# H*i*MSS Electronic Health Record Association

33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 252-946-3546
Fax: 252-940-1130
E-mail:
himssEHRA@himss.org

AllMeds, Inc.
Allscripts Healthcare Solutions
Amazing Charts
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Workflow.com LLC
Xpress Technologies

June 20, 2012

Farzad Mostashari, MD, ScM
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Governance RFI
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave. SW
Washington, DC 20201

[Filed Electronically]

Dear Dr. Mostashari:

On behalf of the members of the EHR Association, we are pleased to submit our response to the Office of the National Coordinator for Health IT's (ONC) Request for Information (RFI) for the Nationwide Health Information Network: Conditions for Trusted Exchange.

We appreciate that ONC chose to engage health IT industry stakeholders in the context of an RFI which, we believe, reflects a thoughtful starting point to this important and complex topic. The EHR Association has wholly supported national, regional and local initiatives to implement standards-based health information exchange (HIE) since our inception in 2004. Speaking for our 41 member companies, we believe that your careful consideration of the responses to this RFI will set the direction for a governance model that must work for provider organizations, software developers, and most importantly, consumers who must trust industry to protect the security and integrity of their healthcare information.

The following is a summary of the most critical points from our detailed response. We look forward to participating in this ongoing dialog with ONC and others to ensure that, together, we meet those objectives.

- Use a public/private governance model – The RFI puts particular emphasis on proposing individual conditions for trusted exchange (CTEs). We suggest, rather, that the initial focus should be on the governance model itself—how to establish and sunset CTEs, validation and enforcement, etc.—rather than the initial set of CTEs and their

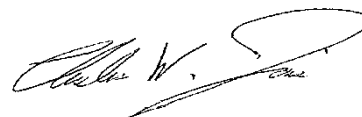maintenance, which are more appropriately the output of a governance framework, not the framework itself.

- Making governance operational – A public/private governing entity should be established to engage a broader group of stakeholders (e.g., the states), as has already proven effective in other US and international health care settings. This entity would address the rapidly evolving processes needed to establish CTEs, conduct pilot programs, and adjust them for practical deployment constraints. Although we have great respect for their work, we do not believe that the Federal Advisory Committees and ONC regulatory processes are the most appropriate approach to NwHIN governance and therefore propose creation of a public/private governing entity.  In addition, although the RFI is very clear that the governance model described therein will be voluntary, we are concerned that the use of a regulatory approach as well as the anticipated ways in which the CTEs and NVE status will be used will make these processes a *de facto* mandate in the industry and therefor see the broader and more robust governance that could be provided by a public/private process.

- Network validated entity (NVE) required clearer definition – While examples of potential NVEs are provided, the term NVE is not clearly defined.  In particular, the RFI does not appear to include the parties among whom the NVE is facilitating information exchange.  In many aspects, they are integral to ensuring interoperability in the NwHIN.

- Use of more flexible approach to CTEs - The RFI has a fairly rigid approach to CTEs, which is not reflective of the interoperability use cases to be supported, nor the efficiencies to be gained by adjusting the CTEs to address the level of risk, nor to best fit the actual deployment models. We are also concerned that an inflexible CTE approach will hinder industry innovation.

- Address broader use cases in initial governance proposed regulations - We disagree with the stated plan to issue the first set of regulations only for the known sender to known receiver use case (i.e. directed exchange) as opposed to a parallel approach that includes both directed and query exchange.  This plan could have the unintended consequence of discouraging interoperability when query exchange is the best match for a particular use case.

- Safeguard CTE should not go beyond the HIPAA Privacy and Security Framework – The Safeguard CTEs introduce several requirements that are either duplicative of existing HIPAA requirements, or go beyond them to establish new requirements for covered entities. It is not clear that these additional requirements are actually needed.

The RFI is an important step forward and provides a good framework to begin the process of determining how best to manage the NwHIN as a foundational component of the national health IT infrastructure.  We look forward to the next steps in maturing this important work.
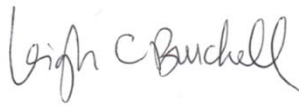
Sincerely,

|  |  |
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| Carl Dvorak | Charles Jarvis |
| Chair, EHR Association | Vice Chair, EHR Association |
| Epic | NextGen Healthcare |

**HIMSS EHR Association Executive Committee**

Leigh C. Burchell
Allscripts Healthcare Solutions

Jason Colquitt
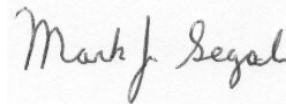Greenway Medical Technologies

Lauren Fifield
athenahealth, Inc.

Michele McGlynn
Siemens

Rick W. Reeves
CPSI

Mark Segal
GE Healthcare IT

cc: Steve Lieber, President and CEO, HIMSS
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Gail Arnett, Senior Director, HIMSS Corporate Relations and EHR Association

**HIMSS Electronic Health Record Association**

**EHR Association Response to**
**Office of the National Coordinator for Health Information Technology**
**Request for Information**
**Nationwide Health Information Network: Conditions for Trusted Exchange**

On behalf of the 41 corporate members of the Electronic Health Record (EHR) Association, we are pleased to respond to ONC's Request for Information on NwHIN governance and related issues. We appreciate ONC's decision to release a Request for Information (RFI) ahead of proposed rulemaking, allowing the industry the opportunity to provide input on this important initiative. We will address ONC's specific questions from the RFI below, but first we provide several general comments on the RFI:

1. We appreciate that ONC issued this document as a Request for Information.
2. It is essential that the next version of the process be an Advance Notice of Proposed Rulemaking or a Notice of Proposed Rule Making, rather than an Interim Final Rule.
3. Governance model – The RFI puts particular emphasis on proposing individual conditions for trusted exchange (CTEs). In contrast, we believe that the initial rules should focus on the governance model itself— how to establish and sunset CTEs, validation and enforcement, etc.—rather than the initial set of CTEs. CTEs and their maintenance are the output of a governance framework, not the framework itself.
4. Making the governance operational – We do not believe that the Federal Advisory Committees and ONC regulatory processes are the best approach for the NwHIN governance. A public/private governing entity should be established to engage a broader group of stakeholders (e.g., the states), as already proven effective, and required to address the rapidly evolving processes needed to establish CTEs, conduct pilot programs and adjust them for practical deployment constraints.
5. The phrase "network validated entity" (NVE) is not clearly defined and we ask that ONC do so in – While the RFI provides examples of organizations that may want to become NVEs, the term NVE is not clearly defined and requires detailed clarification.
6. Voluntary nature – Although the RFI is very clear that the governance model described therein will be voluntary, we are concerned that the use of the proposed regulatory approach to NwHIN governance, as well as envisioned use of the NVE accreditations by public and private sector organizations, will make it a *de facto* mandate in the industry. To that extent, the process would require a higher level of specificity, rigor and due process than is proposed by ONC. .
7. Rigid approach to CTEs - The RFI has a very rigid approach to CTEs and their application, which is not reflective of the interoperability use case to be supported. This also does not exhibit the efficiencies to be gained by adjusting the CTEs to address the level of risk, nor does it best fit the actual deployment models that are in use today.
8. Impact to industry innovation – We are concerned that the approach proposed in the RFI, with its fairly rigid CTE approach, will serve as a disincentive to industry innovation as it will tend to constrain the variety and use of innovation in models of exchange..

9. The safeguard CTEs go beyond the HIPAA Privacy and Security Framework – The Safeguard CTEs introduce several requirements that are either duplicative of existing HIPAA Privacy and Security requirements or go beyond them to establish new requirements on covered entities. It is not clear that these additional requirements are not actually needed nor that NwHIN governance should exceed HIPAA requirements, which have already been expanded in their applicability by HITECH.

