eHEALTH INITIATIVE
Real Solutions. Better Health.

June 26, 2012

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
200 Independence Avenue SW, Suite 729D
Washington, DC 20201
Attn: Steven Posnack

Attention: Governance RFI

Submitted via http://www.regulations.gov

Dear Mr. Posnack,

eHealth Initiative appreciates the opportunity to respond to the Request for Information on the Nationwide Health Information Network: Conditions for Trusted Exchange

eHealth Initiative (eHI) is an independent, non-profit, multi-stakeholder organization. Our mission is to drive improvements in the quality, safety and efficiency of healthcare through information and information technology (IT). eHI advocates for the use of health information technology (HIT) that is practical, sustainable and addresses stakeholder needs, particularly those of patients. Since 2004, eHI has tracked the progress of organizations and initiatives across the country working in health information exchange. eHI has identified and collected information on over 250 health information exchange initiatives (HIEs) in the country. eHI and its membership support exchange efforts through research and educational activities. The comments below were developed through our multi-stakeholder consensus process.

From its inception, eHI has emphasized the importance of health information exchange in achieving the goal of a healthcare system that improves the delivery, management and cost of care, and that supports development of therapies, tools,

818 Connecticut Avenue NW Suite 500 Washington, D.C. 20006
Tel: 202.624-3270 Fax: 202.429.5553
www.ehealthinitiative.org

and services for ongoing improvements in the healthcare of patients and populations. Today's health system redesign initiatives underscore the need to accelerate the availability and use of health information exchange.

eHI applauds ONC for issuing an RFI on NwHIN governance in order to solicit input from multiple stakeholders on the trust framework for exchange. An RFI enables flexibility for input and altering the proposal based on input from stakeholders. eHI strongly supports government efforts to accelerate the use of health information exchange through federal delivery and payment reforms that incentivize the use of health data in support of advanced care processes and improved outcomes. We also recognize that the American Recovery and Reinvestment Act of 2009 (ARRA), specifically Title XXX, section 3001(c)(8), directs ONC to establish a governance mechanism for the nationwide health information network. Nevertheless, we note that ARRA does not mandate accomplishment of the governance requirement by regulation. We believe that a governance framework for health information exchange must achieve a correct balance between guidance and flexibility, constraints and enablement, and regulation may not be the appropriate framework to achieve governance. This balance is particularly appropriate given the developmental stages of some health information exchange initiatives.

eHI offers several comments from our perspective on the question of governance that provide context to the responses to the RFI questions that follow. Our comments raise additional questions concerning the governance approach presented in the RFI. Therefore, we recommend that ONC seek additional stakeholder input in the development of the framework for NwHIN governance. Additional due diligence in the solicitation of public input, such as town hall meetings and forums, and additional solicitation of the perspectives from providers, will allow consideration of other public and private processes to support governance. We believe that the number and scope of the outstanding questions support this approach as a next step, in advance of proceeding via an ANPRM, NPRM or IFR.

1. The timetable for the development of governance should be reconsidered.

Health information exchange business models and sustainability are still evolving. The number of data exchange users and use cases have not yet achieved the critical mass necessary to establish a regulatory approach of this scale and nature. The majority of HIEs are in a nascent stage of development with limited data being

exchanged among a small number of participants. The timing, scale and reach of a governance framework should be proportional to the activity to be regulated. More time is needed to consider what needs to be governed and to allow a phased approach to the development of an appropriate framework. Additional time will allow for the growth of health information exchange. As a result, we urge ONC to continue and accelerate efforts to encourage health information exchange before advancing a regulatory framework.

