hard to segregate data that came in via its NVE role. The HITPC recommends the general principle of local autonomy: governance rules would apply to exchanges between NVEs, but local rules (rules of the end users) would be respected.

NOTE: See **Question 38** for HITPC comments on this CTE.

Safeguard CTEs

Question 38: On what other entities would this have an effect?

Question Context: In reference to CTE [S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.

The HITPC believes that EHR and PHR vendors, the NVEs, the covered entities they serve and other third party affiliates would be affected by the proposed

Condition S-6.

The HITPC also had a difference of opinion on this issue. A number of HITPC members agreed with the following:

- Prohibiting NVEs from using or disclosing de-identified data for commercial purposes could eliminate a potential model of sustainability. Other entities would be permitted to do this, whereas this would be prohibited for NVEs.
- Defining what is a “commercial” purpose in health care can be a challenge, as health care entities must generate revenue in order to remain in the business of providing health care.

However, other HITPC members expressed concern that allowing NVEs to use or disclose de-identified data for commercial purposes could significantly disrupt the trust environment of the NwHIN. For example, some patients might object to certain commercial uses of health information, such as data sales for detailing, or data sales for the purpose of identifying providers who might be paid for entering patients into clinical trials. Additionally, some commercial uses of data could be used to create market advantages (or disadvantages) for competitors in the health care system. NVE participants will not always have the power to prohibit certain uses of de-identified data due to disparities in bargaining power. (NVE business associate agreements in some cases could become contracts of adhesion). Nevertheless, the HITPC did agree on the following:

- ONC should require NVEs to commit to not re-identifying de-identified data, and require NVEs to bind their downstream de-identified data recipients to this policy. (This is consistent with the FTC’s recent report on consumer privacy.)
- As the HITPC/HIT Policy Committee previously recommended, NVEs should be required to disclose uses and disclosures of de-identified data.

*[See also **Question 37]** The HITPC believes that a clear definition of “commercial” is needed, including but not limited to whether “for profit” is a part of the definition. The Committee agreed that NVEs should be prohibited from re-identifying data. The committee did not reach consensus on whether or not NVEs should be prohibited from using or disclosing de-identified health information to which it has access for any commercial purpose, but recognized it is a balance between promoting trust and promoting exchange.. The following issues were raised.*

General comments/concerns

- *There was consensus that establishing trust is essential for providers to gain confidence in HIE and to use NVEs.*
- *There needs to be more discussion and analysis of options for defining categories of commercial uses that could be acceptable with meaningful consent, acceptable without consent, or unacceptable; about how consent would be implemented if required; and about the appropriate transparency and notice that would be required for each category. However, it would be difficult to define what is/is not acceptable.*

- *Another approach discussed was to apply the prohibition on commercial use only to the HIE function of an NVE. If any other use or disclosure of data is contemplated by the NVE, those uses would have to be covered under a separate contract, and may require meaningful consent.*
- *ONC should be careful not to conflate de-identified and identifiable data in the final policy. Adding additional privacy/security requirements to de-identified data will create more regulations than are currently in place in business practices today that use de-identified data for commercial purposes.*
- *There needs to be more discussion about NVEs as BAs, and what additional requirements beyond HIPAA would be needed, if any.*
- *Some felt that narrowly limiting this CTE could be helpful; others felt that limiting it narrowly undermines the purpose and wouldn't contribute anything.*

In favor of the prohibition:

- *This CTE is needed to build trust and to avoid consumer surprises at uses of their data that they may oppose.*
- *Providers may not be aware that this is happening, or may feel compelled to sign agreements that allow their data to be sold unless such practices are prohibite*

Against the prohibition

- *This could negatively impact the business model of an NVE.*
- *Payment to enable exchange on behalf of a covered entity or public health should be allowed.*

Safeguard CTEs

Question 39: What standard of availability, if any, is appropriate?

Question Context: In reference to CTE [S-7]: An NVE must operate its services with high availability.

Safeguard CTEs

Question 40: What further parameters, if any, should be placed on what constitutes a “unique set of IIHI”?

Question Context: In reference to CTE [S-8]: If an NVE assembles or aggregates health information that results in a unique set of IIHI, then it must provide individuals with electronic access to their unique set of IIHI.

