

HIT Standards Committee

NwHIN Power Team

Recommendations for NwHIN Governance RFI Assigned Questions

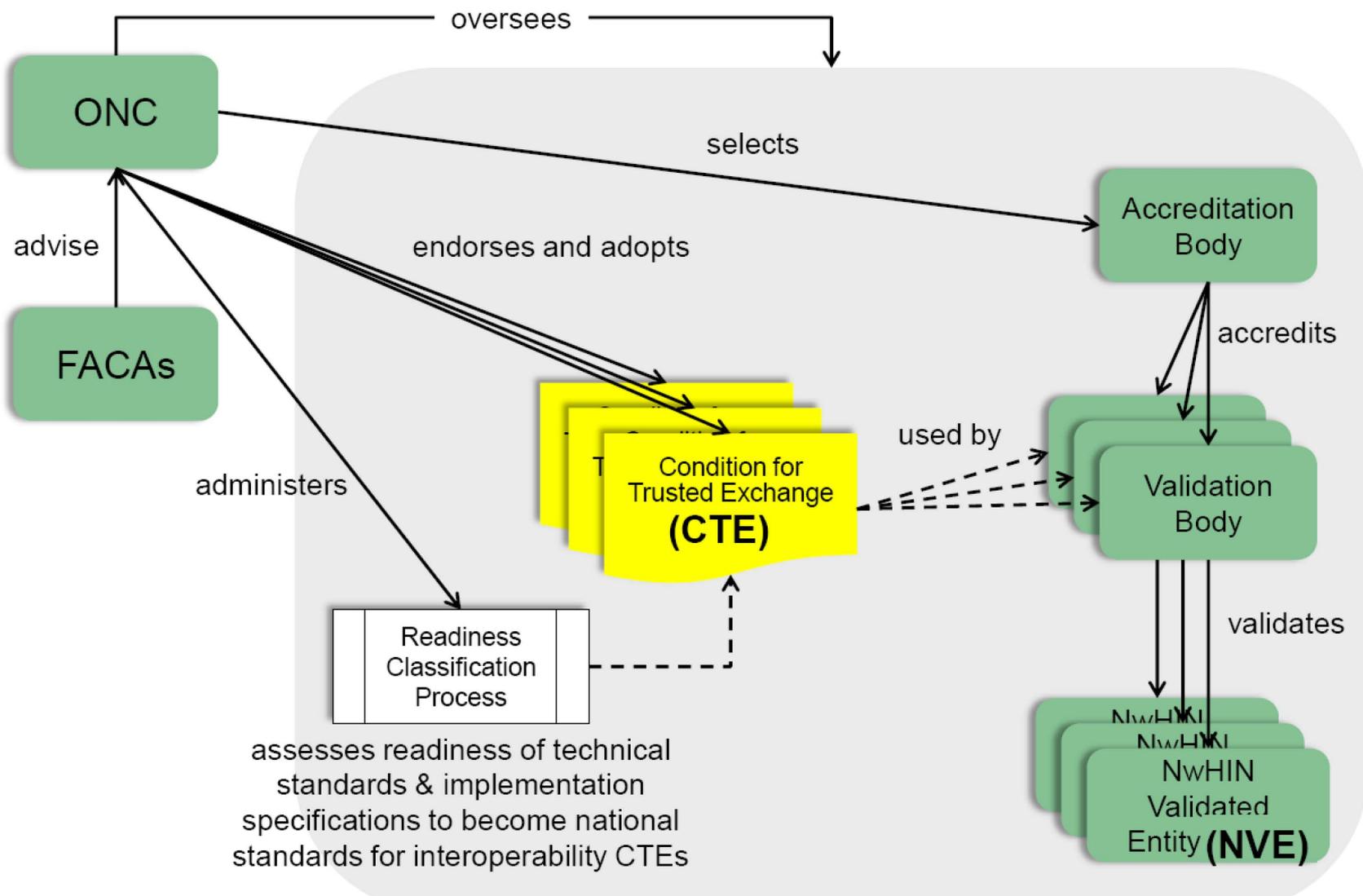
Dixie Baker, Chair

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NwHIN Power Team 2012

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Context Refresher: Governance RFI Concepts



Conditions for Trusted Exchange (CTE)

- RFI proposes three categories of CTEs
 - Safeguards (10 CTEs)
 - Interoperability (3 CTEs) – these are the CTEs for which technical standards and implementation specifications are prescribed
 - Business Practices (3 CTEs)
- Proposed CTEs are provided in Appendix A

NwHIN Power Team Assignment

- RFI poses 66 questions, 22 of which were assigned to the NwHIN Power Team to address
 - 8 questions address broad NwHIN governance policy
 - 6 questions address policy and process for selecting national standards and for adopting or modifying CTEs
 - 8 questions address technology standards to support CTEs
- We will present one overarching recommendation, followed by specific responses to the assigned questions

NwHIN Power Team: Overarching Comments and Recommendations (1 of 2)

- A core value of the NwHIN, and of the NVEs, is a trust fabric – 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
- 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”

NwHIN Power Team: Overarching Comments and Recommendations (2 of 2)

The NwHIN Power Team recommends:

- ONC should establish core Safeguards CTEs, codified in federal regulations
- Interoperability CTEs should be established collaboratively by the Validation Bodies, with oversight from ONC and the accreditation body
- 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 anti-competitive practices that inhibit free-flowing data exchange, without imposing absolute requirements through CTEs

**Responses to questions addressing broad
NwHIN governance policy**

NwHIN Power Team Responses: Governance Process

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?

