

June 27, 2012

Farzad Mostashari, M.D., ScM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W., Suite 729-D
Washington, D.C. 20201

***Re: Request for Information: Nationwide Health Information Network Conditions for
Trusted Exchange***

Dear Dr. Mostashari:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office of the National Coordinator of Health Information Technology's (ONC) May 15 request for information (RFI) regarding the governance structure of the nationwide health information network (NwHIN).

America's hospitals strongly believe that the exchange of health information presents tremendous opportunities to enhance the delivery of high-quality, person-centered care in all types of health care settings. Hospitals are equally dedicated to safeguarding the privacy and integrity of that health information, which is critical to building trust among health care providers and patients regarding mechanisms for exchange; the AHA and its members agree with ONC that such trust will be integral to the success of widespread health information exchange.

Across the health care field, there is enormous variation among organizations in the level of electronic health information exchange undertaken and the particular mechanisms used. Given this variation, the AHA appreciates the need for a governance structure that draws together existing privacy and security and interoperability standards and that appropriately balances the need for uniformity with the need for flexibility to reflect the wide variation in the size and resources of health care organizations, in order to promote the widespread adoption of health information exchange.



While we generally endorse the concept of a governance structure to facilitate nationwide exchange of health information, we have a number of concerns about the proposed approach outlined in the RFI. ONC proposes to establish a voluntary process for entities that facilitate electronic health information exchange to be “validated” (deeming such entities “Network Validated Entities” or “NVEs”) if they demonstrate compliance with a suite of “conditions for trusted exchange” (CTEs).¹ These CTEs would serve as the foundational “rules of the road” for trusted, secure and interoperable electronic health information exchange nationwide.

We recognize that the RFI represents ONC’s preliminary thoughts on the appropriate governance structure and that further details will be forthcoming in a notice of proposed rulemaking. However, we respectfully request that ONC consider the following comments prior to issuing a proposed rule:

- The RFI does not clearly articulate the problem that the governance structure is trying to address and, as a result, the scope of the proposed governance structure remains loosely defined. The AHA is concerned that uncertainty about scope may impede rather than facilitate widespread participation in the NwHIN. Specifically, **we urge ONC to clarify that the CTEs are intended to govern the flow of information between health care organizations, and not the flow of information within existing health care organizations or delivery systems.**
- In light of the significant variation among health care organizations in terms of the degree to which they use electronic exchange and the mechanisms for that exchange, the AHA believes that it may be too early for ONC to establish specific CTEs to govern the nationwide exchange of health information. The AHA appreciates ONC’s clear recognition that CTEs need to be tested and validated before they are adopted as “best practices” nationwide. Accordingly, **we recommend that ONC’s notice of proposed rulemaking focus on establishing the processes for setting CTE standards in the future and for validating NVE compliance with those CTEs, rather than on setting out specific CTEs at this time.**
- While the AHA and its members are deeply committed to protecting the privacy and security of patient information and strongly support the adoption of additional safeguards that meaningfully enhance those patient protections, we are concerned that many of the safeguards CTEs proposed would create yet another set of distinct standards or duplicate existing standards with which hospitals and health care organizations already must comply. Imposing requirements beyond the *Health Insurance Portability and Accountability Act* (HIPAA) on covered entities and their business associates may discourage participation in the NwHIN, as entities will have to incorporate both sets of standards in order to participate, and may exacerbate confusion among health care providers and patients alike. **We urge ONC to adopt only those safeguards CTEs that yield *meaningful* privacy and security benefits to patients without creating undue burden on participants.**

Each of these comments is explained in detail below. We also have included a number of recommendations and responses to specific questions related to the proposed safeguards

¹ 77 Fed. Reg. 28,543, 28,550 (May 15, 2012).

and interoperability CTEs, as well as the proposed process for developing and adopting CTEs in the future.