10. We also disagree with the plan to issue the first set of regulations only for the known sender to known receiver use case (i.e. directed exchange) as opposed to a parallel approach that includes both directed and query exchange.  This plan could have the unintended consequence of discouraging interoperability when query exchange is the best match for a particular use case.

## Comments on Individual Questions in the RFI

| Questions | EHRA Comments |
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| **II. Request for Information** | |
| **A. 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? | The categories of Safeguard, Interoperability and Business Practices are overlapping. The business practices required under HIPAA Privacy and Security regulations have already been taken into account in the development of appropriate interoperability and security standards built into the NwHIN Exchange and NwHIN Direct specifications. |
| | Several CTEs do not fall into the three stated categories (e.g., several CTEs are actually accreditation/validation CTEs). |
| | Perhaps there could be a core and menu set similar to meaningful use requirements, e.g., minimum requirements for an NVE, plus additional optional capabilities that can be validated.  In addition: |
| | • The Interoperability CTEs should focus on what is minimally required but not be framed as an exclusive set of requirements or a ceiling, allowing for other standards/approaches to be used as well, creating added value. |
| | • The Business Practices CTEs should focus on essentials that do not preclude innovation. |
| | Validations should be "modular" rather than "one-size-fits-all" because not all organizations will need to do all functions. This is implicit in the phrase "voluntary framework for entities that facilitate electronic exchange to be validated to CTEs adopted for the exchange services or activities they are capable of supporting," but it should be made very explicit. |
| **Question 2:** What | There are several existing approaches to governance that have already been successful |

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| kind of governance approach would best produce a trusted, secure, and interoperable electronic exchange nationwide? | in the development of security and interoperability standards and which take into account business practices required under regulation. We encourage ONC to take advantage of existing standards development organizations, profiling and enforcement organizations, certifying bodies and education bodies in a national program.

Canada, Austria, Australia, France, the UK and many other countries have a national standards program devoted to healthcare. We encourage ONC to learn from these programs and develop a U.S. program in support of standardized health information exchange. These countries have been careful not to use legal or regulatory channels for CTEs and validating NVEs. They have used the legal and regulatory process to empower national governance authorities as a public/private authority.

ONC should use its regulatory authority to establish such a public/private NwHIN governance authority that could:
1.   Delegate the work of standards and implementation specification development and maintenance to these standards and profiling organizations;
2.   Participate in the organizational governance of standards organizations (as many federal agencies already do);
3.   Allow important stakeholders (e.g. the states) to engage and accelerate adoption.

Such an approach would improve the trust and confidence in international standards and profiling efforts. Approaches that duplicate existing processes for developing consensus and creating standards and implementation guides compete with and reduce the effectiveness of global standardization.

A voluntary approach is preferred. Industry pressure and transparency will enable further development of best practices, while leaving room for innovation. Since an NwHIN Exchange data use and reciprocal support agreement (DURSA) exists and was mentioned in the RFI, please explain how this DURSA relates to the rest of "governance." Please clarify what should be retained and what should be superseded re DURSA or HIPAA. |
| **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 | We share ONC's goal of real health information exchange. We urge that caution be taken that this regulatory process and the resulting activity in revision and validation not cause the unintended consequence of slowing momentum already within the industry while stakeholders wait to see how final regulations and requirements unfold. Conversely, governance is a means to ensure sustainability and remove other potential barriers to exchange, such as trust issues. Putting out an RFI is a good start, but ONC should not rush to publish regulations except where the situation is truly "broken". |

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| to be developed and why. | |
| **Question 4:** Would a voluntary validation approach as described above sufficiently achieve this goal? If not, why? | The RFI approach appears to focus around a certification approach, building on the model used for the EHR incentive program.  There are other appropriate validation approaches to consider, including self-attestation, voluntary attestation (e.g., IHE Connect-a-thon), etc.  Even where a certification approach is voluntary, it can still be overly burdensome.

A voluntary approach could work for some CTEs, but a grievance process must be outlined.  Other participants in the trusted exchange need to know how to address identified gaps in their exchange partners' performance.  Appropriate transparency is necessary, but it must be balanced with minimal compliance overhead.

Validation and testing need to be better structured. There is an important distinction between testing the technology and testing a deployed instance of the technology.  The governance model described in this RFI does not reflect this distinction.  Industry needs a governance model to match the mature deployment model of NwHIN.  For example, if the deployment is hierarchical, then governance needs to be hierarchical.  Right now, we lack clarity on the NwHIN deployment model.

We agree that a voluntary validation approach is sufficient to achieve the goals set forth in the RFI.  However, as described, the current approach uses the term "voluntary" only in a formal regulatory sense.  If we anticipate that this certification will become the basis of required exchanges in certain geographic regions, then certification is not fully voluntary as proposed. |
| **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? | We encourage a governance process that takes input from the individual states and works to provide uniformity across the states.

To ensure that state-specific requirements do not yield cross-state exchange conflicts, the engagement of the states in a public/private NwHIN governance authority is an important foundation and mediator.  Facilitating the establishment of a consistent superset of CTEs consisting of a federal minimum and state-specific menu items, as needed, can result in a cohesive set of CTEs based on the state(s) that NVEs cover/interact with. We also recommend that ONC consider the voluntary efforts of some states that have been underway for about 15 months (e.g., NY EHR/HIE Interoperability Workgroup, which involves several populous states and many EHR and HIE vendors).

It is not clear that establishing a national validation process would relieve any burden on the states to regulate local and regional exchange markets.  Even existing EHR certification (which is a national validation process) does not prevent states from requiring conformance to additional specifications to support reporting to state-specific immunization registries.  It would appear that one way to get states to agree is to give |

| | them sufficient opportunity to collaborate in the development of national or regional level specifications, as has been done through the EHR HIE Interoperability workgroup. |
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| **Question 6:** How could we ensure alignment between the governance mechanism and existing State governance approaches? | See Answer to Question 5. Including the states in the process is critical to success. Allowing states to continue to add custom requirements on top of federal floor requirements will ultimately undermine the success of the NwHIN.

It is absolutely vital that any national program be something that states are willing to participate in.  In order to obtain state participation, they must be given a stake in not just the outcomes, but also in setting the priorities for development of interoperability specifications. |
| **Question 7:** What other approaches to exercising our authority to establish a governance mechanism for the nationwide health information network should we consider? | We recommend a public/private partnership distinct from the ONC HITECH model.  The core program objectives of the NwHIN are well aligned with the ONC Strategic Plan. We believe that the strategic planning process, which already supports substantial stakeholder input, should be one of the major drivers in development of NwHIN priorities.

A public/private governance authority should be responsible for development of principles and implementation of processes which enable:
• 	 Identification and prioritization of CTE's;
• 	 Objective assessment and risk analysis of specifications;
• 	 Monitoring of CTE usage; and
• 	 Versioning and retirement of CTEs.

ONC should further consider adopting existing principles for the development and validation of consensus-based standards published by ANSI as found in:
• 	 ANSI Essential Requirements: Due process requirements for American National Standards, and
• 	 United States Conformity Assessment Principles.

We believe that a public/private governance authority, involving all stakeholders in health information exchange should be able to promote the development, testing, deployment and maintenance of specifications which could become CTEs and utilize the same processes to develop those specifications.  It could easily develop a standardized process for filing grievances.  ONC does not necessarily need to be the grievance board, but it should provide guidance. |
| **B. Actors and Associated Responsibilities** | |
| **Question 8:** We solicit feedback on the appropriateness of ONC's role in | Again, we recommend a public/private process.