The HITPC had a difference of opinion on this question, and the questions related to S-9. Some members supported both conditions as applied to “unique” information generated by the NVE. The sense of these members is that the patient’s right under HIPAA to obtain an electronic copy of their health information, and to seek amendments to that information, should apply to NVEs that create unique information from information contributed by providers. However, other HITPC members expressed concern that NVEs would not have sufficient relationships with patients to support requiring them to provide patients with data and potentially make amendments, and that providers are in the best position to identity proof and authenticate patients, to ensure they get copies of their information with sufficient explanation, and to determine when and if amendments should be made to data.

The HITPC did not reach consensus on this question. Some members supported the CTE on access as essential to trust and made the analogy of a credit bureau. Others felt that it could discourage entities from becoming NVEs because they would need to be able to translate the data into lay terms and would not want to be accountable to consumers. Some felt NVEs should be required to have a mechanism to provide information back to the consumer, but that the rule should not specify who does it or how.

Safeguard CTEs

Question 41: If an NVE were to honor an individual’s request for a correction to the unique set of IIHI that it maintains, what impact could such a correction have if the corrected information was accessible by health care providers and not used solely for the NVE’s own business processes?

Question Context: In reference to CTE [S-9]: If an NVE assembles or aggregates health information which results in a unique set of IIHI, then it must provide individuals with the right to request a correction and/or annotation to this unique set of IIHI.

See Q. 40

Safeguard CTEs

Question 42: Are there any circumstances where an NVE should not be required to provide individuals with the ability to correct their IIHI?

Question Context: In reference to CTE [S-9]: If an NVE assembles or aggregates health information which results in a unique set of IIHI, then it must provide individuals with the right to request a correction and/or annotation to this unique set of IIHI.

See Q 40

Safeguard CTEs

Question 43: What method or methods would be least burdensome but still appropriate for verifying a treatment relationship?

Question Context: In reference to CTE [S-10]: An NVE must have the means to verify that a provider requesting an individual’s health information through a query and response model has or is in the process of establishing a treatment relationship with that individual

In making its recommendations regarding the adoption of fair information practices for intermediaries, and in specifically addressing meaningful choice, the HITPC assumed an environment where exchange would take place for purposes established in Stage 1 of Meaningful Use – for treatment and care coordination, some public health reporting to public health authorities, and reporting of aggregate quality data to CMS.

However, it does not appear from this RFI that exchange in NwHIN is limited to just these purposes. The HITPC believes that for query/response models in particular, allowing additional purposes for exchange in the NwHIN should not take place without additional discussion of needed privacy and security policies.

The HITPC has not yet considered query/response models. However, in the context of provider-to-provider exchange for purposes of Stage 1, the HITPC previously recommended that the requesting provider seek information in compliance with applicable law and the requirements for NwHIN meaningful consent, and have a treatment relationship (either existing or pending) with the individual who is the subject of the health information exchange. There should be mechanisms to establish this relationship (such as through attestation by the provider or his/her designee, or automatically through the booking of an office visit/appointment/etc.) NVEs should be able to delegate the means for establishing the treatment relationship to its participants.

In models where patients can opt-in for “any provider that I see for treatment”, there would be an additional need to acknowledge that a “treatment purpose” exists.

The most viable method for verifying a provider's treatment relationship to a patient is through provider attestation.

Safeguard CTEs

Question 44: Are there circumstances where a provider should be allowed access through the NVE to the health information of one or more individuals with whom it does not have a treatment relationship for the purpose of treating one of its patients?

Question Context: In reference to CTE [S-10]: An NVE must have the means to verify that a provider requesting an individual’s health information through a query and response model has or is in the process of establishing a treatment relationship with that individual.

The Policy Committee previously noted that its recommendations on consent—which stated that the exchange of identifiable health information for “treatment” should be limited to treatment of the individual who is the subject of the information—might need to be further refined to ensure the appropriate care of infants or children when a parent’s or other family member’s information is needed to provide treatment and it is not possible or practical to obtain even a general oral assent to use a parent’s information. Similarly, permitting access to the NVE of the records of one or more individuals with whom the provider does not have a treatment relationship in other circumstances should be the subject of further policy discussion.

