HIT Standards Committee Comments
Office of the National Coordinator for Health IT
Governance RFI

Establishing a governance mechanism for the nationwide health information network

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?

The HITSC makes the following observations:

- A core value of the NwHIN, and of the NVEs, is a <u>trust fabric</u> – preserving this core trust fabric is essential. Safeguards CTEs should be top-level trust principles that should persist over time – changes and additions to Safeguards CTEs should occur infrequently.
- The NVE industry that will emerge does not yet exist, so it is unclear what services the NVEs will offer in addition to simple exchange between providers. For example, it is not clear whether or how payers would use NVEs in their administrative transactions.
- Interoperability CTEs will be influenced by market evolution to a greater extent than the Safeguard CTEs – innovation should be allowed to happen from the bottom up; top-to-bottom filtering should be avoided.
- NwHIN Governance should be light-handed – establishing and preserving trust while enabling and fostering innovation in the market.
- Even a voluntary process can have a profound impact on business if NVEs and their subscribers are denied "meaningful choice."

The HITSC recommends the following roles, as depicted in the figure shown on the graphic below:

- The ONC should retain responsibility for establishing the high-level CTEs essential for establishing and maintaining the trust fabric. Only these core, trust-fabric CTEs should be codified in federal regulations.
- The ONC should establish a Public-Private Standards Entity to be responsible for recommending CTEs relating to interoperability and business practices, and for recommending standards, implementation specifications, and certification criteria to support all CTEs. This entity should represent the interests of the NVEs, the Validation Bodies and the ONC. Note that although we refer to this as a Public-Private "Standards" Entity, we are not suggesting that this be a standards-development organization, but rather an entity that would select and recommend to the ONC standards, implementation guidance, and certification criteria, similar to the HITSC. In fact, the HITSC should be considered for this role.
- To allow the agility needed to enable the Interoperability and Business Practices CTEs to be changed over time, the Interoperability and Business Practices CTEs should be considered national standards under NwHIN Governance, but should not be codified in Federal regulations.
- Governance over Business Practices should be achieved through transparency of business practices and of measured performance against agreed-upon service levels. NVE oversight should seek to address any monopolistic practices that inhibit free-flowing data exchange, without imposing absolute requirements through CTEs.