ESTABLISHING A GOVERNANCE MECHANISM

As noted, ONC proposes to establish a voluntary framework in which entities that facilitate electronic health information exchange would validate their compliance with CTEs in three broad categories:

- Safeguards CTEs, which would focus on the protection of individually identifiable health information (IIHI) to promote its confidentiality, integrity and availability and to prevent authorized or inappropriate access, use or disclosure of those data;
- Interoperability CTEs, which would focus on the technical standards for the exchange and integration of health information so that it is useful for the recipient; and
- Business practices CTEs, which would focus on the operational and financial practices or standards to which NVEs would need to adhere in support of trusted electronic exchange.²

ONC proposes that, to become an NVE, an entity would need to be validated to CTEs adopted for the particular exchange services and activities it performs. ONC does not specifically describe the types of services or activities that it intends be subject to the CTEs. To the contrary, ONC appears to contemplate that CTEs will apply to any and all entities that have contact with electronic health information, as it proposes an expansive definition of entities that will be eligible to qualify as NVEs, including, but not limited to: “EHR developers; regional, state, local or specialty-based health information exchanges; health information service providers; state agencies; federal agencies; and integrated delivery networks.”³ ONC further proposes that the voluntary CTE framework would apply even to entities that already are HIPAA-covered entities or business associates.⁴

The AHA and its members strongly support ONC’s goal of achieving the flow of robust, accurate health information between different types of entities and arrangements when it is needed to support high-quality patient care and inform and engage patients. We believe that provider and patient trust in the security of electronic exchange of that information is essential to optimize the use of health information to enhance patient care. Thus, we support measures that add meaningful protections to the privacy and security of that information for a range of entities and/or transactions. Accordingly, we appreciate that ONC is attempting to propose a governance structure that is sufficiently inclusive and flexible to take into account the wide variety of entities and transaction types that exist in the market place already, as well as the new electronic exchange services and activities that will develop as a result of new technology and innovations in this rapidly changing industry.

² *Id.*

³ 77 Fed. Reg. at 28,551.

⁴ *Id.*

We are concerned, however, that by using such a flexible definition, ONC has not clearly identified the problem that the proposed governance structure is supposed to address or delineated the scope of the governance structure. In particular, we are troubled that the broad definition of entities that would be eligible to qualify as NVEs suggests that the voluntary CTE framework also would apply to information exchanges that support the flow of data within an organization, such as an integrated care delivery network or an accountable care organization (ACO). These types of exchanges already are required to comply with multiple different privacy and security standards and, therefore, already have in place robust, well-established policies and practices to safeguard patients' health information. These exchanges also have successfully established technical requirements and specifications to ensure interoperability across the organization. To impose the CTEs, many of which overlap with and/or duplicate some of the standards that enterprise exchanges already must satisfy, on the internal transactions or activities of integrated delivery systems or ACOs adds yet another set of regulatory requirements without yielding any measurable benefit to patients or furthering the establishment of a nationwide exchange network.

We urge ONC to clarify that because the proposed governance structure is intended to help facilitate the NwHIN—namely a nationwide set of standards, services and policies that enable secure health information exchange over the Internet—ONC's primary focus is to establish a governance structure that applies to the exchange of information *across* health care organizations, not *within* health care organizations. Focusing on the exchange of information across organizations will mean that the CTEs will serve to help build the necessary infrastructure to create a nationwide health information network because they will provide more uniform standards to transactions for which guidance does not yet exist. More specifically, we urge ONC to revise the definition of entities that are eligible to qualify as NVEs and to describe the types of transactions that would be governed by the CTEs in any notice of proposed rulemaking to make clear that the voluntary CTE framework would not apply to health information exchange transactions within an organization.