2. A clearer articulation of the problem to be solved is needed.

The preamble to the RFI references an absence of a common set of rules to guide development and nationwide expansion of electronic exchange, resulting in asymmetries in policies and technical standards. The RFI states that stakeholders have requested a "consistent, baseline set of 'rules of the road' for electronic exchange." Additional references are offered in the RFI to reducing the burden of governance on the states. eHI agrees that a governance framework can support the acceleration of electronic exchange. However, it is unclear that the proposed governance approach addresses the requests from stakeholders. A clearer articulation of the problem will help determine the appropriate course of action. eHI is concerned that the barriers to information exchange are not addressed by the framework presented. Moreover, an ecosystem of electronic exchange that encompasses many forms of exchange will not be supported by the approach articulated in the RFI. The proposed governance approach presumes a level of maturity of health information exchange that is not yet widespread. eHI recommends that ONC consider the existing landscape and develop a governance framework that addresses a clearly articulated challenge and the current state of the field.

3. Greater coordination between ONC and the states and other stakeholders should be emphasized.

Coordination by ONC with the states and localities that leads to deeper involvement by these actors and results in representative governance for NwHIN is recommended. Additionally, ONC is urged to consider existing and parallel processes as a basis for an NwHIN governance framework. Coordinating bodies driving exchange exist in several of the states and are sharing best practices with other states. Existing private organizations can serve as a model or actual elements of governance. The existing Federal Coordinating Committee and the NwHIN Coordinating Committee, and their public-private process for developing policies supporting health data exchange are examples of existing processes to be modeled, modified and built upon for NwHIN governance. Moreover, the NwHIN Exchange Coordinating Committee is in the process of moving the NwHIN Exchange

to a public-private body this year. We recommend that any rulemaking concerning NwHIN governance not occur prior to this change to the NwHIN Exchange.

4. A heavy regulatory approach should be reconsidered

The federally focused, heavy regulatory approach suggested in this RFI should be reconsidered in light of the early and emerging nature of health information exchange efforts. Governance should focus on advancing key principles that any electronic exchange should adhere to in order to support ongoing innovation and not create unintended consequences that favor one type of exchange over another or slow the overall growth of exchange. We recommend that ONC consider an approach that utilizes public/private partnerships rather than a process entirely within federal regulatory processes.

5. The scope of who is being governed by the NwHIN Governance needs clarification.

The organizations to be regulated, and the level at which they are regulated is vaguely referenced in the RFI. The RFI sets a higher bar for the proposed NVEs, including health information exchange organizations than for others involved in controlling sensitive health data. eHI urges reconsideration of this point. Providers and other covered entities already are subject to requirements to safeguard the security of individually identifiable health information (IIHI) pursuant to HIPAA. The RFI could create requirements that are distinct based on organizational structure rather than access and use of IIHI. eHI urges ONC to coordinate with the HHS Office of Civil Rights (OCR) to ensure that the scope of who is governed by NwHIN Governance is aligned with requirements under HIPAA.

6. HIE governance will require participation by distinct yet interlocking organizations

Complying with the proposed approach to governance would be onerous. The administration of the overall framework and the accreditation of NVEs for adherence to the CTEs will require multiple participants including independent bodies, public-private partnerships, and individual states. A more streamlined and straightforward approach will enable all parties to understand and comply with requirements without hindering their ability to move forward with building exchange.

7. Leverage existing experience and expertise in the development of HIE governance

Many organizations have experience and expertise in the domains of Safeguards, Interoperability, and Business Practices. In developing their organizations they have worked extensively with these domains. These organizations and others with

skill and expertise in the respective domains should be utilized to ensure adherence to the diverse set of conditions and encourage a common, standards-based approach. We recommend ONC work to leverage the existing experience in the field to support continued growth and maturation of exchange while providing guidelines and guidance that encourage trusted exchange while balancing constraints and enablement of exchange. Again, we urge ONC to consider using a public/private partnership, rather than exclusively governmental, approach to governance.

8. Separate the management of distinct domains within the approach to HIE governance

The three included domains for conditions of trusted exchange – Safeguards, Interoperability and Business Practices - are collectively important within the governance construct, yet are very different. eHI believes that the domains should be separated in order to support many governance considerations. Safeguards, Interoperability and Business Practice involve distinct processes to manage, to stimulate, and to motivate compliance. We are not urging three new regulatory processes for the different domains, but request that each domain is addressed within the context of laws, regulations and processes that pertain to that domain. This approach to the management of the distinct domains recognizes the unique attributes of each and will encourage the engagement of subject-matter experts in the validation process.

