Health Level Seven® International
Unlocking the Power of Health Information

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June 28, 2012

Office of the National Coordinator for Health Information Technology
Hubert H. Humphrey Building
Suite 729 D
200 Independence Avenue, S. W,
Washington, DC 20201

Attention: Nationwide Health Information Network Governance RFI

To Whom It May Concern:

Health Level Seven International (HL7) appreciates the opportunity to provide feedback and comment on the governance of the Nationwide Health Information Network (NwHIN). We believe we have valid interest in a portion of the questions. Our comments are representative of the requirements of our stakeholders.

HL7 (www.HL7.org) is a not-for-profit, ANSI-accredited standards developing organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. Its 2,300+ members represent approximately 500 organizations that represent more than 90% of the information systems vendors serving healthcare in the US.

We appreciate the use of an RFI to initiate the discussion in advance of an NPRM as the issue of governance could be resolved in a number of different ways. In that context we like to note that the challenge of governance should not be looked at within the confines of NwHIN. Many cross-provider data exchanges can and should occur that would not be governed by NwHIN, and/or state and regional initiatives may have varying needs. As evidenced by the efforts of the SCO and predecessors over time, there is a need to harmonize the development and use of data exchange standards in the healthcare environment. ONC can and should play a critical role in facilitating such US realm focused harmonization, not only at the federal level, but holistically across the US realm.

The focus of governance should be the ability across providers and patients to consistently and predictably be able to exchange data. Such endeavor is akin to establishing the same gauge railroads across the country that enables transport of all kinds of data content between providers

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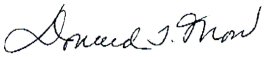
and patients. This focus should include standards for protocols, syntax, and semantics, as well as privacy/security guidelines, while it should avoid constraints on capabilities within providers or data exchange organizations.

HL7's responses to the specific FRI questions are provided on the following pages. We appreciate the opportunity to provide input on the NwHIN governance process, and stand ready to offer our assistance and expertise when and as needed.

Sincerely,



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Responses to Questions

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?

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

> ***Response:*** Based on our experience, we suggest that voluntary participation yields the best opportunity to foster buy-in and remain flexible enough to meet the constantly changing standards environment. Wherever possible, governance should be achieved outside regulatory framework. A strong, open and transparent public-private framework that enables all stakeholders to participate and focuses on removing obstacles to achieve key target objectives is essential.
>
> An NwHIN Governance Authority (NGA) could and should delegate the work of standards development and maintenance to existing standards development organizations, profiling and enforcer organizations, certifying bodies and education bodies, while ensuring transparency and coordination across these organizations.
>
> We should also recognize that data exchange occurs well beyond NwHIN and consistency of data exchange across all settings is essential. Many cross-provider data exchanges can and should occur that would not be governed by NwHIN, and/or state and regional initiatives may have varying needs. As evidenced by the efforts of the SCO and predecessors over time, there is a need to harmonize the development and use of data exchange standards in the healthcare environment. ONC can and should play a critical role in facilitating such US realm focused harmonization, not only at the federal level, but holistically across the US realm.
>
> All cross-provider/patient data exchange can benefit from a level of governance that enables efficient, consistent, and secure flow of data across providers and patients.
>
> The focus of governance should be the ability across providers and patients to consistently and predictably be able to exchange data. Such endeavor is akin to establishing the same gauge railroads across the country that enables transport of all kinds of data content between providers and patients. This focus should include standards for protocols, syntax, and semantics, as well as privacy/security guidelines, while it should avoid constraints on capabilities within providers or data exchange organizations.

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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:*** We believe establishing clear governance is both urgent and important to foster consistency across programs and coordination across all stakeholders.

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

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

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

> ***Response:*** We believe that federal and state governance mechanisms must be harmonized to support consistent use of standards that facilitate local and national data exchange without unnecessary data transformations.

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

> ***Response:*** To further support a transparent process with wide stakeholder participation, we strongly suggest that an NwHIN governance mechanism includes 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[1]
> - United States Conformity Assessment Principles[2]

B. Actors and Associated Responsibilities

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

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[1] See http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2010%20ANSI%20Essential%20Requirements%20and%20Related/2010%20ANSI%20Essential%20Requirements.pdf

[2] See http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/USCAP%202011.pdf

Response: We believe it is appropriate for ONC to have a critical role in establishing and facilitating a governance process that involves all stakeholders to arrive at a commonly agreed to set of CTEs. We do request further clarification of ONC's statutory authority visa vis other agencies. Considering data exchange crosses many jurisdictions and authorities, a harmonized governance mechanism is essential to prevent contradictory and/or duplicative guidance leading to inefficient, ineffective, or lacking data exchange. It is therefore critical that ONC includes not only the private sector, but other agencies, States and SDOs as well where ONC can provide an important coordinating and facilitating role. As an example, under HIPAA a number of Designated Standards Maintenance organizations have been identified, HL7 being one of them, who should be an integral part of the governance process.