NwHIN PT Comments:

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.

NwHIN Power Team Responses: Governance Process

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.

NwHIN PT Comments:

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.

NwHIN Power Team Responses: Governance Process

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.

NwHIN PT Comments:

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 ONC's responsibility, but the CTEs that are focused on interoperability should be delegated to the validating bodies of private entities in order to foster innovation and efficiency.

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.

NwHIN Power Team Responses: Governance Process

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.

NwHIN PT Comments:

Yes

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.”)

NwHIN PT Comments:

For a given CTE the validation method should be consistent across validating bodies.

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?

NwHIN PT Comments:

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)

NwHIN Power Team Responses: Governance Process

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?

NwHIN PT Comments:

The Governance of each Validating body should seek to have stakeholder representation in its internal governance. We believe that both the NVEs and the validating bodies should have input into overall NwHIN Governance and changes to the CTEs.

NwHIN Power Team Responses: Governance Process

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

NwHIN PT Comments:

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-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

NwHIN Power Team Responses: Governance Process

Question 56 (cont.)

NwHIN PT Comments (cont.):

- [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 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 validating bodies should collaboratively determine what performance measures are reportable.

**Responses to questions addressing policy
and process for selecting national standards
and for adopting or modifying CTEs**

NwHIN Power Team Responses: Selection Processes

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

NwHIN PT Comments:

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."

NwHIN Power Team Responses: Selection Processes

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

NwHIN PT Comments:

Yes, we see the experiential value of piloting CTEs.

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?

NwHIN PT Comments:

Validating bodies could set up a community of their own through which CTEs could be developed. collaboratively

NwHIN Power Team Responses: Selection Processes

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?

NwHIN PT Comments:

We believe that the validating bodies 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.

NwHIN Power Team Responses: Selection Processes

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

NwHIN PT Comments:

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 need to be clearly defined, including interactions among ONC, the validating bodies, and the NVEs. Recognition of the need to refresh and update an interoperability CTE will likely emerge through the NVEs and the validating 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 validating bodies be responsible for collaboratively identifying interoperability CTEs, with oversight from ONC.

NwHIN Power Team Responses: Selection Processes

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.

NwHIN PT Comments:

The NwHIN Power Team recommends 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

NwHIN Power Team Responses: Selection Processes

Question 65 (cont.)

NwHIN PT Comments (cont.):

- 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

**Responses to questions addressing
technology standards to support CTEs**

NwHIN Power Team Response: Technology

Re Condition [S-7]: An NVE must operate its services with high availability.

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

NwHIN PT Comments:

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.

NwHIN Power Team Responses: Technology

Re Condition [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.

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 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?

NwHIN PT Comments:

1. The Condition does not address all the reasonable circumstances for exchange and does not use language common in other regulations. 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.

NwHIN Power Team Response: Technology

Re Condition [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.

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?

NwHIN PT Comments:

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.

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?

NwHIN PT Comments:

This is a policy question and will be looked at by the Privacy and Security Workgroup.

NwHIN Responses: Technology

Re Condition [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.

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?

NwHIN PT Comments:

No, NVEs should not be required to meet a specific accuracy level. They should publish their accuracy levels and method of calculation.

This CTE should only apply to those NVEs that need to match a specific individual to IHI 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.

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

NwHIN PT Comments:

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

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

NwHIN PT Comments:

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

Back to the Business at Hand...

- Review of the Governance RFI was a diversion from our core task of developing recommendations for criteria and metrics for assessing the readiness of standards and implementation specifications to become National standards
- We will resume that work starting at our next meeting, scheduled for June 28
- Next steps:
 - Complete definition of metrics for defined criteria
 - Define process for applying criteria and metrics to the evaluation of standards and implementation specifications
 - Report preliminary findings and recommendations at July HITSC meeting
 - Test criteria and metrics
 - Make final recommendations at August HITSC meeting

Appendix A: CTEs Proposed in RFI

Safeguards CTEs S-1 through S-4

- [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.” [EXPLANATION: This CTE points to the HIPAA Security Rule and says that all of the implementation specifications labeled “addressable” are “required” for NVEs.]
- [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.
- [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.
- [S-4]: An NVE must only exchange encrypted IIHI.

Safeguards CTEs S-5 through S-9

- [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.
- [S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.
- [S-7]: An NVE must operate its services with high availability.
- [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.
- [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.

Safeguards CTE S-10

- [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.

Interoperability CTEs

- [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.
- [I-2]: An NVE must follow required standards for establishing and discovering digital certificates.
- [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.

Business Practices CTEs

- [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.
- [BP-2]: An NVE must provide open access to the directory services it provides to enable planned electronic exchange.
- [BP-3]: An NVE must report on users and transaction volume for validated services.