9. Leverage existing laws and regulations to support HIE governance wherever possible

Existing laws and regulations at the federal and state levels provide requirements for trusted exchange relative to privacy and security and the relationships of businesses with one another. These laws and regulations also include enforcement mechanisms to motivate compliance. Additionally, the final rule implementing the HITECH amendments to HIPAA is expected in summer 2012. Conditions in the domain of Business Practices are likewise addressable within the context of existing federal and state laws, regulations and codes applicable to parties engaged in business. As a result, it is not apparent that the additional conditions proposed in the RFI relative to Safeguards and Business Practices are necessary at this time. We recommend ONC give particular focus to the development of conditions in the domain of Interoperability in order to accelerate health information exchange that supports a redesigned healthcare system dependent on successful collaboration by multiple participants. Specifically, we recommend a public – private representative governance approach that builds upon existing and emerging practices to foster exchange.

10. Encouraging and incentivizing interoperability should occur outside of a regulatory framework

eHI recommends that ONC separate the policy from the technical standards for interoperability in order to focus on the encouragement and incentivizing of interoperability. A regulatory approach to standards as proposed in the RFI may not be the correct tool to use to instill standards. The development of governance, on the other hand, is benefited by the greater specificity of requirements found in the construct of policy development. We believe this recommendation is consistent with the HIT Policy Committee recommendation to follow a "governance of governance" approach and urge ONC to adopt this construct.

11. Utilize and build upon the work of consensus-based standards organizations

eHI urges ONC to build on the work of existing voluntary consensus-based standards organizations to advance needed interoperability standards. The transparent collaboration of public and private stakeholders has resulted in the development of existing standards and a process for the creation of new standards that enjoy widespread support. In addition, the National Technology Transfer Act requires federal agencies to participate in voluntary consensus-based bodies in the private sector and utilize the standards developed therein whenever possible. We encourage ONC to follow this existing construct.

12. Support the strategic use of standards to advance interoperability

eHI encourages ONC to support the use of standards in a manner that advances interoperability. We urge accomplishment of this within a public-private framework that enables identification of standards that are modular and highly specified, but not all encompassing in order to foster flexibility for the continuous innovation needed to support the current and future demands for data exchange.

eHI urges ONC to continue to work with stakeholders to support this public-private approach, rather than pursue a course that would attempt to bring this dynamic activity within a federal regulatory scheme. We believe this approach will best advance the use of the nationwide health information network.

13. Support concurrent healthcare redesign initiatives

The RFI approach to governance of nationwide health information exchange must support concurrent healthcare redesign initiatives. Examples include Accountable Care Organizations, Patient-Centered Medical Homes in addition to the EHR Incentive Program. The governance framework must accelerate the exchange necessary to support population health, public health, quality management and

improvement, research and patient engagement. A focus on interoperability that supports only one type of exchange is inconsistent with the direction of these initiatives.

eHealth Initiative appreciates the opportunity to respond to the Request for Information on the Nationwide Health Information Network: Conditions for Trusted Exchange.

Again, we applaud ONC's efforts, but strongly recommend that ONC seek additional stakeholder input in the development of the framework for NwHIN governance. As a multi-stakeholder organization with significant experience in health information exchange, eHI is well positioned to help ONC further define the problem, and provide additional input as a framework is developed. If you have any questions, please contact me at Jennifer.Covich@ehealthinitiative.org.

Sincerely,

Jennifer Covich Bordenick
Chief Executive Officer
eHealth Initiative

Responses to RFI Questions:

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?

Response: Safeguards and Business Practices should not be part of this governance effort, as there are already strict, effective guidelines available in these areas from HIPAA and the states. The focus for ONC should be on Interoperability, as there are unmet needs in this area.