We would like ONC to clarify in the proposed rule how the statutory authority granted under HITECH to establish a governance mechanism for the NwHIN will be coordinated |

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| coordinating the governance mechanism and whether certain responsibilities might be better delegated to, and/or fulfilled by, the private sector. | with statutory authority granted to CMS and other entities under Title XI, Part C of the Social Security Act, specifically with sections 1171 through 1179, and with current regulations promulgated (e.g., the HIPAA Transactions and Code Sets rules) under the authority granted. We are concerned that without further clarification and coordination, a bifurcated process will be created impacting the development of standards and policies used for healthcare information exchange.<br><br>We believe that many of the responsibilities for the development, testing, deployment and maintenance of specifications used in CTEs can be delegated to a public/private authority whose responsibilities would be to prioritize, objectively assess and perform risk analysis, provide for monitoring, and develop principles by which CTEs are maintained and retired. Some CTEs should be addressed by one organization, some by another. Not all need to be federally chartered. All organizations involved in CTE validation should be engaged.<br><br>While ONC may coordinate these activities, it is not the sole stakeholder. It must enable other stakeholders (patients and consumers, state government, federal agencies, medical professionals, and industry) to participate actively in the public/private NwHIN governance authority. |
| **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. | Alone, a single voluntary validation approach does not accomplish this goal.<br><br>The focus in the current RFI on accreditation and on validation by accountability agents seems to imply an overreliance on a certification model, which can be detrimental to innovation and more importantly to collaborative work among competing and non-competing entities that create a vibrant ecosystem. We note that there are a number of different ways that validation can be performed to increase trust in a marketplace. The following methods have been used successfully in healthcare and other markets to increase trust and enable interoperable exchange of information:<br><br>Self-Attestation<br>Organizations can self-attest their conformance to standards and specifications. Self-attestation by an organization that it conforms to a specification is a low cost model for validation. It allows organizations to build conformance testing into product development and integration processes.<br><br>Self-attestation is a form of product labeling and/or marketing, and thus it is subject to laws and regulations governing such activities, which provides some mechanisms supporting monitoring. DICOM, HL7 and IHE define the format of conformance statements for documenting product conformance to a specification.<br><br>The FDA accepts DICOM conformance statements as part of its submission processes for medical devices. These conformance statements also become part of the regulated product labeling.<br><br>IHE conformance statements are commonly accepted and/or required in procurement |

activities soliciting products supporting health information exchange. Several US health information exchange organizations request – and even require in some instances – submission of an IHE conformance statement. For example, the Veterans' Administration (VA) requires an IHE conformance statement in their RFPs.

In the HL7 Version 2 standards, there are ways to represent and register a "conformance profile" to document and test Version 2 message conformance. HL7 makes conformance testing tools available, which enable messages to be validated according to a conformance profile and generate test messages that are valid according to a conformance profile. These HL7 Version 2 testing tools have been developed with assistance from both the VA and NIST.

HL7 also provides a definition of Version 3 conformance statements (see http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.html#v3gconfclaims). The definition is admittedly thin, and it could be enhanced to better support the needs of industry.

Self-attestation is greatly assisted by the availability of testing tools. W3C hosts several testing tools that can be used to validate use of their standards, and they also provide a way for organizations to visually self-attest conformance to the standard (see http://www.w3.org/QA/Tools/Icons). The availability of freely available testing tools and conformance icons makes it easy for vendors to test their own claims of conformance and to show that they comply.

There are numerous freely available testing tools for DICOM, IHE, HL7 and other standards. IHE makes the same tools it uses in voluntary testing events (see below) freely available to anyone after the event, and these are also made available to testing event participants prior to the testing event.

Voluntary Testing Events
Several standards setting organizations provide for voluntary testing mechanisms. For example, Continua Health Alliance conducts "Plugfest" events to allow manufacturers to test interoperability with other devices. IHE conducts "Connect-a-thon" and "Project-a-thon" events which allow product developers to test interoperability with other products, and with regionally- developed specifications. Several health information exchanges have hosted their own Connect-a-thon-like events, including a testing event for participants in NwHIN Exchange. The Direct Project used "Code-A-Thons" and "Virtual Connect-A-Thons" for its reference implementations.

Many countries and even multi-national projects recognize the results from IHE Connect-a-thons and Project-a-thons as satisfying validation requirements for their projects. IHE does publish Connect-a-thon results, but only associated with a specific organization, not for a specific product. It does make links to an organization's product conformance statements (see Self-Attestation above) available on its web site.

Although there are fees associated with testing events, these are often much less than

| | any fees and overhead costs associated with accreditation or certification processes. |
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| | **Connect-a-thon vs. Project-a-thon**<br>Testing of technology needs to be separated from testing of deployments. Testing that a technology is capable of secure, interoperable exchange does not ensure that, as implemented, it performs appropriately. It is only by testing the technology as appropriately configured for a specific project that one can assure successful deployment. This is the distinction made between Connect-a-thon and Project-a-thon. It is also important to note that, unlike the standard Connect-a-thons where some products are in a pre-release state while others have been released, the Projectathon validation process we are recommending would include testing of only production level "released" (or completed, but pre-market) products with some potential for configuration modification to account for localized requirements.<br><br>**Certification**<br>Certification is perhaps the most well understood of the different validation frameworks, and it is also the one which the NwHIN RFI seems to find the most compelling. The point of validation of CTEs, and the development and adoption of CTEs, is to engender trust within exchanges. We note that there are numerous existing certification programs for health information exchange, including certifications from CAQH/CORE, EHNAC and SureScripts. A proliferation of certifications could become another source of confusion to the marketplace, especially when such certifications overlap in the assurances that they provide.<br><br>Market pressure from providers and states will be sufficient to encourage facilitators of information exchange to receive the NVE status as a badge of trust, making it unnecessary to mandate validation. And there should be a documented "complaint" process whereby customers of an NVE can raise complaints that the NVE may not be fulfilling the CTEs that they claim to meet. This could be similar to the CEHRT complaint process for meaningful use. This point is covered on page 28552 column 1, which we think will be sufficient. |
| **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 | Variation of validation method by CTE should be allowed as needed.<br><br>Each of the mentioned frameworks for validation listed in the answer to Question 9 provides for a different level of assurance and trust. The level of assurance and trust needed for an information exchange varies based upon the purpose of exchange, the timeframe in which information used in the exchange is going to be acted upon, and the criticality of the information to patient care. An exchange in which de-identified patient profiles are communicated to central locations in support of disease surveillance may not require the same level of assurance as exchanges which are used to communicate life-critical health information with respect to degree of validation.<br><br>One question that the NwHIN governance authority needs to address is the degree to which validation is needed for a particular CTE. In developing the answers to this |