Roles Recommended by the HITSC
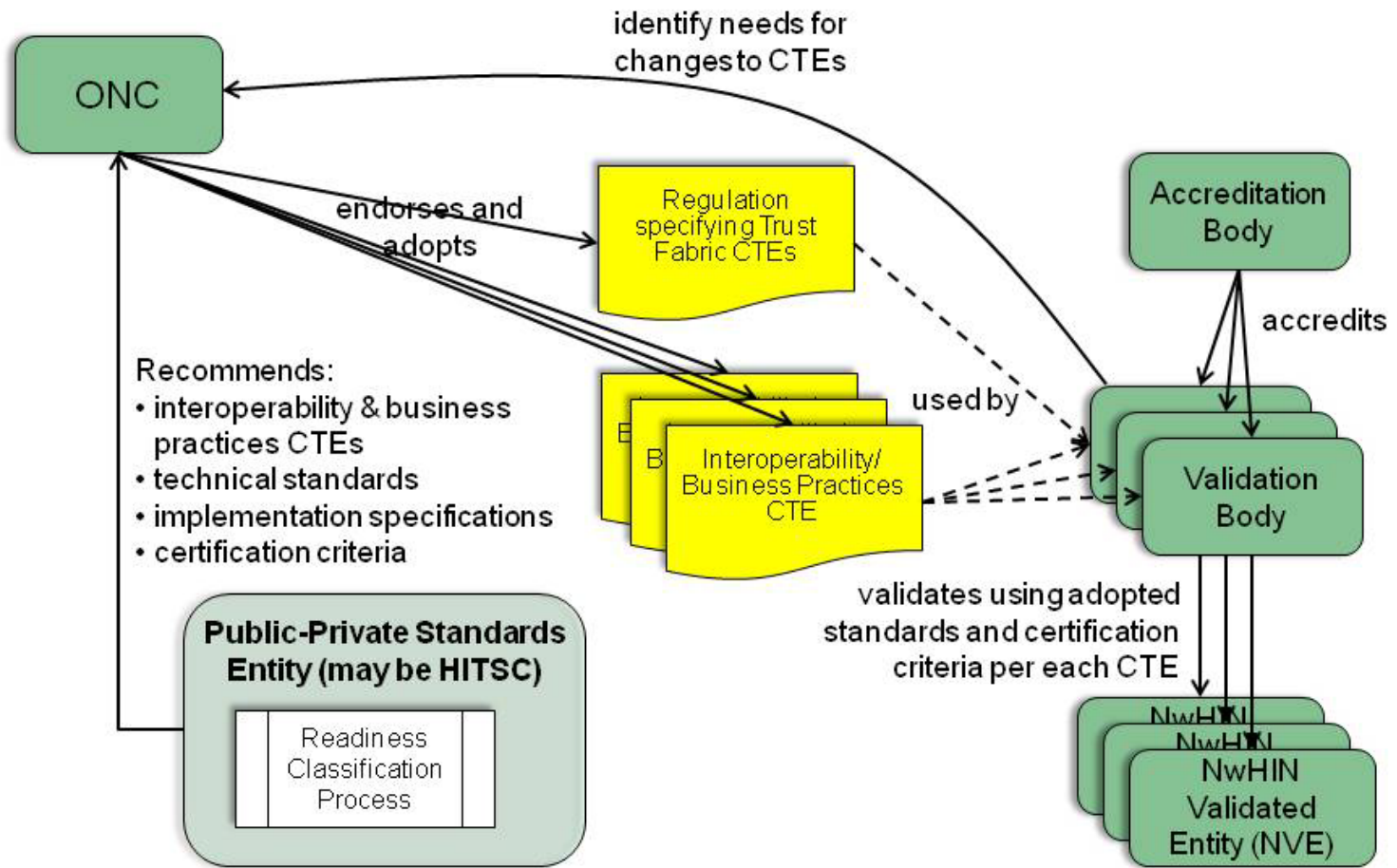
Establishing a Governance Mechanism
Question 3: How urgent is the need for a nationwide governance approach for electronic health information exchange? Conversely, please indicate if you believe that it is untimely for a nationwide approach to be developed and why.
Question Context: Why is it important for ONC to exercise its statutory authority to establish a governance mechanism now?
Electronic health information exchange will simply not occur without trust, and effective Governance is critical to establishing and maintaining the trustworthiness of the NwHIN. The NPRM for Stage 2 of meaningful use put a great deal of emphasis on interoperability. Interoperability is important, but just because it is important does not mean it needs to be large, heavy handed, or obstructive. We believe that the key requirement for Governance is to establish and maintain the core trustworthiness of the NwHIN. We question the need for additional regulation beyond that needed to assure the trustworthiness of the NwHIN trust fabric. We do not see a need for regulated CTEs addressing interoperability and business practices other than those essential to preserve the trust fabric. We believe that service assurances such as competitive pricing, scope of services, and service performance levels are best left to transparency and market competition, with oversight from ONC.

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.
The key factor is building a trust fabric to support health information exchange – NVE validation must clearly contribute to this goal. People in the marketplace do not know about or understand yet what "NwHIN" or "NVE" mean. The recognition and perceived value of the NVE 'brand' will need to build over time. Make clear what NVE validation enables exchanging parties to do that without validation they could not do. Federal partners can play a key role here; for example, a CMS requirement that health information be exchanged with them only through an NVE would clearly demonstrate value. The integrity of the validation process, and ongoing oversight and policy enforcement, are critical to the success of the voluntary approach. We agree with the voluntary approach. However we note that if Federal entities require their business partners to use NVEs for all exchanges, the "voluntary" becomes moot. Given the possibility that NVE validation may become a de facto requirement, it is extremely important that ONC be mindful of the profound impact some of the proposed CTEs could have on the private sector, especially those CTEs that address practices beyond those necessary to preserve the trust fabric.