NVEs should be transparent with participants about the purposes for which information can be exchanged using the NVE.

Interoperability CTEs

Question 45: What types of transport methods/standards should NVEs be able to support? Should they support both types of transport methods/standards (i.e., SMTP and SOAP), or should they only have to meet one of the two as well as have a way to translate (e.g., XDR/XDM)?

Question Context: In reference to CTE [I-1]: An NVE must be able to facilitate secure electronic health information exchange in two circumstances: 1) when the sender and receiver are known; and 2) when the exchange occurs at the patient’s direction.

If it is preferable for NVEs to support only one mechanism, the HITPC recommends that NVEs be required adhere to the transport requirements included in HER vendor certification.

The HITPC also recognizes that SOAP is currently supported by Public Health efforts such as the Immunization Information System as well as the Direct Project and should therefore be prioritized.

Rather than require NVEs to support one or multiple transport mechanisms, NVEs should be left to determine which transport mechanism is preferable for the clients they serve and the use cases involved in the services they provide. Many potential NVEs, such as lab vendors, are likely to support one specific use case. Accordingly, market forces should influence the transport mechanism preferred by NVEs, and CTEs should be able to certify NVEs for one or more mechanism. Further clarification is necessary for the responsibilities NVEs will have to recognize recipients’ certificates when Condition I-1. 2. Exchange occurs at the patient’s direction.

The HITPC recommends that NVEs should be able to determine what transport it prefers for particular transactions. The Standards & Certification Criteria should specify standards and certification criteria for particular transactions/use cases. Implementation guides that overlap with the S&CC 2014 edition should be synchronized.

Interoperability CTEs

Question 46: If a secure “RESTful” transport specification is developed during the course of this rulemaking, should we also propose it as a way of demonstrating compliance with this CTE?

Question Context: In reference to CTE [I-1]: An NVE must be able to facilitate secure electronic health information exchange in two circumstances: 1) when the sender and receiver are known; and 2) when the exchange occurs at the patient’s direction.

The HITPC recommends proposing a secure “RESTful” transport specification as a way of demonstrating compliance with this CTE if available. However, the HITPC recognizes that Public Health has little experience with this protocol.

The HITPC also believes that NVEs should be left to determine which transport specification(s) meets their clients’ needs and be certified accordingly.

Interoperability CTEs

Question 47: Are the technical specifications (i.e., Domain Name System (DNS) and the Lightweight Directory Access Protocol (LDAP)) appropriate and sufficient for enabling easy location of organizational certificates? Are there other specifications that we should also consider?

Question Context: In reference to CTE [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.

The HITPC believes that DNS and LDAP specifications are appropriate and sufficient for the easy location of organizational certificates. This approach is aligned with recommendations for certificate discovery from the Standards & Interoperability Framework.

However, the HITPC does not recommend that NVEs be required to adhere to DNS, LDAP, or both specifically. Entities seeking to serve as NVEs should be permitted to determine which technical specifications best align with their services as long as they are congruent with Directed exchange.

One committee member recommended that NwHIN Connect standards also be acceptable.

Interoperability CTEs

Question 48: Should this CTE require all participants engaged in planned electronic exchange to obtain an organizational (or group) digital certificate consistent with the policies of the Federal Bridge³?

Question Context: In reference to CTE [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.

The HITPC recommends that the Interoperability CTE require participants engaged in electronic exchange obtain digital certificates consistent with the policies of Federal Bridge Certification Authority.

Entities serving as NVEs should be permitted to use a market based approach with federal guidance for establishing policies pertaining to organization or group digital certificates.

The Health IT Policy Committee previously stated that NwHIN certificates be issued at an organization/entity level, with a high degree of assurance as to the organization/entity's identity. The certificate also should be acceptable to federal agencies. Consistent with these principles, the Committee specifically recommended that certificates meet Federal Bridge standards and must be issued by a Certificate Authority (or one of its authorized resellers) that is a member of the Federal PKI framework.