| adopt, see section "VI. Conditions for Trusted Exchange.") | question, it must consider: |
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| | 1. What validation activities are already in place; |
| | 2. What level of assurance to those activities provide; and |
| | 3. What additional activities may be needed to provide the right level of assurance to industry that a particular CTE is validated for a given NVE? |
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| | For example, to achieve the right level of assurance for a CTE using self-attestation, the proposed public/private NwHIN governance authority may determine that an appropriate voluntary monitoring and reporting program must be present. |
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| | The answers to these questions will often be related to industry readiness for adopting a particular specification as a CTE.  When a CTE is fairly new and not well understood or implemented, high assurance in validation can help ensure that all NVEs executing to that CTE are doing so consistently.  CTEs for which there is a higher degree of readiness in industry with respect to adoption may need a lower level of validation assurance.  For example, one should not spend much time on a CTE for conformance to HTTP because this is a very mature and well-adopted standard. |
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| | Establishment of a certification requirement for validation is something that needs to be evaluated periodically through monitoring and evaluation of effectiveness. |
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| | Some CTEs may also start out using a validation method with a lower level of assurance, only to find later in practice that a higher level of assurance is necessary. Again, ongoing monitoring of the effectiveness of the validation approach is needed. |
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| | Multiple validation approaches might be considered, allowing market forces to determine what level of assurance is required.  One could have "bronze," "silver" and "gold" levels of validation for some kinds of CTEs representing different levels of assurance. |
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| | One example where multiple validation approaches have been successfully used is in the Stark Relaxation regulation. In that regulation, CMS determined that EHRs which could be provided by hospitals to ambulatory providers needed to be interoperable, but it did not require those EHRs to be certified as being interoperable.  There was a "deeming clause" that enabled providers to skip a step in determining whether the EHR was interoperable when it had already been certified by an authorized body. |
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| | Note: there is a typo in the reference to "Section VI. Conditions for Trusted Exchange." The correct reference is Section <u>D</u>, not VI. |
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| **Question 11:** What successful validation models or approaches exist in other industries that | The W3C provides a validation service and icons that can be used to voluntarily identify conforming content.  Use of these icons according to W3C terms makes it easy for "customers" of conforming content to test for themselves that the content is valid.  The availability of simple, consumer-usable testing tools and easily identified labeling makes it very easy for consumers to trust that a website that says it is conforming to the |

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| could be used as a model for our purposes in this context? | standards is doing so.<br><br>For example, there are numerous devices that support the USB specification; although there is also a certification program, not every manufacturer goes through that certification program to deploy a USB device. For some, the reputation of the manufacturer is sufficient to assure compliance with the USB specification. However, for other manufacturers, the use of the USB logo provides additional confidence to consumers that the device is conforming. Note that both USB and W3C are truly voluntary. That is, Apple does not use the USB logo even if its products implement USB.<br><br>Connect-a-thons and Plugfests did not start in healthcare. IHE and Continua borrowed these names from traditional IT events. Oracle (formerly Sun) has used Connect-a-thons to test NFS (Network File System) and other networking protocols for the past two decades. It has been used to test AMPQ, IPv6 and a variety of other protocols. Plugfest is also used to describe similar activities, some hosted by Microsoft, for networking and many other integration initiatives. What is distinct about Connect-a-thons or Plugfests from traditional certification processes is that they provide a mechanism to ensure interoperability between organizations that would otherwise be competitive. |
| **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? | A balanced model that ensures the appropriate level of assurance through a combination of self-attestation, voluntary testing and certification will increase the volume and efficiency of exchange.<br><br>A model that leans too heavily upon certification can create confusion. The present ONC EHR certification model, which relies on multiple certifiers, is sometimes confusing to the market because of the multiple logos, types of certification (modular or full EHR), and even competing certification processes which do not provide the necessary benefits for which certification is sought or which purchasers expect to receive. |
| **Question 13:** Should there be an eligibility | No. The fact that it is providing an exchange service is sufficient purpose given the national priority for information exchange. We are concerned that the purpose of the |

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| 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? | different entities involved in exchange is being confused. The NVE simply provides tools to facilitate exchange while providers themselves are treating patients. Also, the purpose could vary on an exchange-by-exchange basis. It is the responsibility of exchange participants, rather than NVEs, to determine the appropriateness of the exchange.<br><br>An analogy that illustrates why treatment, or a similar rationale, should not be an eligibility criterion would be asking the phone company or Internet Service Provider if they have a valid clinical purpose for their infrastructure. |
| **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? | We do not believe that an entity should need to have prior electronic exchange experience.   Many of the organizations facilitating exchange today did not exist two years ago, and they could not have been said to have had any prior experience with electronic exchange (although some of the individuals in the organization may have had that experience).  This sort of requirement creates a "chicken-and-egg" problem.  You cannot participate unless you have prior exchange experience, but you cannot get that experience if you cannot participate.<br><br>With regard to the number of participants served, we believe that there should not be eligibility criteria for this aspect of exchange.  Restricting an entity based on the size of the population served could prevent remote populations from participating in exchange. The "little guy" organization should have equal opportunity if it can meet the agreed-to CTEs. The emphasis should be on quality of service rather than quantity of experience and participants. |
| **Question 15:** Are there other eligibility criteria that we should also consider? | "Valid business or governmental entity operating in U.S." – Please clarify how this criterion is defined and determined.<br><br>"Have not had civil monetary penalties, criminal penalties, or damages imposed, or have been enjoined for a HIPAA violation (by HHS, the Department of Justice, or State Attorneys General) within two years prior to seeking validation." – We recommend dropping this as an overly restrictive eligibility criterion. Several well-established HIEs have had civil monetary penalties and would thus be ineligible under this criterion.<br><br>"Serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion, however, no prospective NVE would be deemed ineligible if it only served providers located in a single State." – This would be an undesirable requirement because it would essentially penalize a small organization because it is not big enough for the government to measure.<br><br>While many on the Excluded Parties List appear to make sense, it is unclear why one's ineligibility for federal contracts should mean that one cannot run an NVE. |

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| **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. | No. We disagree with this eligibility criterion. There is no evidence or argument that a tax-exempt or non-tax exempt entity would run a better or worse NVE. We also point out that there are many for-profit health systems that may wish to seek NVE status.

There are numerous entities today that participate in health information exchange which are not tax-exempt under section 501(c)(3) of the IRC. We do not believe that those entities should be treated differently from entities that are for the purpose of facilitating exchange. |
| **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? | We believe that all stakeholders should be eligible to engage in governance of the nationwide health information network. There are natural tensions between federal and state government, industry, providers, and patients that should be balanced through consensus processes that are not dominated by any single stakeholder.

Consumers (including patients) deserve special attention because they are most often the least able to make themselves heard. Most consumers lack the necessary funding and support to participate fully in governance activities. ONC should consider funding or providing some sort of additional support to ensure that consumer voices are part of the governance process at a level equal to that of any other stakeholder. For example, it is not enough to have consumers call in when everyone else can be present face-to-face.

Consensus on minimum required CTEs with target timeframes is critical to ensure buy-in and broad participation. Better to take more small steps that can build on success than fewer big steps that leave many out of the process.

As for stakeholder representation, although we recommend leveraging established mechanisms, such as the Health IT Policy Committee or Health IT Standards Committee workgroups, we believe that an NwHIN governance process should not focus or rely solely on these committees, and we recommend reviewing whether the current composition of those workgroups is appropriately balanced among stakeholders, especially the full range of providers who would actually participate in the exchanges. |
| **C. Monitoring and Transparent Oversight** | |
| **Question 18:** What are the most appropriate monitoring and oversight methods to include as part of the governance | Monitoring and oversight methods should be delegated to the organization that manages the exchange. (e.g., HIE is responsible for providing oversight of exchange participants), with the NVEs monitored by the public/private governing entity that we suggest in our response to Question 8.

The degree of monitoring and oversight that validation bodies perform depends upon the type of validation. Certification bodies provide a mechanism for ongoing monitoring of products that they have certified, and failures in the field of certified product can be |

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| mechanism for the nationwide health information network? Why? | sufficient reason for those bodies to revoke a certification. However, other validation processes, such as voluntary testing or self-attestation, do not necessarily have a built-in monitoring process.