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:

ONC should focus on governance mechanisms to ensure trusted exchange and let the private sector through validating bodies focus on interoperability. We believe that this is consistent with what is proposed in the RFI.

We believe that some CTEs should apply to all NVEs and the degree that they are related to the core trust framework could be ONCs responsibility, but the CTEs that are focused on interoperability or business practices should be delegated to the Public-Private Standards Entity (see question 2) in order to foster innovation and efficiency. This approach would be consistent with OMB Circular A-119 (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities) and the National Technology Transfer and Advancement Act of 1995, which requires Federal agencies to participate in voluntary consensus standards bodies and to use voluntary consensus standards.

We anticipate that validated entities will create additional CTEs as needed for the efficient operation of the NwHIN. We suggest that ONC focus on those CTEs essential for establishing and preserving the trust framework of the NwHIN, and avoid codifying into regulation CTEs that might inhibit innovation. The CTEs essential for establishing and preserving core trust should be codified in regulation, and required for NVE validation. Additional certification requirements and processes necessary to guarantee interoperability should be the responsibility of the NVEs.

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:

Yes, but validation needs to be modular, with every NVE required to be validated against all of the core trust-fabric CTES, with other CTE modules required based upon the services provided. In any case, each validation must clearly indicate the CTE modules against which that NVE has been validated.

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:

For a given CTE the validation method, standards, implementation specifications, and criteria should be consistent across all Validation Bodies.

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 following validation models have similarities that could be drawn upon: Payment Card Industry (PCI), Extended Validation Certificate, and National Voluntary Laboratory Accreditation Program (NIST).

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 Governance of each Validation Body should seek to have stakeholder representation in its internal governance. We believe that both the NVEs and the Validation Bodies should have input into overall NwHIN Governance and changes to the CTEs, through a Public-Private Standards Entity. representing all major NwHIN stakeholders. The existing FACAs HITSC may be an appropriate body to assume the role of Public-Private Standards Entity.

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."

Agree that making "addressable" implementation specifications (IS) "required" would build trust and reduce variability.

Note that implementation specifications are very general and that to truly reduce variability, standards may be needed to constrain implementations for validation. Such "standards" may include both SDO standards (e.g., encryption) and specific processes and procedures.

After further review, the P&S WG concluded that none of the addressable implementation specifications are unreasonable to "require" of an NVE.

Safeguard CTEs
Questions/concerns about the voluntary nature of the validation process, and the potentially side-effects from making all of these addressable specifications 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 Exchanges[1]? 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."
NISTIR 7497 focuses on the Exchange architecture and specifications and was developed before the Direct protocol was developed, and would need to be refreshed. Good guidance for organizations implementing the Exchange specifications. However, as guidance, it should not be mentioned or prescribed in the governance regulation. As mentioned in our response to question 45, we do not believe the governance regulation should be transport-specific. However, we do think it would be appropriate for ONC to make transport-specific guidance, such as NISTIR 7497, known to NVEs implementing such transports.

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.
Availability requirements are service-specific; so it would be unrealistic to specify a single availability level across all services and NVEs. We question whether there is a market failure that really compels a standard for availability. We think transparency is more important than establishing a specific availability floor; especially publication of actual, measured availability over time. Better to leave specific availability level as a contractual provision between an NVE and its subscribers.

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

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.

We do not think it is appropriate for an NwHIN governance model to dictate the transport protocols NVEs should support. Rather, the model should be equally appropriate regardless of the transport mechanism(s) supported.

Most importantly, the NVEs should be required to publish the transport protocol(s) they support and the mechanisms they use to implement these protocols.

The governance model should specify a standard for publishing the protocol(s) supported and mechanisms used.

For questions 45 and 46:

1. Condition I-1 does not address all the reasonable circumstances for exchange and does not use language common in other regulations so it is unclear what this CTE is intending to convey. The conditions under which it is appropriate to exchange health information are specified elsewhere and should not be included in the Governance regulation.
2. Trust fabric should be decoupled from the transport mechanisms. Transport standards should not be specified in this Governance regulation. However, the Governance regulation should require transparency with regard to the transport protocols that an NVE supports, and how it supports those protocols.