It is not clear that the above policy objectives endorsed by the Committee can be met through Federal Bridge certification. This is an evolving field, and ONC is still investigating the whether Federal Bridge certification is possible. The HITPC recommends that ONC, as quickly as possible, seek a solution for NwHIN exchange that meets the initial policy objectives recommended by the Policy Committee.

³ Additional information on the Federal Bridge can be viewed at: <http://www.idmanagement.gov/pages.cfm/page/Federal-PKI>

Interoperability CTEs

Question 49: Should we adopt a CTE that requires NVEs to employ matching algorithms that meet a specific accuracy level or a CTE that limits false positives to certain minimum ratio? What should the required levels be?

Question Context: In reference to CTE [I-3]: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.

As the Policy Committee previously recommended, ONC should develop and disseminate best practices in improving data capture/data quality and matching accuracy.

The HITPC further notes that setting specific accuracy levels is premature. Data matching is an area of rapid evolution, and establishing and disseminating best practices is more desirable (and achievable) than establishing quantified standards or specific numeric targets.

Also consistent with past recommendation, NVEs should have a process in place to (1) evaluate the effectiveness of their matching strategies in achieving matching accuracy on an ongoing basis and (2) use such evaluations to internally improve matching accuracy.

The HITPC does not recommend establishing a universal accuracy level or minimal error ratio for all NVEs.

Matching algorithms may not be appropriate for NVEs that act as a relay system without storing or analyzing data. Entities serving as NVEs should look to market and industry requirements, with federal guidance, for establishing patient matching accuracy levels appropriate to their services.

This CTE could be applied to NVEs that are operating under a public health utility model or are building repositories of patient information. In these instances, Public Health usually has to match at two levels of interest: 1. At the patient level and 2. At the unit of interest such as a vaccine. Creating a minimal ratio for each matching level would be more appropriate than establishing a universal accuracy level.

Pilot projects should be considered to explore the role of an NVE in patient or unit matching services.

One member suggested that ONC focus on standardizing data sets rather than algorithms.

Interoperability CTEs

Question 50: What core data elements should be included for patient matching queries?

Question Context: In reference to CTE [I-3]: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.

The HITPC previously observed that the use of any particular data field should not be required for matching, as choice of fields used to match depends on a number of factors, including the purpose of the data access. Universal identifiers are not a panacea.

The HITPC recommends dropping Condition I-3 as a requirement for every NVE's validation. Establishing core data elements needed for patient matching is best left to those NVEs sending and receiving patient information or otherwise working with systems able to produce unique patient identifiers.

Interoperability CTEs

Question 51: What standards should we consider for patient matching queries?

Question Context: In reference to CTE [I-3]: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.

See Q. 50.

The Privacy and Security Tiger Team's recent efforts to create patient identification and matching standards should be used to inform this CTE.

Business Practices

Question 52: Should this CTE be limited to only preventing one NVE from imposing a financial precondition on another NVE (such as fees), or should it be broader to cover other instances in which an NVE could create an inequitable electronic exchange environment?

Question Context: In reference to CTE [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.

See general overarching comment at beginning. It could be difficult to determine if an NVE is creating an inequitable exchange environment. The HITPC does not support requiring NVEs to publish their fee structures, because pricing is both complicated and proprietary.

The HITPC recommends using a net neutrality framework that encourages an open network and level playing field for all providers to participate in health information exchange. Providers using one NVE should be able to easily and without precondition send information to providers using another NVE.

While fees might be permitted in some cases, the framework should a) prohibit NVEs with large market shares from using their influence to impose excessive fees on their customers as well as other NVEs and b) avoid the need for NVEs to negotiate business agreements with each other before their customers can exchange information.

The HITPC recommends that NVEs should not be permitted to impose fees or requirements on other NVEs for basic services for the operation of exchange services in their role as a NVE including transporting messages and discovering digital certificates.

If an NVE offers value added services to other NVEs, fees for such services should be reasonable and non-discriminatory

The HITPC does not find it appropriate for ONC or federal regulatory agencies to regulate the fees for value-added services.

Business Practices

Question providers 53: Should this CTE (or another CTE) address the fees an NVE could charge its customers to facilitate electronic exchange or should this be left to the market to determine?

Question Context: In reference to CTE [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.