As noted in the RFI, there are existing laws and regulations governing marketing and sales practices over which FTC has jurisdiction, and these can serve self-attestation to some degree.

We believe that there is a role for an ombudsman to support industry self-policing in the monitoring process. The role of a trusted third party in industry self-policing is important. It creates a necessary separation allowing advocacy for consumers, yet maintaining confidentiality for industry, and it creates a bridge of trust between them.

With regard to other enforcement mechanisms, we return to our example of how the W3C supports declarations of interoperability. The W3C has very minimal licensing requirements to use its logos to promote the interoperability of a web page. However, we note this is still a license and, should an organization misuse these images, the W3C has the right to take action. Similar programs could be established by bodies which develop specifications upon which CTEs are built, provided that there are readily available mechanisms to test conformance to those specifications. We encourage ONC to prevail upon those bodies to develop similar programs.

We suggest that one of the first priorities of the NwHIN Governance Authority would be to assess the degree to which monitoring and oversight are needed for different CTEs, then developing proposals to address gaps. |
| **Question 19:** What other approaches might ONC consider for addressing violations of compliance with CTEs? | Dealing with violations of compliance is an element of governance that we suggest be placed under the same public/private NwHIN Governance Authority we recommend elsewhere. This single organization (see answers to Questions 7 and 8) would also act as a validation body responsible for monitoring and overseeing the NVEs that have been validated. Having a single entity will avoid inconsistencies between validation entities.

At the same time, we also believe, as discussed elsewhere, that various CTEs might be the responsibility of multiple organizations that are applicable for these CTEs and that some assessment of compliance should likewise be distributed among these organizations rather than fully centralized in a single body.

A tiered approach to remedial actions should be considered to address CTE violations, with allowance for corrective action plans, a rapid appeals process when violations are reported, and appropriate transparency into the process of determining a violation and the steps to address any violations. This will also need to be made clear directly to any entity that is cited as violating the CTE. |
| **Question 20:** What limits, if any, would | It would be beneficial to have clear and consistent labeling with respect to validated services and activities, and we agree that labeling should be readily accessible to the |

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| 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? | public. We do not believe that it should necessarily require a registration system such as is presently used in the EHR certification program. So long as labeling guidelines are clear and applied consistently, this should be sufficient. Existing safeguards with respect to contracts and product marketing should be sufficient for most purposes.<br><br>There should be clear delineation between services that have been validated under the NVE banner, including the CTEs covered, versus any other services that organization may offer. This is similar in principle to EHRs which have many functions besides those fulfilling certification criteria. NVEs should not be required to make burdensome statements like, "This is not part of NVE validation" for every function that is not validated. Rather, NVEs should only be required to identify/label those functions which *are* part of their validation. |
| **Question 21:** How long should validation status be effective? | How long validation status is effective depends upon the a) the level of assurance attained by the validation status, b) the likelihood of change in validation status given that an organization has already been validated, and c) the degree of change in the validation criteria. We believe that validation status should be effective for a minimum of two years to ensure market effectiveness. We also believe that revalidation could require less effort than an initial validation for many CTEs, similar to the gap certification in the current EHR certification program.<br><br>We suggest alignment with the length of meaningful use stages, depending on how often the CTEs are updated. If they are updated on a continual "rolling" basis, then it will be hard for customers to know what validation means. There should be "version control" of the validation criteria, and not overly frequent updates. Every two or three years seems reasonable.<br><br>The validation status should not have a single expiration date. This is specific to each CTE. Some CTEs may have an expiration date set when an updated CTE is published, while others may never expire unless a trigger occurs.<br><br>Technical conditions are unlikely to change, and one-time certification should be sufficient, especially since proof of interoperability is demonstrated daily when systems are in production. Business practices, on the other hand, could change instantly. A one-size-fits-all solution once again would fail here. |
| **D. Conditions for** | |

| Trusted Exchange (CTEs) | |
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*Condition [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."*

**General Comments**

The development of conditions for trusted exchange should be the outcome of the governance mechanism, not the first step. We have commented individually on issues presented by the CTEs described below. In general, the intent of the CTE's is sound, but given that they have not been through an adequate development process that would be established through NwHIN Governance, there are numerous cases where these CTEs would need further deliberation that goes beyond the boundaries of a regulatory process as proposed in this RFI.

| **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? | We disagree with this CTE being included. As ONC points out, most NVEs will be business associates of covered entities, and thus they are already subject to the HIPAA Security Rule under the HITECH Act. It is not the role of a validation body to ensure or enforce HIPAA compliance. Restating the compliance requirement here is duplicative and burdensome.<br><br>In addition, we disagree with the departure from the risk-based model outlined in the HIPAA Security Rule. Security best practice recommends a risk-based approach over a checklist approach. As we noted above, the definition of NVE is not entirely understood or agreed upon. However, ONC provides a list of example potential NVEs: EHR developers; regional, state, local or specialty-based health information exchanges; health information service providers; state agencies; federal agencies, and integrated delivery networks. This is a varied list, and there is no "one size fits all" security solution for these various entities. The risk-based approach in the HIPAA Security Rule was originally targeted to address this, and we disagree with a departure from it.<br><br>In addition, "addressable" specifications should not be changed to "required" While we understand the intent that every handler of patient data should act as a covered entity, going beyond the provisions of HIPAA will deter current covered entities from offering exchange services in their community.<br><br>Finally, we point out that the concept of "entities that facilitate electronic exchange" requires much further definition, even under a voluntary model. |
| **Question 23:** Are there other security frameworks or guidance that we | The NwHIN governance model should not go beyond already strong protections for ePHI (Protected Health Information) outlined in the HIPAA Privacy and Security Rule. |

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| should consider for this CTE? Should we look to leverage NISTIR 7497 Security Architecture Design Process for Health Information Exchanges32? If so, please also include information on how this framework would be validated. | |

*Condition [S-2]: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly.*

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| **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? | Following the risk-based approach in the HIPAA Security Rule, specific assurance levels should not be outlined or required for validation as an NVE. Each provider and NVE must perform their own security risk analyses to determine the most appropriate level of assurance for authentication and authorization controls. The level of assurance that is appropriate depends on the type of health information exchanged and the purpose or use case.

Rather than attempting to define an appropriate "level" of assurance in the governance framework, a proper grievance process would support NVEs as good actors in a proper community of exchange. If NVEs were held to the HIPAA Privacy and Security Rules with regard to breach notification, that would also solve this problem. The NVE would take on the level of risk it felt appropriate and would bear the consequences of an improper judgment. Requiring a NVE to be bound as either a covered entity or a business associate of a covered entity would have the same effect. |
| **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 | An indirect approach is most appropriate and, if properly implemented, would not reduce the potential trust provided by an NVE. If ONC intends to propose specific requirements, it needs to tailor those requirements to the specific exchange infrastructures in existence today. Further, this specificity could only be explicit in regards to the known models of current ecosystems, and it could easily lead known models to be out of date or irrelevant as new models for exchange with new actors are adopted. Therefore, we recommend that ONC only discuss intended outcomes, not the means to achieving them. |

| authentication and authorization processes to be implemented consistently across NVEs? | |
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| **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? | The lack of clarity on the role and legal status of NVEs as proposed in the RFI makes the answer to this question quite difficult.

In one sense, there needs to be a clear separation of responsibility between the NVE and the healthcare providers that should adhere to defined practices. A NVE should only require that data transmitted to/from the NVE is done so in a secure fashion.  An NVE should not be held accountable for security breaches or other CTE challenges under the control of the provider.