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.
See question 45.

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.

Yes, these specifications are appropriate for use, but we do not think the Governance regulation should specify these approaches as exclusive. There may be other ways to discover certificates, and we do not believe a Governance regulation should specify protocols for certificate discovery. We believe questions 45-47 are at a much more granular level than is appropriate for a Governance regulation.

Interoperability CTEs

Governance regulation should not include this level of detail.

The definition and scope, and associated roles and responsibilities, of validation, accreditation, and certification are confusing and need to be clarified. For example, what role would existing bodies such as DirectTrust.org, NwHIN Oversight Committee, existing certificate authorities, and EHR technology certification play in these activities?

Governance process needs to capitalize on existing processes and services.

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 Bridge[2]?

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

See question 56 comment on S-2.

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.

We recognize that NVEs are likely to adopt different business models, and to offer services other than those currently anticipated. This CTE should apply only to those NVEs that need to match a specific individual to IIHI data. The accuracy level, sensitivity and specificity required is situational. The CTE should not require a particular algorithm nor is it possible to specify a minimum accuracy level.   So no, NVEs should not be required to meet a specific accuracy level.

Further, we believe NVEs should be validated against only those CTEs related to the services that NVE plans to offer. Within the context of the services validated, the NVE should publish their accuracy levels and method of calculation. The Public-Private Standards Entity should establish standards for reporting accuracy levels such that the reports are meaningful to both potential NVE subscribers and other consumers.

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[2] Additional information on the Federal Bridge can be viewed at: http://www.idmanagement.gov/federal-public-key-infrastructure

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.**

Recommendations of last summer's NwHIN Patient Matching Power Team should be the baseline, but work to further refine these recommendations should continue. See:
http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_16869_956006_0_0_18/8_17_2011Transmittal_HITSC_Patient_Matching.pdf

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.**

The standards are protocol dependent. For example, for exchanges using the Direct protocol, CDA Header, for exchanges using the Exchange protocol, XCPD.

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.

Some of the CTEs are duplicative with S-1 (which makes HIPAA Security Rule "addressable" implementation specifications "required"). Duplicate requirements will create revision problems downstream. We recommend eliminating all duplicative requirements in the final regulation.

Detailed comments:

S-1: Comments provided earlier (see question 22)

S-2: Revise to read: "An NVE must facilitate electronic health information exchange only for organizations it has authenticated consistent with assurance level 2 or higher, as defined in the Federal Identity, Credential, and Access Management (FICAM) Trust Framework. An NVE must implement an appropriate certificate policy (CP/CPS) that accounts for identity proofing and level of assurance."

The HITSC reasserts the recommendation that all digital certificates used by organizations exchanging information within the NwHIN must be issued by certificate authorities that meet FICAM standards.

S-3: Revise to read: "An NVE must ensure that individuals are provided with a meaningful choice by the NVE, as consistent with existing applicable law."
This CTE would not apply to every NVE. Would apply if they have their own repository and a consumer-facing presence. HIE participants (e.g., providers) will also have a responsibility to offer meaningful choice.

S-4: revise to read: An NVE must only ensure that IIHI is exchange encrypted IIHI when being exchanged.

S-5: This CTE does not capture the nuances explained in the RFI re how this notice differs from the HIPAA Notice of Privacy Practices (NPP). Need to clarify what information the notice needs to include when describing the actual instances when IIHI is collected, used, disclosed, including to whom and for what purpose, and when/how the notice would need to be updated. Also, we assume this is a public notice and not a customized notice sent to each individual. Many details remain to be worked out.

What if there is no consumer-facing presence? May not apply to every NVE.

The overarching Governance Authority should make these Notices available for every validated NVE.