For the same reason, we are concerned that, as proposed, the governance structure would add yet another layer of privacy and security standards for HIPAA-covered entities and business associates. Indeed, the RFI explicitly states that ONC expects that most entities that would qualify as NVEs would be HIPAA business associates of covered entities, and therefore would be subject to the requirements and standards of the HIPAA Privacy, Security and Breach Notification Rules.⁵ The HHS Office of Civil Rights (OCR) also has proposed to make clear in its HIPAA Privacy Rule regulations that health information organizations would be business associates under HIPAA, consistent with the *Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009*. It is not clear that establishing a new and distinct set of privacy and security safeguards through the CTEs to apply to NVEs is necessary or would add any value in terms of the protection of health information. To the contrary, imposing NwHIN-specific privacy and

⁵ *Id.*

security standards on HIPAA business associates and covered entities risks discouraging those entities from participating in the NwHIN because of the costs associated with complying with yet another set of standards and exacerbating patient and provider confusion about which standards apply in which circumstances. **The AHA strongly urges ONC to instead rely on existing privacy standards and not impose any additional requirements unless those requirements meaningfully increase protections for patients or enhance patient and provider trust.** As an alternative, we urge ONC to delay issuing any proposed rule that sets forth substantive CTEs until it has an opportunity to fully consider the provisions in OCR's final rule implementing the HITECH Act to determine whether any additional requirements are needed.

The AHA endorses ONC's proposal to make the NwHIN structure voluntary. A voluntary framework appropriately balances the need for more uniformity in the exchange of information with the need for flexibility to account for the variety of entities that facilitate health information exchange and the range of services that they perform. The AHA also believes that a voluntary approach will help ensure that the CTEs that are adopted do not unnecessarily duplicate existing regulatory requirements for these entities or mandate requirements that are unduly burdensome for entities that are small or that offer very limited services related to health information exchange. The AHA encourages ONC to adopt this voluntary approach and to ensure that participation remains truly voluntary by making clear that compliance with CTEs or use of a NVE is not and will not be required as part of other regulatory obligations affecting health care providers.

The RFI specifically requests comments regarding the urgency of the need to establish a nationwide governance approach. The AHA and its members agree with ONC that a governance structure could enhance nationwide coordination, and especially nationwide interoperability, for electronic exchanges of health information.⁶ Not only are there many different exchange activities at the local, regional and state level that are not necessarily compatible with each other, but also these activities are subject to multiple state and federal regulations that do not align with each other. This variability impedes uniform, trusted and secure information exchange nationwide. Moreover, the AHA agrees with ONC that a designation like the NVE validation could represent added value to a hospital when it enters into contracts with these types of entities, as a hospital will be able to specify that qualification as an NVE is a condition for the contract and will have increased assurances that any such entity has satisfied certain standards, which can make the contract negotiation process more efficient. The structure could also enhance trust in exchange partners that are not HIPAA-covered entities or business associates.

That said, it may be too soon to adopt specific safeguards or interoperability CTEs to apply nationwide. Experience with health information exchange is still growing. Entities that seek to facilitate health information exchange, and health care providers and others who do business with those entities, still face significant barriers to the actual implementation of nationwide health information exchange, such as interoperability

⁶ See 77 Fed. Reg. at 28,545.

limitations and difficulties developing workable business models for this space. Until there is a more developed infrastructure to actually implement the NwHIN, it may be difficult to anticipate where specific safeguards or interoperability standards are needed in order to facilitate nationwide exchange. Moreover, as ONC also recognizes in the RFI, it is highly likely that both the technology and the services provided in this area will continue to change rapidly, which will require ONC to modify the CTEs or add new CTEs to those proposed. Accordingly, **the AHA recommends that ONC focus on establishing the overall governance structure for the NwHIN, as well as the process for testing and developing CTEs in the future, rather than setting forth specific CTEs, in any future rulemaking.**

ACTORS AND ASSOCIATED RESPONSIBILITIES

The AHA also respectfully requests that ONC consider the following specific comments regarding the entities that it proposes be eligible to qualify as NVEs and the role of health care providers in the proposed governance structure.