ONC should not only consider the needs for data exchange through NwHIN, but HIEs, VANs, PRMs, ACHs, etc. as well. NwHIN represents a piece of the puzzle that requires stakeholders to come together on agreed to data exchange standards, while consistency is essential across all data exchanges as the interconnect.

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: Adoption of HL7 standards has been most successful when there is the right mix of voluntary market pressures and governmental incentives. The challenge is to establish a governance process across the myriad of stakeholders that is efficient, effective, yet flexible to adjust, but does not require constant change either. Strong leadership to maintain focus and address what matters most will be critical to the success of any proposed governance process.

Validation can occur in a number of different ways, from self-attestation against clearly defined conformance profiles, accreditation by an organization, to certification. The appropriateness of using one method versus another depends on the level of trust required and complexity of the CTE. Certain interoperability CTEs may lend themselves more towards self attestation complemented with various public testing events, while safeguard CTEs may lend themselves more towards certification. When higher levels of consistency are required, either approach could still be effective as consensus processes to arrive at and improve on implementation guidance can substantially reduce ambiguity.

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: Considering our response to Question 9, we do believe that the validation method can vary by CTE.

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Over time, validation methods for a given CTE may adjust to the then current state of technology and adoption rates, thus should be re-assessed periodically.

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*:** We believe that different validation models will be needed to address different types of CTEs. Within health care we find several models that could be applied, including Joint Commission accreditation, Kantara Initiative certification, and EHNAC certification. Other industry models could also be applied, including ACORD certification for insurance data standards, SysTrust and WebTrust certification for websites, and PCI Security Standards Council certification processes for payment card activities.

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: We believe that regardless of approach or approaches chosen, that for interoperability CTEs there is a clear set of implementation guidance where the SDOs and profilers work closely together to continuously reduce ambiguity and improve clarity so it is clear what it means to support certain agreed to standard data exchange formats and content.

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*:** We suggest that, to enable clear, consistent, and relevant data exchange and support the development of necessary standards, clarity on the purpose of the NVE is essential and transparent to all stakeholders.

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

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

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

Question 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:*** We suggest that consensus on minimum required CTEs, including target implementation timeframes, is critical to ensure buy-in and broad participation. All stakeholders should be able to engage in the process to arrive at such a minimum set.
>
> The current relationship between HL7 and ONC relative to the S&I Framework demonstrates key elements where broad participation can be managed and focused on key components of the overall data exchange strategy.
>
> In general, we need to recognize that considering the complexity of changes and the number of stakeholders that are impacted by the changes that it is better to take more smaller steps that can build on success make solid, steady progress, than attempting to take one big step with a high risk of many stakeholder missing the step or not even trying to take that step.

C. Monitoring and Transparent Oversight

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

> ***Response***: See our response to Question 2.

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

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*:** We believe that clear labeling of services should be made available by the NGA to enable stakeholders to understand what the services offered represent..

Question 21: How long should validation status be effective?

> ***Response:*** The effective time of a validation status may vary based on the CTE. For example, considering the typical life cycle for developing an interoperability standard is 2-3, the validation status of interoperability CTEs should be about that long as well to support ongoing development and revision cycle.

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At the same time, vocabulary used in those standards changes much more frequently and more current versions should be adopted more quickly.

Consequently, governance should allow for different validation status cycles based on the specific CTE requirement to change and the industry's ability to adopt such change.

D. Conditions for Trusted Exchange (CTEs)

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

Question 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: We suggest that NISTIR 7497 is an excellent choice for a "level-setting" framework. NVEs should be required to document their application of the framework to their HIE Privacy and Security Architecture design.

Many of the enabling services should be able to be testable and certifiable, and some are already via MU tests. Additionally, vendors can claim conformance to the IHE standards.

Validation of the framework should be one of the first activities of the NGA with all the stakeholders involved

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: We would suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that it should first review and identify resources for performing risk assessments, such as the HL7 Security Risk Assessment Cookbook, and determine how to apply Risk Assessment techniques to necessary capabilities. For functions such as authentication and authorization, it should then determine the appropriate levels of assurance needed for directly or indirectly authenticating or authorizing a party for which it facilitates electronic exchange. We note, for example, that the level of assurance needed for accessing patient demographic data might be different than that needed to access certain clinical data, such as mental health data.

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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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

> ***Response***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach. HL7 provides both a V2 and V3, including a CDA Consent Directive document, based standards to support a number of consent data exchanges.