S-6: "Commercial purpose" needs to be defined. This requirement goes beyond current HIPAA and HITECH policy regarding de-identified information. Tiger Team and ONC should discuss.
Having the statement focus only on de-identified information gives the impression that use/disclosure of identified information is OK

S-7: Revise to read: An NVE must publish its actual availability, and describe the method used to measure availability."

Transparency of actual availability is essential.) An NVE must publish its actual availability, and describe the method used to measure availability operate its services with high availability.

GENERAL COMMENT RE S-8 and S-9. These CTEs provide a channel that undermines a clinician's professional responsibility to withhold information deemed potentially harmful to the patient. References to a "unique set of IIHI" raise concerns about what a "unique set" might be. However, we recognize that some NVEs may in fact create "new" information based on information they have aggregated from multiple sources. Need more work regarding the services an NVE may provide around aggregation.

Request for Additional CTEs

S-8: Revise to read: "If an NVE assembles or aggregates health information, then it must provide individuals with an electronic copy of their IIHI."

Recommended change regarding electronic access is necessary to clarify that the NVEs are not required to provide individuals direct access to the NVE's electronic repositories.

S-9: Revise to read: "If an NVE assembles or aggregates health information, then it must provide individuals with the right to request a correction and/or annotation of this IIHI."

An NVE should not be responsible for changing clinical data; rather the NVE should refer the patient to the organization that provided the data, should any corrections be warranted. Also, this CTE provides an opportunity for a malicious patient to wrongfully change data (e.g., a drug abuser).

S-10: Revise to read: "An NVE must have the means to verify that a provider requesting an individual's health information through a query-and-response model is authorized to request the information for a permitted purpose."

We think that the regulatory CTEs should be limited to those necessary to establish and preserve the trust fabric, and that CTEs that address interoperability and business practices other than those necessary to preserve the trustworthiness of the NwHIN should be in the purview of the validating bodies, with oversight from ONC.

Comments on specific CTEs:

- **[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."
  - None of the addressable implementation specifications are unreasonable to "require" of an NVE. However, rather than having the NwHIN Governance regulation change the addressability of HIPAA implementation specifications, we recommend creating a unique CTE for each of these "addressable" implementation specifications, effectively making them "required" for NVEs.

- **[S-3]:** An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.
  - "Meaningful choice" needs to be defined.

- **[I-2]:** An NVE must follow required standards for establishing and discovering digital certificates.
  - Suggest changing to "Digital certificates must be used to authenticate the identity of organizations on the NwHIN."

- **[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.
  - This Interoperability CTE will not apply to all NVEs

- **[BP-1]:** An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on anyother NVE.
  - The oversight of the NVE should seek to address any anti-competitive practices that inhibit free-flowing data exchange, but without imposing an absolute requirement that no fees be involved.

- **[BP-2]:** An NVE must provide open access to the directory services it provides to enable planned electronic exchange.
  - This CTE is protocol specific and is not appropriate as a top-level interoperability CTE.

- **[BP-3]:** An NVE must report on users and transaction volume for validated services.
  - Actual performance should be transparent, but minimal levels should be left up to the market.
  - The Public-Private Standards Entity (see question 2) should establish what performance measures are reportable.

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:

Tight governance as described in the Data Use and Reciprocal Support Agreement (DURSA) is unlikely to work on a national scale that encompasses both public and private entities, ranging in size from small private practices to federal agencies.

While service level agreements (SLAs) like those contained in the DURSA may be appropriate and enforceable within a tightly controlled consortium like the Exchange, this level of specificity is inappropriate for a national governance model.

We recommend a governance model that requires NVEs to publish their SLAs and their performance against these SLAs.

CTE Life Cycle

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

Question Context:

Top-level CTEs should focus on policy and should not change often. Lower-level CTEs should specify standards and criteria for certifying an NVE against a top-level CTE.

We recognize that market needs may encourage an NVE to provide services, and to support standards, other than those endorsed by the CTEs against which the NVE was validated. We suggest that an approach modeled after the HIPAA "hybrid entity" approach might allow for an entity to be regulated as an NVE for certain activities and to operate outside its NVE validation for other services. Transparency will be important here.