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

Response: Across the nation, the health of HIEs is fragile and their sustainability is challenged. At this point, exchange needs to be encouraged and facilitated. Heavy-handed regulation would be detrimental to this goal. NwHIN governance should be participatory, involve representative stakeholders, and follow a consensus approach. The goal should be to achieve a common understanding of how to communicate health information nationwide, which will not be achieved if stakeholders are not included in development and invested in the result. Governance should be lightweight and flexible; a regulatory approach could be too restrictive and would not facilitate the necessary discussion to achieve a resolution that is workable for stakeholders.

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

Response: There is no urgency for new governance approaches for Safeguards and Business Processes; these already exist and are working. There is some urgency for governance related to Interoperability, but it is more important to take the time necessary to include relevant stakeholders in the development process and find the most effective approach. In the near term, ONC could convene stakeholders and request public comments to help identify barriers to the nationwide exchange of health information that could be surmounted by future standards and governance.

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

Response: It is too early to know. Initial efforts should be focused on characterizing the problem, which we believe is the set of barriers that inhibit nationwide health information exchange. Structures and processes to address these barriers should not be developed until stakeholders are involved and the problem is better understood.

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?

Response: There is a wide range of involvement among the states in HIE regulation. Some states have established or are establishing intensive regulatory regimes, while others are minimally involved. There is no indication that states are prepared to drop their involvement in HIE regulation as the result of any new federal governance approach. Therefore, it is not clear that a national validation process would have any effect on the burdens related to regulation of health information exchange by the states.

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

Response: States are critical stakeholders that should be included in a participatory, consensus-driven approach to NwHIN governance. Involving states in the development and governance of NwHIN may encourage eventual alignment of state and federal approaches to health information exchange.

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

Response: We recommend that ONC involve representative stakeholders, including HIEs, vendors, providers, consumer groups, states, and other federal agencies, in a participatory process to clarify the problem that ONC is attempting to address with NwHIN governance and begin to address the barriers to nationwide HIE. This process and resulting governance should focus exclusively on Interoperability; existing mechanisms are sufficient for Safeguards and Business Processes, which

should be excluded from this effort. We encourage flexible, consensus-driven approaches to governance instead of a regulatory approach. As part of this effort, ONC should assume a coordinating role among the various federal agencies with HIT interests, including OCR, FDA, and FTC. The approach should accommodate efforts related to population health, public health, research, patient engagement and quality improvement in support of initiatives such as Accountable Care Organizations, Meaningful Use, and Patient-Centered Medical Homes. Governance should not be driven by a strict timeline, but should advance based on progress at articulation of the problems inhibiting nationwide HIE and the achievement of consensus about the governance structures best able to address these problems.

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

Response: ONC should serve a coordinating, not regulatory, role, and consider other governance models, emphasizing involvement of stakeholders and representative governance. ONC already has a potential governance model in the NHIN Coordinating Committee, which could be expanded to fulfill a larger mission. Relevant stakeholders include states, localities, federal agencies, existing standards organizations, health information exchanges, health systems, consumers, and other private sector organizations with involvement in exchange. There are existing accreditation and standards organizations that could play a role in governance. ONC should act as a convener that brings together the relevant stakeholders to better define the problems inhibiting nationwide exchange of health information and develop appropriate mechanisms, in coordination with existing efforts, to address these problems.

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.

Response: It is premature to determine whether a voluntary validation process would be effective. There are existing accreditation and standards organizations that could play a role in governance and validation, such as EHNAC, CCHIT, and NIST, but first it is necessary to involve stakeholders and define the problems to be addressed in order to encourage nationwide exchange before settling on a

validation approach. Additionally, it is unclear that the proposed approach is actually voluntary. If contracts and grants from the federal government are awarded on the basis of NwHIN participation, it may become effectively mandatory.

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

Response: It is premature to determine, for the reasons included in the answer to question 9. In general, it would be better for HIEs to interface with one body instead of several. In addition, the approach to validation should be "modular" rather than "one-size-fits-all."