See general overarching comment at beginning. NwHIN fees could be hard to separate; some may be bundled in different ways, including being rolled into membership fees. The HITPC would not support requiring an NVE to publish its fees for its clients.

The HITPC does not believe that any CTE should determine the fees NVEs charge their customers.

Business Practices

Question 54: providers Under what circumstances, if any, should an NVE be permitted to impose requirements on other NVEs?providers

Question Context: In reference to CTE [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.

The general principle stated previously about respecting local autonomy should apply. However, there may be instances where state law in another state needs to be respected. This can be accomplished through separate data sharing agreements. The DURSA has been an excellent example of how a single data exchange agreement can be uniformly applied for the more complex (e.g., Exchange) types of data exchange systems where there are significant liability issues. Having a single uniform agreement like the DURSA creates significant transparency which builds trust.

As stated in response to questions 52 and 53, the HITPC believes that NVEs should be permitted to impose requirements on other NVEs only when it pertains to value added services provided beyond the responsibilities of providing basic services essential to the function of NwHIN. Aprtotal providersil program to dateAprtotal providersilAprtotal providersil OK program to date program to date

Business Practices

Question 55: What data would be most useful to be collected? How should it be made available to the public? Should NVEs be required to report on the transaction volume by end user type (e.g., provider, lab, public health, patient, etc)?

Question Context: In reference to CTE [BP-3]: An NVE must report on users and transaction volume for validated services.

The HITPC supports the principle of reporting transaction data but has several concerns. First, tracking by end user isn't easy—for example, if the NVE receives a request from VA or SSA about a patient's data from multiple sources and sends back all the responses together, it would record that as a single transaction. It will be critical to carefully define the metrics and assess operational issues related to collecting/reporting them. Additionally, individual NVE data should be considered proprietary and not released to the public. If the metrics issues are resolved, individual NVEs could report data to a governance entity, but the entity should only publish aggregated data. The HITPC did not reach consensus on whether the aggregation should also occur at the local level.

The HITPC believes that NVE reporting of transaction volumes to federal agencies such as ONC and state regulatory agencies is appropriate.

Reporting standards should be transparent to both the public and NVEs to ensure their participation. Public reporting should be in de-identified, aggregate form to evaluate the progress of national- and statewide health information exchange. Reporting should not reveal transaction volume or type of transactions facilitated for specific NVEs.

The HITPC believes that operational and adoption, or use rates data, will most likely be useful to be reported for the purposes of promoting NwHIN. Reporting requirements for NVEs should vary according to the services they offer.

Request for Additional CTEs

Question 56: Which CTEs would you revise or delete and why? Are there other CTEs not listed here that we should also consider?

Question Context: The question solicits general input on the comprehensive list of CTEs.

See answer to **Question 37**, about S-6:

COMMENT on S-10: [An NVE must have the means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a treatment relationship with that individual.]

The HITPC respects the intent of this condition but does not support it as stated. The WG has concerns about the verification process, and more detail is needed about the process. It seems likely it would rest on an attestation, which would need to be monitored, and operationally it might be difficult for the requestor to attest. The WG prefers that liability remain with the provider, as HIPAA requires, not the NVE.

The HITPC believes that in addition to the CTEs proposed, a national governance structure should include a grievances process. NVEs, CTEs, federal and state regulatory agents, as well as their clients should be able to bring grievances for compliance failures or inappropriate business practices.

Establishing a model for grievances will increase trust in interoperability and exchange among states or new participants in health information exchange.

Request for Additional CTEs

Question 57: Should one or more of the performance and service specifications implemented by the participants in the Exchange be included in our proposed set of CTEs? If so, please indicate which one(s) and provide your reasons for including them in one or more CTEs. If not, please indicate which one(s) and your reasons (including any technical or policy challenges you believe exist) for not including them in one or more CTEs.

Question Context:

Request for Additional CTEs

Question 58: In the notice of proposed rulemaking (NPRM) we intend to subsequently issue, should the above CTEs as well as any others we consider for the NPRM be packaged together for the purposes of validation? In other words, would it make sense to allow for validation to different bundles of safeguard, interoperability, and business practice CTEs for different electronic exchange circumstances?