However, there needs to be a means by which a NVE ensures that requirements are met by its participants. For example, one NVE might choose to allow its participant organizations to self-verify their practices, while another might choose to audit, and a third might require a real-time technical assertion. With respect to this CTE and others, if the NVE is responsible for the outcome, the means by which it is assured or enforced should remain flexible.

Therefore, if some form of flow-down of requirements to parties served by NVE is necessary for some CTEs, it should be done in a way that provides balanced responsibilities between the NVE and the providers and also provides some level of consistency across NVEs for the same CTEs. |
| *Condition [S-3]: An NVE must ensure that individuals are provided with a meaningful choice regarding whether their IIHI may be exchanged by the NVE.* | |
| **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 | This CTE, more than any other, is perhaps the most inconsistently implemented and understood concept in the interoperability landscape today. However, to define it more narrowly could inappropriately limit our current understanding of "meaningful choice" to our current understanding of popular exchange models today. As indicated above, as long as the NVE is exchanging data only, or facilitating the exchange (push-pull-query-response), then it should be incumbent on the provider to obtain appropriate consent where the NVE can execute according to that consent. The NVE should not have to directly obtain such consent from the patient unless it starts to use the data for other purposes than a) exchange between providers or b) other legitimate purposes allowed under its business associate agreements with participating providers.

Under HIPAA, individual choice with respect to information exchange used for |

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| 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? | treatment, payment or operations is quite limited, and consent (opt-in, opt-out or otherwise) is not necessary.  Operationally, requiring an additional "choice" mechanism creates a higher bar for exchange, and thus for treatment, than currently exists, and this could have detrimental impacts on patients.  We agree with the goal that individuals need to be protected, but it is not clear that this CTE can be broadly applied to the variety of exchange that could occur on the NwHIN without having negative consequences.

In instances where the NVE has to directly obtain consent from the patient, we suggest that ONC model five to ten approaches to meaningful consent, in the context of different types of exchange (pushing point-to-point, querying an intermediary, submitting to public health) in which those approaches are recommended. An NVE could satisfy a CTE by describing a model, or introducing a new model based on the needs of the exchange community it serves. We believe that this approach would serve to reduce minute differences and confusion while still allowing for flexibility based on needs.

If the patient becomes a participant in the exchange, e.g., their connected PHR generates an exchange to a provider, then consent should be implied.

In addition, we would like to clarify the meaning of consent revocation. Consent revocation should mean that the providers/NVE do not have consent to make future exchanges of the patient's data. Past exchanges would be unaffected by the revocation. It would be technically challenging and unreasonable to expect past exchanges to be revoked when a patient revokes their consent. |
| **Question 28:** Under what circumstances and in what manner should individual choice be required for other electronic exchange purposes? | Unless fully de-identified, when data is used beyond the purposes of exchange or other legitimate purposes allowed in the business associate agreement, the NVE should be held to the same information disclosure request requirements as providers and research institutes. It should be possible to obtain such consent through participating providers, but should be able to obtain the consent from the patient directly.

Regardless of the models, however, ONC should define the consent models paying specific attention to:
•       The entity responsible for collecting consent
•       The entities who depend on that consent |
| **Question 29:** Should an additional "meaningful choice" Safeguards CTE be considered to address electronic exchange scenarios | Rather than creating more CTEs, ONC should define exemplar models that given communities of exchange can adopt or refine for their own purposes, giving all a common language to discuss consent. |

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| (e.g., distributed query) that do not take place following Interoperability CTE I-1? | |
| **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? | In such a model, one would anticipate that the NVE would not need to satisfy a CTE for this criterion.<br><br>We do not believe that patients' meaningful choice would be violated if delegated to providers or other users. In many instances, the patient may not even be aware of the services that a provider uses for exchange. All the rules under the HIPAA Privacy Rule still apply—the provider will still need to acquire the patient's consent prior to using or disclosing the IIHI if required under regulations pursuant HIPAA.<br><br>When the provider sends patient data, the model should assume that the provider obtained the appropriate consent and that a consent record can be sent along with the data to enable the NVE to act accordingly.  Such a consent record currently does not exist in standard form and must be developed for messaging/service and document exchange paradigms.<br><br>When the patient initiates exchange directly, e.g., through their PHR, full consent must be assumed to be in place. |
| *Condition [S-4]: An NVE must only exchange encrypted IIHI.* | |
| **Question 31:** Should there be exceptions to this CTE? If so, please describe these exceptions. | This CTE is already covered under CTE S-1 and existing HIPAA requirements for covered entities and business associates, and it need not be duplicated if S-1 is maintained. In addition, the proposed transport methods have encryption requirements built in, and this level of specificity is not needed in this governance process. In addition, if the NVE operates in the same private network as one or more of the participant's systems, encryption may not be required in the case where the exchange never leaves the "building." The decision to encrypt this type of exchange should be driven by the NVE and participants' HIPAA security risk assessments. |
| *Condition [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.* | |
| **Question 32:** Are there specific uses or actions about which we should consider explicitly requiring an NVE to be transparent? | De-identification and the use of that de-identified data beyond the actual exchange and support of that exchange should be made known but not require patient consent. |

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| **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? | Disclosure of data practices requires flexibility.<br><br>Summarization should be permitted. We suggest that a model privacy notice be provided similar to the Model PHR Privacy Notice, but it should be created with more input from the community (including a standardized categorization of disclosure activities).<br>In addition, this CTE should account for the fact that single entities such as state and federal agencies or EHR vendors may participate in multiple exchanges. The NVE may have different uses or actions it performs with individually identifiable health information (IIHI) for the various exchanges. This may make it difficult to have a single notice of privacy practices.<br><br>Such disclosure should not be necessary for all uses.  For example, the fact that an NVE de-identifies and uses that information beyond exchange for any purpose should be sufficient.  However, use of IIHI should be more specifically disclosed at specific activity levels. |
| **Question 34:** What is the anticipated cost and administrative burden for providing such notice? | Developing, publishing and supporting such a policy statement is no small task.  It would be similar in scope to privacy policy statements published on web sites, and can involve legal, IT, engineering and marketing staff to be accurate and in accordance with state and federal laws and regulations.  The policy should be structured such that it does not require frequent updates, e.g. every time there is a detailed or slight, but not substantive, modification, or whenever a new contract is signed. |
| **Question 35:** Should this CTE require that an NVE disclose its activities related to deidentified and aggregated data? | No. This requirement would be overly burdensome, depending upon how NVEs are defined. For example, the guidance implies that an integrated delivery network could be considered an NVE. If it were, this requirement could prevent it from attempting to discover correlations between, for example, obesity and exercise to determine whether associated payers should reimburse health club memberships. In fact, as written, this requirement could stop an ACO from doing analytics to help deliver care more efficiently and deliver, perhaps, the opposite outcome from the benefits that interoperability has promised us.<br><br>Since no patients are identified, there should not be any restriction on novel use of that data. Much benefit in accountable care can be achieved through population management, but overregulation that creates barriers to such uses could cripple the effort to improve efficiencies and outcomes through analytics. The recent "open government data" initiatives are positive examples of using de-identified data for the public good. Because of the fear over "re-identification", it would be reasonable to identify standards that define acceptable levels of de-identification. |
| **Question 36:** Should this CTE require that an NVE just post its | Per our input in above question 35, an NVE may participate in multiple exchanges and have a different notice for each based on the various requirements and uses of the exchanged data. It is more appropriate to provide notice to each exchange participant |

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| 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? | rather than post it on a public website. |

| *Condition [S-6]: An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.* | |
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| **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? | This CTE would disrupt long-standing business models and development of knowledge, and it could be expected to disrupt innovative business models for health information exchange.  We believe that disclosure of the purposes for which de-identified health information is used is sufficient to create trust, and it still offers opportunities from both viewpoints.  In addition, many NVEs would have organizational and business activities that are not directly within the scope of the exchange intended to be covered by an NVE role, and this prohibition could interfere with both exchange and non-exchange-related activities.