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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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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:*** We would suggest that to enable various choices, particularly the choice of a patient to determine who may or may not be able to see their data, requires clear standard consent data set that can be communicated along with the data. We cannot expect the NVE to collect this information directly from the patient, rather through the patient's provider(s). HL7 provides both a V2 and V3, including a CDA Consent Directive document, based standards to support a number of consent data exchanges.

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

> ***Response***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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

> ***Response***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that

multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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

> ***Response***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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

> ***Response***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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***: We suggest that once the governance mechanism has been established, e.g., with NGA as suggested and all the stakeholders engaged, that process should further review and establish a suitable approach. The complexity of this issue suggests that multiple, open discussions among stakeholders are essential to arrive at such a suitable approach.

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

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

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

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

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?

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

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

> ***Response:*** A treatment relationship is established in the provider environment, outside the NVE. Consequently, some form of data exchange needs to occur with the NVE to make them aware of that relationship to enable the NVE to enable access and exchange accordingly. One can envision on virtual query capability where every provider must expose their patient relationships that an NVE can interrogate, or the NVE establishes effectively a patient registry or index to track those relationships. Whether a "key" is involved that authenticates the patient indeed provided that access or not may help, but not essential to the data exchange paradigms.
>
> Standards to support either paradigm are basically available, although further enhancements may be required to support this particular use case. HL7 would be happy to work with ONC through an S&I Framework initiative to review, identify and/or establish appropriate standards and/or guidance.
>
> Regardless of the paradigm, it seems that appropriate "Break the glass" capabilities, with associated data exchanges are required to facilitate emergency access to relevant patient data.

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

Question 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:*** While these potentially are reasonable minimum requirements, other methods with associated validation should be recognized and established as well. As indicated in our response to Question 29, we should consider multiple, voluntary validation opportunities to enable an NVE to have one or more exchange methods that fit their exchange partners.

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:*** While we support multiple exchange methods to support different use cases, we are concerned with providing alternative standards for the same data exchange as that would require additional mappings. Certainly, as requirements evolve, new standards

may be necessary to fulfill those requirements, but until such time, we should not proliferate alternative standards for the same exchange requirements.

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: The use of these or other specifications depends on the protocol or exchange use case. If certificate discovery is required, these seem adequate, but otherwise may not always be appropriate or necessary.

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: We do recognize that while some data exchanges may not require certificates, most data exchanges will require the use of certificates for all exchange partners, whether organizations or individuals, patients or providers. It is essential to enable systems to properly authenticate sender, receiver, requester in a data exchange. We must recognize that the current state of directory deployment to support such an infrastructure has not yet matured to a point where this can be widely used.

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

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

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

Response: The IHE framework provides implementation guidance of HL7 messages, both V2 and V3 to support query/response messages that can include matching information. The actual matching is within an NVE and should not require standards on how to best match, at most a minimum accuracy level.

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

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

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

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)?

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?

> ***Response:*** We suggest that the actual CTEs should not be proposed until the governance mechanism is put in place with the appropriate stakeholders to then use that process to arrive at an initial set of CTEs. The then current draft of CTEs can and should form that starting point for review and use the new process to finalize the initial CTEs.

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

> ***Response:*** See our answer 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 CTEs for different electronic exchange circumstances?

> ***Response:*** Considering the different data exchanges that could be managed by an NVE, we do believe that NVEs should be able to address one or more individual interoperability CTEs, while the safeguard CTEs and business practice CTEs reflect a minimum could be bundled in a base plus a menu set based on the types of data exchanges being supported.

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

F. CTE Processes and Standards and Implementation Specification Classifications

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

Response: We suggest that the process should follow the governance considerations outlined earlier, particularly the need for open, transparent, and inclusive participation of all stakeholders. HL7 can provide substantial support related to its suite of standards and the processes in place to arrive at consensus standards in support of the CTEs.

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

Response: While validation of pilots can be helpful, it should be non-binding so that the validation is considered part of the pilot process to "validate the validation".

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: Other than as it relates to Question 60, which fits within the HIT-SC/PC framework effectively, we do not believe that further committees are necessary at the federal level. However, in line with our considerations regarding the need for governance beyond NwHIN, additional organizational structures may be required.

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: We suggest that this process is fully synchronized with the process intended for MU editions, as the exchange objectives, criteria, and standards must align with NwHIN standards. The proposed diagram would be very informative to apply to MU editions.

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

Response: We believe that as long as NwHIN governance is synchronized with MU edition, this approach is reasonable to begin the process.

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

Response: We suggest that further categorization indicating whether standards are co-owned, as well as what normative level the standard/implementation guid is at would be helpful. For example, for standards and implementation guides, one could consider that standards or implementation guides designated as DSTU are ideally suited for pilots, while normative documents are ideally suited for national adoption. Lastly, adoption rates should be further indicative of when national adoption is called for.

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G. Economic Impact

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.

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