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

Response: It is not clear whether validation is a necessary component of governance. If validation is ultimately pursued, several models are possibilities, including accreditation, self-attestation, and state-run certification processes, but it is premature to select an appropriate validation model until there is agreement among stakeholders about what barriers to exchange need to be addressed and how.

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?

Response: Our members are concerned that the potential impact of this model could be to discourage query exchange in favor of directed exchange for nationwide data transfer, jeopardizing the success of population health, public health, research, patient engagement, and quality improvement efforts. The best way to maximize benefits and minimize the burden of governance is to have an inclusive process to identify the steps needed to encourage nationwide exchange and develop an implementation strategy that has multi-stakeholder support. Technical interoperability is a major challenge that must be met in order to facilitate

successful triple aim and accountable care initiatives. The benefit to health information exchange would be maximized by an effort that focuses on interoperability, leaving safeguards and business processes to existing efforts.

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

Response: It is premature to establish a specific eligibility criterion. However, it is important that any governance model and related definition of "valid purpose" for exchange is inclusive of population health, public health, research, patient engagement, and quality improvement efforts, as well as other needs that could be identified as a part of an initial fact-finding process.

We urge ONC to clarify that it is seeking to identify the purpose of the exchange, rather than the purpose of the entity facilitating exchange. We do not believe that an eligibility criterion focused on an entity's purpose for exchange is warranted or workable.

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?

Response: No. Any eligibility criterion requiring prior experience with exchange or a minimum number of participants would stifle innovation, would present a barrier to new organizations entering the marketplace, and would negatively impact local and regional efforts, particularly in rural areas.

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

Response: It is premature to determine what other eligibility criteria should be established.

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.

Response: No, eligibility should not be limited to tax-exempt organizations. Business entities other than tax-exempt organizations should not only be allowed to participate, they should be encouraged to participate. Such a restriction would be a

setback for interoperability and health information exchange, as there are longstanding for-profit information exchange organizations that are contributing to improvements in our health care system.

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?

Response: It is premature to determine the optimum role for stakeholders in governance of the nationwide health information network. Stakeholders, including states, localities, federal agencies, existing standards organizations, health information exchanges, health systems, consumers, and other private sector organizations with involvement in exchange, should be involved in the identification of problems inhibiting nationwide exchange of health information. It also is critical that this group in the development of the framework, structure, and specifics of new, representative governance mechanisms and coordination of existing mechanisms to address identified problems.

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

Response: It is premature to determine the most appropriate monitoring and oversight methods until the problem is better defined and stakeholders have been enlisted to develop governance mechanisms that will be effective. When it is time to address the issue of monitoring and oversight, existing organizations and methods should be considered for this role. In general, we believe a flexible, representative governance approach would be superior to a heavy-handed, regulatory model. Additionally, mechanisms for the encouragement and advancement of health information exchange should be developed and emphasized concurrently with mechanisms for monitoring and oversight.

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

Response: It is too early to determine.

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

Response: The first question, about limits to prevent misrepresentation, is confusing and is not possible to answer without an understanding of the problem that is being addressed. Regarding the second question, about public disclosure and labeling associated with validated activities, we are generally supportive of public disclosure. We would encourage the use of a registered trademark and/or logo that indicates to consumers and stakeholders that a particular health information exchange initiative is compliant with the NwHIN governance approach, similar to the Energy Star logo that is displayed on energy efficient appliances. Rather than being a requirement, we envision such a trademark/logo as an incentive that qualifying exchange initiatives would be allowed to display and could play a significant, positive role in encouraging exchange of health information.

Question 21: How long should validation status be effective?

Response: It is premature to determine, as it depends on the specifics and complexity of the governance approach. In general, validation status should be effective for as long as possible, especially when it requires significant effort from participants. Possibilities to consider include aligning validation timelines with Meaningful Use (2-3 years), establishing an initial, comprehensive certification/validation process, followed by periodic re-certifications that would be less intensive, or a certification period that is valid for as long as it is possible for a given function to be accomplished. It is important to emphasize that the three areas of the RFI, Safeguards, Business Practices, and Interoperability, all have different timeframes, which is another reason that these three areas should be handled through different methods of governance, and we again urge ONC to focus its efforts on Interoperability and leave Safeguards and Business Practices to existing governance arrangements.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

Question 23: Are there other security frameworks or guidance that we should consider for this CTE? Should we look to leverage NISTIR 7497 Security Architecture Design Process for Health Information Exchanges32? If so, please also include information on how this framework would be validated.