We therefore do not support this CTE. Rather than being concerned about re-identification, application of such re-identification capability should not be allowed without patients' consent. However, use of de-identified data for any purpose, including monetizing it, should not be prohibited. It is unclear what individual harm can be attributed from use of de-identified data. Where does one draw the line between being monetized or not? Is research in any form not going to result in monetizing it by reducing costs, improving cost-benefit ratios, or generating revenue?

It seems that requiring NVEs to validate the ongoing de-identified use of the data they share outside their organization provides a reasonable balance to the concerns raised.

In addition, current business practices may be disallowed under this CTE, creating a disincentive for participation. |
| **Question 38:** On what other entities would this have an effect? | Please see question 35 and 37. Like many of the CTEs, this does not apply to all types of NVEs and should be clarified.

This provision could negatively affect health researchers and developers of medical devices and interventions, as it would require them to seek out other less readily available aggregate data sources to support their activities. It could also harm current and potential HIEs and other NVEs whose business models may include HIPAA-permitted and ethically conducted uses of de-identified data. |

| Condition [S-7]: An NVE must operate its services with high availability. | |
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| **Question 39:** What standard of availability, if any, is appropriate? | Availability should be driven through contractual agreements and service level agreements (SLAs) between the NVE and exchange participants. Penalties for violating SLAs should be driven by contractual agreements. Thus, this should not be a CTE but rather driven by market forces. |

| Condition [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. | |
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| **Question 40:** What further parameters, if any, should be placed on what constitutes a "unique set of IIHI"? | Per clarification in the guidance, we suggest adding the language, "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, *if the individual is unable to access the same set of information through some other means, and if the NVE is allowed or required to release the IIHI by law.*" There are several scenarios under which an entity should not release information to an individual. Research protocols suggest that a certain IIHI not be shared with a patient during clinical trials, for example. The NVE's obligations under HIPAA and other regulation must be contemplated by this CTE. Otherwise, a situation may be created, especially in cases involving suspected abuse, mental health notes, etc., where they are required under this CTE to provide patient access to the IIHI, but required to withhold access under HIPAA or other laws & professional standards. This situation must be avoided to prevent confusion, inconsistencies, and legal challenges.

In addition, as in our answers to 13 and 37, the scope of the applicability of this CTE to the range of activities of an organization that is an NVE must be considered and limited only to those activities that are subject to the NVE designation. In addition, the purposes for which the unique set of IIHI will be used should be considered in addressing electronic access and specifically what constitutes a unique set. Finally, we can imagine examples where an intermediary may be able to be construed as assembling a unique set with two or more messages in an in-box or stored message in an XDS registry, etc. |

| Condition [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. | |
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| **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 | We do not recommend this CTE. It could introduce serious technical and legal challenges as participants in the exchange community define their own responsibilities for working with corrected information. Since the NVE is not creating new source data, only combinations of data, it is an unreasonable requirement to enable corrections to the data at the NVE.  Rather, the patient should be able to correct/annotate the data at the source where the error originated, which in turn should forward such data to the NVE if the NVE not only exchanges but aggregates as well in support of query/response. If the NVE truly generated new data (not from any source), then it should permit annotations and corrections at the patient's request following its obligations under HIPAA.

We also point out that an NVE might choose to honor a correction that the authoring |

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| accessible by health care providers and not used solely for the NVE's own business processes? | organization would have not chosen to honor, leading to patient confusion, unreasonable expectations, and possible legal challenges.<br><br>If providers use the data as a system of record, patient safety issues are a concern. All data that is corrected based on a request from an individual should be flagged as such, with the original retained.<br><br>We suggest that further deliberation by the public/private NwHIN Governance Authority is necessary. |
| **Question 42:** Are there any circumstances where an NVE should not be required to provide individuals with the ability to correct their IIHI? | Yes. When the assembled IHII is made of meta-data elements that are 1) not created by the NVE, but directly contributed by the source healthcare providers, and 2) exclusively used by the NVE for locating source attested records (query for locations). See also our answer to question 41. |
| *Condition [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.* | |
| **Question 43:** What method or methods would be least burdensome but still appropriate for verifying a treatment relationship? | Some NVEs may not be in the position to perform this verification. The decision whether or not to verify a treatment relationship should be left to individual NVEs. The least burdensome method of verification is an attestation (e.g., electronic check box) by the party served by the NVE that it has or is in the process of establishing a treatment relationship with that individual.<br><br>Another approach is through agreement with providers that they will only use query and response under these conditions to audit use of query/response by providers and to investigate suspicious uses.  These are common practices.<br><br>In addition, it will be important that the NVE be able to validate the identity of those providers who have access to its IIHI. Purpose of use can be included in an "assertion" as part of the exchange request but we also have concerns with the application of the specific "treatment" criterion to accountable, integrated and coordinated care models in which a specific treatment relationship may not be present (i.e., the purpose for access could be payment or operations and or access could be via specific consent models.) |
| **Question 44:** Are there circumstances where a provider should be allowed access through the NVE to the health | If the data the provider is accessing has been de-identified, we do not see any harm in allowing this access and in fact believe it can offer great benefit, especially for the purposes of clinical analytics. In addition, there are other legitimate scenarios where a provider should be allowed access without a treatment relationship with the individual. One such example would be allowing providers to identify patients who need to be notified about a drug recall.  In this case, only those patients at an organization who are |

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| information of one or more individuals with whom it does **not** have a treatment relationship for the purpose of treating one of its patients? | on a given drug need be notified, but the records of all possible patients who may have been given that drug would need to be queried to create the accurate list. Is the provider performing that query in a "treatment relationship" with the patient whose data is being queried? It is not clear, however, that this may be a permitted use of query response in exchange. Other examples might include providers acting in a public health role who are seeking information on the spread of disease but are not necessarily seeking a treatment relationship with patients whose records they must query. In addition, the kind of population health management required of an ACO or similar organization might require access under a "payment" or "operations" criterion. |

*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.*

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| **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)? | It should not be required that a NVE offers any specific type of exchange (e.g., directed, query-based via a record locator, peer-to-peer query, etc.). If a portfolio approach is offered as clearly expressed in the introduction of this RFI, no single type of exchange should be imposed. It should be the NVE's choice to select among the CTEs for each type of transport defined by the NwHIN.

If one of the CTEs covers directed exchange as a transport, we recommend that both types of transport be required (i.e., SMTP and SOAP), as well as support of the translation between them (e.g., SMTP⇔XDR/XDM mapping). This approach ensures flexibility of choice for providers while preserving nationwide interoperability. This is the choice already made by the more than 10 states engaged in the EHR/HIE Interoperability Workgroup. |
| **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? | No. The above two choices are sufficient for directed exchanges; the addition of a RESTful transport would only add complexity. Therefore, we do not propose that a CTE be developed and be ready for deployment at a national level during the period in which this rulemaking could occur. While we are aware of and supporting one such project to develop RESTful transport in IHE for documents and another to develop a new HL7 standard that is RESTful, we suggest that specifications which become part of a CTE go through an appropriate objective review, including risk analysis before they become adopted. Given that both of these specifications are currently in the developmental stages, we do not believe that it would be appropriate to adopt them during this rule-making period.

