



Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to <http://www.regulations.gov>

June 22, 2012

Mr. Steve Posnak
Director, Federal Policy Division
Department of Health and Human Services
Office of the National Coordinator for Health
Information Technology
Attn: Governance RFI
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW
Washington, DC 20201

Re: Governance RFI – 46 CFR Part 171 – National Health Information Network:
Conditions for Trusted Exchange

Dear Mr. Posnak:

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased to respond to the Office of the National Coordinator for Health Information Technology's (ONC) Governance RFI for the National Health Information Network: Conditions for Trusted Exchange (CTE), published in the *Federal Register* on May 15, 2012.

The Collaborative recommends that pharmacists be included in the CTE governance process so as to integrate pharmacy health information technology (HIT) into the national HIT infrastructure and to assure that pharmacists can connect to other health care providers through secure bidirectional communication. As recognized health care providers, pharmacists play an important role in providing treatments and care to patients. In some settings, pharmacists are first-line-of-care providers, and as such, access to health information through the health information network is critical.

Pharmacists need HIT systems that have the functionality and connectivity to support the numerous patient-care services they provide. Integration of pharmacy HIT into the national HIT infrastructure and access to the HIT network will improve communication among health care team members and improve the overall quality of patient outcomes.

Pharmacy e-Health Information Technology Collaborative

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As our responses to the questions posed by ONC demonstrate, the use of the national HIT infrastructure by pharmacists is critical to the integration of pharmacist-provided patient care services into the national HIT plan.

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?

Pharmacists use health information exchanges. We agree that a suite of conditions for trusted exchanges (CTEs), especially for medications, is important. We agree that these conditions should focus on safeguards to protect individual identifiable health information (IIHI) and interoperability with regard to technical standards for the exchange and integration of electronic health information.

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

We believe safeguards and interoperability are vitally important. It is essential that the health information in the health information exchange (HIE) is secure and that the patient's identity and other patient identifiable information is protected, accurately reconciled, and recognized.

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.

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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 believe establishing a national validation process as described could relieve states of some burden to regulate local and regional health information exchange markets. For a national process to work, however, it would need to be the ceiling rather than the floor, though this may not be acceptable to states.

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

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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.

The Collaborative and its members appreciate the role that ONC is playing. We support private sector involvement as long as private sector entities ensure access to HIEs by pharmacists. One of the goals of the Collaborative is to assure that pharmacists can connect with providers through bidirectional communication. The active participation of pharmacists in HIEs is aligned with overall HIE goals to improve patient safety, enhance quality of clinical care, increase clinical and administrative efficiency, reduce duplication of services, enhance identification of threats to public health, and expand consumer access to their own health information.

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.

We agree that a voluntary validation process would be effective in facilitating electronic exchange compliance with adopted CTEs provided there is a mechanism to assure CTEs can be validated.

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.")

We believe standardization would facilitate compliance with the CTEs. Standardization would provide assurance that there would be a measurable method of voluntary validation.

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?

Not in a position at this time to comment.

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?

Not in a position at this time to comment.

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?

We agree that there should be an eligibility criterion that requires an entity to have a valid purpose. As recognized health care providers, pharmacists provide treatments. Such valid purposes may include medication therapy management, immunizations, glucose monitoring, and medication reconciliation, to name a few. In some settings, pharmacists are first-line-of-care providers, and as such, access to health information is critical. The pharmacist plays a key role in the care of patients.

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 believe that as long as there is a CTE validation process and an entity can comply with the requirements they should be included.

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

Not in a position at this time to comment.

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.

Not in a position at this time to comment.

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 the optimum role for stakeholders is to provide input into the development and governance through the nationwide HIN with the health information exchange. As recognized health care providers and stakeholders, pharmacists play an important role in providing treatments and care to patients and need to be included in the CTE governance process. Including pharmacists in the governance process is critical for integrating pharmacy health information technology (HIT) and treatment documentation into the national HIT infrastructure

and for assuring that pharmacists can connect to other health care providers through secure bidirectional communication.

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?

We believe that security, access, and standardization are the main areas. Patient information and access need to be secure and must follow the HIPAA and HITECH Act requirements. Standardization will foster adoption and improve use-ability.

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

Not in a position at this time to comment.

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?

We believe it is important that any validating should have public disclosure and that information remain secure.

Question 21: How long should validation status be effective?

Not in a position at this time to comment.

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?

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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?

We believe that as long as the validation process is secure and that the NVE provides access to pharmacists this will provide a level of assurance. Pharmacists currently use health information exchanges with providers and payers. Again, as recognized providers of care and authorized users of HIEs, pharmacists are bound by the HIPAA regulations to ensure the security of patient information.

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?

We believe there are situations in which indirect authentication is needed and should be available, especially by pharmacists, for the electronic exchange of health information. It would be up to the NVE to assure that the exchange of this information is secure. As recognized providers of care, pharmacists are bound by the HIPAA regulations to ensure the security of patient information.

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?

We agree that safeguards should be in place. Patient information and access need to be secure and must follow the HIPAA and HITECH Act requirements.

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?