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2 and 4.

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

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2 and 4.

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?

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2 and 4.

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

established certain "choice" policies, how could we ensure consistency in implementing this CTE?

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 4, 9, 10, 11 and 12.

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

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 3 and 4.

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

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 3 and 4.

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?

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 4, 7 and 9.

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

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 4, 5 and 7.

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

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2, 3, 4, 7 and 9.

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?

Response: It is premature to determine. See numbered paragraphs in the letter particularly numbers 1, 2 and 4.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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)?

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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)?

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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.

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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?

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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

Response: It is premature to determine. See numbered paragraphs in the letter.

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.

Response: It is premature to determine. See numbered paragraphs in the letter.

Question 66: We encourage comment and citations to publicly available data regarding the following: 1. The potential costs of validation; 2. The potential savings to States or other organizations that could be realized with the establishment of a validation process to CTEs; 3. The potential increase in the secure exchange of health information that might result from the establishment of CTEs; 4. The potential number of entities that would seek to become NVEs; and 5. The NVE application and reporting burden associated with the conceptual proposals we discuss.

Response: Overall, we are concerned that the impact of the NwHIN governance conditions are far reaching and may trigger unintended consequences. The possibility that NVE certification may become a condition for participation in health programs or the inclusion of transaction specification use cases that offer the ability to opt out of claims attachment and electronic medical data submissions in support of paying claims are just two examples of consequences that extend beyond NwHIN governance. We also are concerned that this approach could discourage bidirectional, query-based health information exchange in favor of directed exchange, and may not support accountable care and population health goals.

Maintaining several validation bodies will be crucial to keep the cost of validation down. While it is unknown what the costs of compliance will be, adding significant burdens to financial challenged healthcare system participants should proceed after careful consideration and identification of clear benefits for participants so that becoming an NVE outweighs the cost of compliance and validation to the CTEs. Additionally, harmonizing the requirements of this program with existing programs and existing validation mechanisms to avoid duplication and conflicts that can trigger undue costs. Public-private collaboration and use of existing market activities can support this outcome.

The nationwide health information exchange has a benefit to the providers that participate. This benefit will grow as more providers are encouraged to participate in the network. More consideration of increasing the benefits may also shift the focus on a cost vs. benefit analysis. Additionally, moving the emphasis in the requirements from those perceived as too soon or too burdensome and toward those that are perceived as beneficial will move the entire construct to one that is perceived as less costly.

The sub-question 2 presumes that all states will benefit by the removal of a burden. In the first instance, we recommend that ONC do no harm to states that have mature health information exchanges, with governance processes that may exceed the federal requirements articulated in this proposal. As the exchange efforts in these states will continue, the federal requirements proposed in the RFI will constitute an additional burden. In addition, the State Designated Entity (SDE) program for health information exchange required investment in governance and legal policies to advance exchange. The governance approach in the RFI could undermine progress that has been made and may result in a replacement of current efforts at a loss of the costs incurred to date. However, we appreciate that ONC is attempting to assist states that are at more nascent stages of health information exchange. The proposal provides specific guidance for governance that supports exchange and assists these locations to move forward.

Concerning the entities that will seek to become NVEs, ONC should consider that organizations may seek to become NVEs to differentiate themselves from others. However, as the construct is currently proposed it is perceived as coercive although described as a voluntary mechanism.

As the proposal is currently constructed, the application and reporting burden is high, as the value of the reporting varies by domain or CTE category. In the case of the Business Practice domain, the reporting requirements for these CTEs trigger burdens that are not offset by a perceived benefit of the reported information.