Question Context:

Yes, they should be bundled modularly. No one size fits all. The HITPC repeats that interoperability CTEs should be modularly certified. Then, those Safeguard and Business Practice CTEs that are most appropriate to certain Interoperability CTEs and could be packaged together with them. Some Safeguard and Business Practice CTEs might be accreditable even in absence of any Interoperability CTEs, i.e. a combination of Safeguard and Business Practice CTEs would have common applicability, and/or some entity might not be validated for any interoperability CTEs.

Request for Additional CTEs

Question 59: Should we consider including safe harbors for certain CTEs? If so, which CTEs and what should the safe harbor(s) be?

Question Context:

CTE Life Cycle

Question 60: What process should we use to update CTEs?

Question Context:

The HITPC would first repeat its answer to Q 1: that a policy level needs to be added to the CTEs. We believe that the policy level CTEs would change less often than the CTEs expressed at the accreditation/certification level. We believe that processes for updating the policy CTEs should be separate from the accreditation/certification CTEs. Next, the HITPC suggests breaking out the types of updates that would be expected. We anticipate updates would be based on three different new issues: (1) real new challenges—technical, in privacy and security, new business practices; (2) developments in the policy/legal framework in which CTEs operate that require changes in CTEs; and (3) new requirements that those who might provide additional incentives to the voluntary approach might impose, e.g. changes to Meaningful Use. Each needs a different updating process. (1) requires a very participatory process, which could be technologically enhanced, and a way to prioritize or elevate issues. (2) needs legal guidance whether new CTEs are needed (e.g. like General Counsel opinion) ; (3) depends upon stakeholder relationship management to know what new CTEs would actually help. Also there needs to be another process - including the definition of metrics - for evaluating of how current CTEs and the associated accreditation and certification criteria are performing— including a cost-benefit analysis if CTE is achieving its goal in most cost effective way.

With respect particularly to the standards, implementation guidance and certification criteria tied to Interoperability CTEs are likely to evolve significantly faster than the associated Interoperability CTEs; accreditation criteria are likely to evolve somewhat faster than the Safeguard and Business Process CTEs to which they are associated; the policy level CTEs are likely to evolve only slowly in response to significant environmental changes. The governance process should recognize and accommodate these different rates of change. In particular, governance processes that require formal rulemaking should be reserved for the policy level CTEs and the rulemaking process should recognize that new policy level CTEs will likely be in need of active revision and refinement based on real-world practice; accreditation criteria and particularly interoperability standards, implementation guidance, and certification criteria will be in need of active refinement, revision and replacement. The ideal process would establish a fair, transparent and inclusive sub-regulatory process for maintaining and revising these criteria.

There should be a process for retiring CTEs and associated accreditation, standards, implementation guidance and certification criteria. The process for retiring Interoperability CTEs, standards, implementation guidance and certification criteria should recognize that the nationwide health information technology infrastructure will be upgraded piecemeal, leading to multiple versions of Interoperability CTEs and associated standards, implementation guidance and certification criteria in effect at the same time and should accommodate this reality.

The HITPC also suggested that ONC address the potential issue of delays in the validation process, which could negatively impact patient data exchange.

CTE Life Cycle

Question 61: Should we expressly permit validation bodies to provide for validation to pilot CTEs?

Question Context:

Yes, when structured well, this would be valuable in enabling the development of new and innovative approaches.

CTE Life Cycle

Question 62: Should we consider a process outside of our advisory committees through which the identification and development to frame new CTEs could be done?

Question Context:

The HITPC feels that the FACAs are currently the most appropriate mechanism for the “Pilot”, “National” and “Retired” steps in updating policy level CTEs and associated accreditation and certification criteria – taking into account the different kinds of updates anticipated and described above. The “Emergence” process should explicitly allow for innovation, particularly with respect to Interoperability CTEs and their associated certification criteria, enabling them to be developed in the public and private sectors by a range of actors without needing formal FACA oversight. The FACAs can play several other important roles. They are a channel for those affected by the CTEs and participants in the exchange of health information to bring issues forward for national discussion or to showcase developments in the field. They can recommend pilots and innovations. They are a good single place or first place for stakeholders to go to learn about policy discussions and developments in a complex environment. They are important in setting policy-level objectives, and defining metrics to evaluate how these are met.