We recommend that ONC consider a set of core CTEs, required by Federal Regulation, and allow for NVE governing bodies to add optional CTEs by industry consensus in order to balance the need for a trust fabric with the need for industry innovation. We assume that NVEs would need to conform to some CTEs regardless of the specific electronic health information exchange service(s) or activities provided. We believe this approach could create a core trust baseline for all NVEs and that such commonality could strengthen the public's trust of NVEs, and NVEs' trust of each other. Finally, we assume that some NVEs could perform services or activities unrelated to adopted CTEs. In such cases, we believe it would be necessary for there to be a clear differentiation between those services an NVE performs in accordance with NwHIN governance covered by its validation and those services or activities it supports outside its validation.

We also believe that the certification process should allow for bilateral version skew for those standards that continue to evolve, such that an NVE would not sacrifice its validated trust or interoperability during a rolling upgrade to a new version of a certified standard.

CTE Life Cycle

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

Question Context:

Yes, we see the experiential value of piloting CTEs. These pilots should include representative stakeholders, including payers.

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:

We recommend establishing Public-Private Standards Entity (see question 2) to identify interoperability and business practice CTEs to be considered. This entity could be the existing advisory Committees, with the HITPC recommending policy-level CTEs and the HITSC recommending standards, implementation specifications, and certification criteria.

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:

We believe that the Validation bodies and Public-Private Standards Entity should encourage pilot testing and investigation of Emerging and Pilot standards and specifications. ONC's role would be to identify the standards and implementation specifications that have been categorized as Emerging or Pilot. ONC has a role to proactively evaluate a pilot to assess whether the standards and implementation specifications are ready to be categorized as national standards. An important criterion to consider is that there be backward and forward compatibility between new and existing standards. ONC should be willing to step in and test candidate protocols that have not otherwise been properly tested by standards organizations or other protocol entities.

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?

We endorse the framework on page 62 of the RFI for classifying technical standards and implementation specifications, which is consistent with the NwHIN Power Team's work in developing criteria and metrics for assessing the readiness of standards and implementation specifications to become national standards. However, although the process makes sense, the actors and their roles, and how these roles will evolve over time, need to be clearly defined, including interactions among ONC, the Validation bodies, and the NVEs.

Recognition of the need to refresh and update an interoperability CTE will likely emerge through the NVEs and the Validation bodies themselves. So we do not believe that interoperability CTEs should be codified in regulation, nor should updating and refreshing the interoperability CTEs be part of the regulatory process. Instead, we recommend that the Public-Private Standards Entity (see question 2) be responsible for recommending interoperability CTEs, with inputs from the Validation bodies and oversight from ONC.

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.

Recommend using the following criteria and attributes:

- **Maturity of Specification**
  - Attributes: Breadth of Support, Stability, Degree of Interoperability among independent non-coordinated implementations, and Adoption of Specification
- **Maturity of Underlying Technology**
  - Attributes: Breadth of Support, Stability, Degree of Interoperability among independent non-coordinated implementations, Adoption of Technology Components, Platform Support, and Maturity of technology within its life cycle
- **Ease of Implementation/Deployment**
  - Attributes: Effort for average developer to implement from scratch, Effort for average developer to implement with existing infrastructure to support implementation, Deployment Costs, Conformance criteria and Tests, Availability of Reference Implementations, Complexity of Specification, Quality and Clarity of Specifications, Ease of use of specification, Degree to which specification uses familiar terms to describe "real-world" concepts, Number of interfaces with external components or services, and Degree of optionality
- **Ease of Operations**
  - Attributes: Comparison of targeted scale of deployment to actual scale deployed, Number of operational issues identified in deployment, Degree of peer coordination needed, BIG O notation for operation scalability (i.e. operational impact of adding a single node), Cost, and Fit to Purpose
- **Market Adoption**
  - Attributes: Installed User Base, Future projections and anticipated support, Investments in user training ,and Inclusion in other standards
- **Intellectual Property**
  - Attributes: Openness, Accessibility and Fees, Licensing Policy, Copyrights, and Patents