Question 12: As noted, while AHA and its members are dedicated to protecting the privacy and security of patient health information, we believe that it is critical that ONC only impose new privacy and security requirements that serve to meaningfully enhance the protections for patient information beyond those established under HIPAA. This is especially important given that ONC contemplates that most entities that will be eligible to qualify as NVEs will be HIPAA business associates or even covered entities. We are concerned that adding yet another set of privacy and security standards to the requirements already imposed under the HIPAA rules may create a significant burden for HIPAA-covered entities and business associates without resulting in any meaningful benefit for patients. In turn, we fear that these burdens will discourage health care providers and other organizations from participating in the NwHIN and will exacerbate patient and provider confusion, both of which will undermine, rather than enhance, patient and provider trust in electronic exchange. We strongly urge ONC to engage in rigorous analysis to assess whether each of the proposed safeguards CTEs will yield meaningful benefit for patients and to weigh those benefits, and any benefits associated with increased uniformity, against the workability of those standards and the cost burdens of requiring entities to comply with multiple standards. We are confident that such a rigorous analysis will lead to a set of CTEs that simultaneously facilitate participation in the NwHIN while fostering patient and provider trust in electronic information exchange.

Question 17: The RFI asks for input on the optimum role for stakeholders in governance of the NwHIN. Given that hospitals and physicians will likely be primary end-users of the NwHIN, they should have strong representation. Given the wide variability in types of providers, the governance structure should include representation of multiple provider views, such as urban and rural hospitals, community hospitals, academic medical centers, and safety-net facilities. On the ambulatory side, primary care and specialty physicians may have different needs, as well as physicians working in large practices versus those in small offices.

CONDITIONS OF TRUSTED EXCHANGE

In the event that ONC decides to proceed with a notice of proposed rulemaking before there is a more robust infrastructure in place for entities to actually engage in nationwide health information exchange, we offer several comments specific to certain safeguards and interoperability CTEs outlined in the RFI.

Safeguard CTEs

Condition S-2: An NVE must only facilitate electronic health information exchange for parties it has authenticated and authorized, either directly or indirectly. ONC states that it is important for an NVE to offer the parties for which it facilitates exchange a “high degree of certainty” that only authorized parties are able to use its exchange services.⁷ Accordingly, ONC explains that where an NVE cannot directly authenticate and authorize the parties for which it facilitates exchange (such as because the party for which the NVE facilitates the exchange is an organization), “it would be critical for the NVE to ‘flow down’ these responsibilities and obtain reasonable assurance from the party(ies) for which it facilitates exchange that only authenticated and authorized personnel are able to access electronic exchange services it facilitates.”⁸

Questions 24, 25 and 26. The AHA emphatically agrees that to ensure adequate protection of patient health information and to promote patient and provider trust in health information exchange, an NVE must be able to manage the authorization and authentication of the parties for which it facilitates exchange. However, we are concerned that applying the flow-down requirement to the end-users of NVEs would mean that NVEs would in turn enforce compliance with the CTEs on the parties for which they facilitate exchange, most of which are HIPAA-covered entities or business associates that already are subject to HIPAA privacy and security requirements. We urge ONC not to use the CTEs generally, or the flow-down requirement in particular, to impose a potentially different or conflicting set of obligations for privacy and security compliance on HIPAA-covered entities.

As noted, the AHA strongly believes that the CTEs should not impose additional requirements beyond HIPAA related to the electronic exchange of health information unless those requirements result in a meaningful benefit to patients. Mandating requirements beyond HIPAA on covered entities, including hospitals, and their business associates would mean that those entities have to establish an additional set of compliance plans and policies that incorporate NwHIN-specific privacy and security standards. The added burden of compliance with multiple standards may well discourage covered entities and business associates from participating in the NwHIN and also may exacerbate patient and provider confusion. As ONC itself recognizes throughout the RFI,

⁷ 77 Fed. Reg. at 28,553.

⁸ *Id.*

there is a significant need for more uniformity and coordination among state and federal privacy laws, not less.⁹

Condition S-4: An NVE must only exchange encrypted IHHI.

Question 31: The AHA agrees that encryption is often a best practice for maintaining the confidentiality of IHHI transmitted across networks and generally supports requiring NVEs to implement industry best practices for ensuring that IHHI is encrypted. But there also are important circumstances in which encryption may not be appropriate and/or feasible, such as where electronic exchange of health information is necessary to provide emergency care for a patient. The HIPAA Security Rule recognizes this and leaves the determination of whether to encrypt data to the entities covered by that rule, while providing a safe harbor from breach notification requirements when data are encrypted. Similar consideration may be warranted for an NVE that is establishing health information exchange to support health care services delivered in time-sensitive, life-threatening situations.