The Collaborative agrees that patient consent is important. As long as the NVE or providers engage and educate the patient that the information is being used for payment, treatment, operations, and population health, there shouldn't be increased liability.

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

The Collaborative agrees that patient consent is important, especially with regard to areas in which patient information may be used for other than providing treatment or care. As long as the NVE or providers engage and educate the patient that the information is being used for payment, treatment, operations, and population health, and provide opt-in/opt-out consent choices when needed, there shouldn't be increased liability.

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?

Not in a position at this time to comment.

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?

We believe there may be instances in which a patient may have cognitive disabilities that necessitate someone other than the patient to make a choice. There needs to be a way to allow a patient to delegate a meaningful choice.

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

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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?

We agree that an NVE should be able to accurately disclose its data practices and provide advance notice of such practices. Under the HIPAA Privacy Rule, individuals have the right to adequate notice of the uses and disclosures of their protected health information. Some form of summarization could help validate such practices.

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

Not in a position at this time to comment.

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

We agree that this CTE should require an NVE to disclose its activities related to de-identified and aggregate data. Disclosure of activities should be included in the NVE's policies and

procedures when the NVE de-identifies health information and provides such information to third parties.

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

We believe the NVE should make the notice available to anyone who may need to see it (e.g., providers or patients). Consumer/patient education about the privacy of information should be the responsibility of all who are involved in the process of exchanging IIHI.

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?

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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

We believe the standard of availability of an NVE should be very high (24/7 or nearly that much).

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

We believe that since HIPAA rules define IIHI and the protections for such health information, everyone involved in the process of electronic exchange of health information must follow these rules.

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?

We believe that a mechanism should be in place for a consumer or provider to read and request corrections. We do not agree, however, that an NVE should allow an individual to change or remove health information without the provider's knowledge or input. There also should be a process that documents changes made by various stakeholders. At this stage, however, we are not in a position to comment on what the impact would be to the NVE.

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

We believe an NVE should provide individuals with the ability to correct their IIHI. There should be a mechanism in place not only to correct information but also to validate information before it is changed. There should be a process that documents changes made by various stakeholders.

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

We believe that whatever method or methods are used for verifying a treatment relationship, they should not put an undue burden on providers or NVEs. Methods should be straightforward and simple to use (e.g., a checkbox method for verifying treatment status by providers).

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?

There may be circumstances in which a provider who does not have a direct treatment relationship with a patient but will be involved in the patient's treatment in some form should be allowed access to the patient's health information. Pharmacists are such treatment providers and need access through the NVE to health information of patients. For individuals who are not directly under the pharmacist's care, consent to access health information should be obtained. There should be a valid mechanism, such as NPI or provider directories, to assure the treatment provider can access needed patient information.

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)?

Not in a position at this time to comment.

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?

Not in a position at this time to comment.

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?

Not in a position at this time to comment.

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?

We agree that all participants engaged in planned electronic exchange should be required to obtain an organizational digital certificate consistent with the policies of the Federal Bridge.

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?

We agree that matching algorithms should be adopted and that levels should meet industry standards to match patients to the correct data. There also should be a mechanism to notify NVEs if there is not a match.

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

While we do not wish to comment on what the specific core data elements should be, we agree with developing a set of core data elements, and these elements should meet industry standards to match patients to the correct data.

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

Not in a position at this time to comment.

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?

Not in a position at this time to comment.

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?

The fee structure should be balanced among all who use the CTE. We believe fees should be left to the market to determine. If fees are set too high, only then should a governing authority step in to adjust the market.

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

We believe that if an exchange limits access to a delivery system and distorts the market, a mechanism needs to be in place to correct such a distortion.

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)?

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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.

Not in a position at this time to comment.

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?

We believe it would make sense to allow for validation to different bundles of safeguard, interoperability, and business practice 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?

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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

Not in a position at this time to comment.

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?

We agree that the ONC also should consider using a process outside its advisory committees through which the identification and development of new CTEs could be done.

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?

Not in a position at this time to comment.

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

We believe that an annual review process by the HIT Policy Committee, as well as input from those outside the advisory committees, could be effective for updating and refreshing the Interoperability CTEs.

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.

While we are not in a position to provide specific criteria, we agree that criteria should be objective, quantifiable, and include some type of metric.

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.**

We believe that the costs for validation should not be passed on to providers, which includes pharmacists.

Formed in the fall of 2010, the Collaborative's focus is to assure the meaningful use (MU) of standardized electronic health records that supports safe, efficient, and effective medication use, continuity of care, and provides access to the patient-care services of pharmacists with other members of the interdisciplinary patient care team.

The Collaborative seeks to ensure that pharmacist-provided patient care services are integrated into the National HIT interoperable framework. The Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes six associate members from other pharmacy related organizations. For additional information, visit www.pharmacyhit.org

On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the Office of the National Coordinator for Health Information Technology's Governance RFI for the National Health Information Network: Conditions for Trusted Exchange (CTE), published in the *Federal Register* on May 15, 2012. For more information, contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at shelly@pharmacyhit.org.

Respectfully submitted,



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