Technical Standards and Implementation Specifications Classification Process

Question 63: What would be the best way(s) ONC could help facilitate the pilot testing and learning necessary for implementing technical standards and implementation specifications categorized as Emerging or Pilot?

Question Context:

The HITPC recommends ONC provide strategic guidance as well as funding for pilots to implement technical standards. Receiving ONC’s support for the mobilization of pilots galvanizes stakeholders and significantly accelerates consensus on standards specifications and widespread adoption of workable standards.

One member also suggested that ONC create a process for scanning the market to recognize what is working, beyond ONC-sponsored pilots.

Technical Standards and Implementation Specifications Classification Process

Question 64: Would this approach for classifying technical standards and implementation specification be effective for updating and refreshing Interoperability CTEs?

Question Context:

Technical Standards and Implementation Specifications Classification Process

Question 65: What types of criteria could be used for categorizing standards and implementation specifications for Interoperability CTEs? We would prefer criteria that are objective and quantifiable and include some type of metric.

Question Context:

Economic Impact

Question 66: We encourage comment and citations to publicly available data regarding the following:

- The potential costs of validation;
- The potential savings to States or other organizations that could be realized with the establishment of a validation process to CTEs;
- The potential increase in the secure exchange of health information that might result from the establishment of CTEs;
- The potential number of entities that would seek to become NVEs; and
- The NVE application and reporting burden associated with the conceptual proposals we discuss.

Question Context:

Q. 66. 1:

- The HITPC believes that the cost of validating NVEs will vary greatly depending on the range of services offered by the NVE and which CTEs will apply to these services.
- Costs should be reasonable and minimized whenever possible to prevent placing undue burden on entities seeking to operate as NVEs. In particular, validation costs for offering directed exchange services needed for proposed stage 2 meaningful use should be low enough to permit affordable fees for small providers and other participants with limited resources.

Q. 66. 2:

- The proposed governance approach will benefit states by encouraging greater participation in health information exchange, improving quality and reducing the cost of care. Only a few states have established their own accreditation/certification programs for health information exchange. A national governance program will allow those states to eliminate certification programs, producing clear cost savings.

Economic Impact — **Question 66:**

- The HITPC believes that establishing federal validation guidelines would reduce the cost currently incurred when navigating validation and certification standards that differ by state.
- In order to realize savings, federal validation standards will have to be flexible enough to meet the needs of multiple use cases to create sufficiently robust health information exchange that encourages state legislatures to stand down their unique privacy and security standards and adhere to federal standards.
- Further clarification is necessary with regards to the set of security and privacy standards federal regulations would establish for all states to follow.

Q. 66. 3:

- The HITPC foresees a significant increase in health information exchange resulting from the proposed governance structure, including by nontraditional exchange participants.

Q. 66. 4:

- NVEs will not be/should not be a “one size fits all” type of entity. Instead, they will likely come in a variety of shapes and sizes offering a variety of services. If that is the case, and we account for that in everything from validation to reporting requirements, then the likelihood of thousands of entities pursuing NVE status is high. If, on the other hand, NVE status requires a minimum set of services that is far-reaching in scope, these requirements will likely limit the number of organizations seeking NVE status.
- Under the first scenario, the HITPC predicts that hundreds and perhaps thousands of organizations such as EHR vendors, RHIOs, HIOs, patient engagement vendors, large hospital systems, academic centers and more will seek to become NVEs.
- Organizations already facilitating health information exchange will be naturally aligned to serve as a NVE under the proposed governance structure.
- The HITPC cautions that the prohibition of using de-identified data for “commercial purposes” without further clarification of use cases considered to be commercial could be a barrier to the operation of NVEs. Entities that provided care management support, data analysis for ACOs, app developers, market researchers could be prohibited from exchanging data with NVEs thereby excluding their clients from participating in exchange.

Q. 66. 5:

- The HITPC does not have an estimate for the application and reporting burden, which will vary greatly depending on which exchange services are offered and which CTEs need to be validated.
- The NVE application and reporting burden should be kept at a reasonable level to encourage NVE participation and permit modest fees for NVE customers.