The deadline implied by this rule-making will not provide time for a RESTful specification to be ready in time as a high level CTE requirement. However, such an approach could be added in a later CTE. |

| Condition [I-2]: An NVE must follow required standards for establishing and discovering digital certificates. | |
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| **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? | Certificate discovery is not required of all protocols or exchanges. In some cases, certificates need not be discovered at all because the protocol ensures transmission of all necessary certificates. This CTE would seem applicable to cases where certificate discovery is necessary, but without a definition of the exchange being performed, it is difficult to determine which method would be appropriate. |
| **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? | This CTE may be necessary for some kinds of exchange and not for others. Without a description of the kind of exchange being performed, it is not possible to determine if this is necessary. If it is easy to obtain certificates consistent with the policies of the federal bridge in all cases, it could well be a good condition. This would be a good question to ask the public/private NwHIN Governance Authority we propose establishing to execute this NwHIN governance. |
| 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 | Patient matching is not required in all cases for exchange. The simplest use cases for NwHIN Direct require no patient matching algorithm at all because a human intermediary can identify the patient with or without computer assistance. Other cases could require patient matching with NwHIN Direct. When patient matching is required, a CTE requiring a certain level of service in matching patients could be appropriate. However, we note that matching tolerances may vary by region and demographics, depending upon the purpose of the exchange. Again, this is a case where risk analysis would be applied by our proposed public/private NwHIN Governance Authority to determine the appropriate level of service needed. It may also be appropriate to focus on transparency of accuracy levels rather than specifying predetermined levels. In |

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| the required levels be? | addition, accuracy in practice will not simply be a function of the algorithms used but the input data and how the algorithm is used in practice. |
| **Question 50:** What core data elements should be included for patient matching queries? | The NwHIN Exchange has established a core set of patient demographic traits it uses for its subject discovery (based on IHE-XCPD). This is the set among which the various NwHIN Exchange participants should choose, with none being required. This is a good starting point that could be tightened for increased consistency. Rather than a strict regulatory approach, we suggest a formalized best practice approach that would point to an appropriate set of core date elements. |
| **Question 51:** What standards should we consider for patient matching queries? | For patient matching queries in a cross-domain peer-to-peer patient discovery, the IHE-XCPD standard. For patient matching queries in a single-domain MPI based environment, the IHE-PIX and IHE-PDQ standard. |
| *Condition [BP-1]: An NVE must send and receive any planned electronic exchange message from another NVE without imposing financial preconditions on any other NVE.* | |
| **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? | In general, we agree that NVE's should engage in fair business practices, but we do not agree that this CTE establishes a fair and equitable exchange environment. More investigation is needed by our proposed public/private NwHIN Governance Authority to determine what an appropriate CTE would be. |
| **Question 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? | We do not believe that this CTE or another CTE should address the fees that a NVE could charge its customers. |

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| **Question 54:** Under what circumstances, if any, should an NVE be permitted to impose requirements on other NVEs? | NVEs facilitating exchange from one covered entity to another directly or through another NVE must somehow be covered by business partner agreements as required by HIPAA.  We note other discussions within this RFI with respect to flow-down and indirect authentication and authorization.  These also would require an NVE to impose requirements upon other NVEs. |

*Condition [BP-2]: An NVE must provide open access to the directory services it provides to enable planned electronic exchange.*

   While no questions were asked on the CTE, we again note that not every exchange requires use of directory services (e.g., query response).

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*Condition [BP-3]: An NVE must report on users and transaction volume for validated services.*

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| **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)? | We agree that gathering metrics on use of CTEs is vital to ensure appropriate governance, but we believe that it is premature to determine the metrics through this rule-making. |
| **E. 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? | This initial set of CTEs should be revised by the public/private NwHIN Governance Authority we propose ONC establish after determining what the priorities are, as well as what kinds of exchange it will initially be governing for the NwHIN.  The fundamental principles implied by these CTEs should be a good first step in developing the priorities, but the precepts by which governance is to be performed should first be established. |

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| **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. | We do not suggest any additional CTEs at this time. See our response to question 56. |
| **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 | We do believe that different bundles of CTEs would be appropriate for different electronic exchange circumstances. However, we do not believe that a NPRM is the appropriate governance mechanism to establish the initial set of CTEs. What is needed first is to describe the mechanism of governance that would create the initial set of CTEs through our proposed public/private NwHIN Governance Authority and/or its delegates. |

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| CTEs for different electronic exchange circumstances? | |
| **Question 59:** Should we consider including safe harbors for certain CTEs? If so, which CTEs and what should the safe harbor(s) be? | See our responses to question 56 and 58. |
| **F. CTE Processes and Standards and Implementation Specification Classifications** | |
| **Question 60:** What process should we use to update CTEs? | A process to update CTEs should be based on a governance structure which includes participation from all stakeholders and managed by an open public/private NwHIN governance authority (i.e., not ONC and its HITECH Policy and Standards Committees). |
| **Question 61:** Should we expressly permit validation bodies to provide for validation to pilot CTEs? | One should not only permit but engage with validation bodies to provide for validation to pilot 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? | Yes. ONC already uses processes outside its advisory committees through which new interoperability specifications are developed, which eventually can become CTEs for health information exchange. We note a number of S&I Framework projects, and there are others outside of that which were not suggested by ONC advisory committees. The best environment for development is one in which all parties who have a stake can seek to develop and promote interoperable exchange as equal partners. FACAs do not have the charter or bandwidth to include reference implementations and pilots, which are very important in addition to selection of standards and implementation specifications, to validate and refine standards until they are truly workable. |
| **Question 63:** What would be the best | ONC can provide incentives for organizations participating in pilots, facilitate coordination across federal agencies with pilot partners, and provide resources to build |

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| way(s) ONC could help facilitate the pilot testing and learning necessary for implementing technical standards and implementation specifications categorized as Emerging or Pilot? | reference implementations and or testing infrastructures.  We would suggest first that the mechanism by which the NwHIN will be governed be established.  One of that organization's initial goals should be to prioritize exchange needs and perform an assessment of available resources to determine what kinds of assistance might best be provided by ONC to facilitate testing, validation and establishment of trust in exchange. |
| **Question 64:** Would this approach for classifying technical standards and implementation specification be effective for updating and refreshing Interoperability CTEs? | This classification approach is adequate.  The challenge is to objectively apply it. |
| **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. | This classification approach is adequate; the challenge, though, is to apply it objectively.  For example, the Health IT Standards Committee Tiger Team's attempts to develop an objective evaluation of the NwHIN implementation specifications were quite ineffective and biased. |
| **G. Economic Impact** | |
| **Question 66:** We encourage comment and citations to | |

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| publicly available data regarding the following: | |
| 1. The potential costs of validation; | Cost cannot be evaluated until there is a practical approach defined. |
| 2. The potential savings to States or other organizations that could be realized with the establishment of a validation process to CTEs; | Cost cannot be evaluated until there is a practical approach defined. |
| 3. The potential increase in the secure exchange of health information that might result from the establishment of CTEs; | Cost cannot be evaluated until there is a practical approach defined. |
| 4. The potential number of entities that would seek to become NVEs; and | The number of entities cannot be evaluated until there is a practical definition of NVEs. |
| 5. The NVE application and reporting burden associated with the conceptual proposals we discuss. | The NVE application and reporting burden cannot be evaluated until there is a practical definition of governance and underlying CTEs. |