Condition S-10: An NVE must have the means to verify that a provider requesting an individual's health information through a query and response model has or is in the process of establishing a treatment relationship with that individual.

Question 44. The AHA agrees that it is important for entities that facilitate health information exchange to verify that a provider seeking an individual's records has or in the process of establishing a treatment relationship with that individual in order to safeguard that individual's information. However, where such a treatment relationship exists or is in the process of being established, a health care provider also must be permitted to use that health information for other core activities related to the delivery of care, including seeking payment as well as conducting day-to-day business operations or quality improvement activities. We strongly believe that a health care provider's use of an individual's information with whom the health care provider has, or is in the process of developing, a treatment relationship should not be limited to treatment purposes. Therefore, we request that ONC clarify that a provider that has or is in the process of establishing a treatment relationship with an individual may use that individual's information for the same permissible uses of protected health information allowed under the HIPAA Privacy Rule, including for purposes of payment and for health care operations. Varying the permissible uses by the mechanism used to obtain clinically relevant data would create confusion and significantly increase the compliance burden.

Interoperability CTEs

Condition I-3: An NVE must have the ability to verify and match the subject of a message, including the ability to locate a potential source of available information for a specific subject.

⁹ See, e.g., 77 Fed. Reg. at 28,545, 28,550.

Questions 49, 50 and 51. The AHA appreciates the importance the RFI places on the ability to verify and match patient identity as part of health information exchange. However, we believe that the need to accurately match patients to their records is important for the entire health care system nationwide, not just the NVEs. The issue of how to match patients with their medical records remains unresolved despite the acceleration of information exchange on the regional and national level. As a result, hospitals and health systems are forced to expend significant resources on expensive, proprietary vendor solutions to develop siloed master patient indexes that apply only to that particular hospital or health system's patients. Inability to match patients across those silos raises safety concerns from mismatches in either direction – incorrectly matching patients, or missing a match that should have been made.

Therefore, the AHA urges ONC and other departments within HHS to work toward a single, national solution that all parties can draw on to improve the accuracy and cost-effectiveness of patient matching. Such a system would facilitate efforts to increase the safety and quality of care given to patients. It also could support enrollment of individuals in the Health Insurance Exchanges to be established as part of health reform. Specifically, the AHA supports the creation of a national unique identifier system to connect records and to ensure that hospitals and physicians have the best information available when providing care for each patient. Alternative approaches include standardized methods and policies to match patients, shared services, or development of a voluntary or mandatory unique patient identifier. While the AHA prefers the development of a unique patient identifier over these alternatives, we are most concerned that there be a rapid establishment of a single national solution that assures a high level of accuracy and efficient operations in order to best protect patient safety.

CTE PROCESS AND STANDARDS AND IMPLEMENTATION SPECIFICATION CLASSIFICATIONS

Questions 60, 61, and 62. The AHA appreciates the RFI's emphasis on the importance of the need to ensure a timely, robust and sustainable process for maintaining and updating the rules governing the NwHIN to accommodate technical changes and the development of more sophisticated policies over time.¹⁰ We likewise appreciate the RFI's clear recognition that standards must go through a maturation process and pilot testing before they become national requirements.¹¹ As we noted, much of the infrastructure for the NwHIN has yet to be actually implemented, and we imagine there will be significant changes to the technology and services used to facilitate health information exchange in the coming years.

The RFI asks specifically about the mechanisms for updating the CTEs. In general, the AHA suggests that ONC should follow the standard notice and comment process to ensure that all affected groups or individuals have a chance to understand and weigh in

¹⁰ 77 Fed. Reg. at 28,559.

¹¹ *Id.*

on proposals to modify or add CTEs. The AHA recommends that ONC establish a process that includes extensive and systematic consultation with end-users of all sizes and in all locations in order to assess the readiness for adoption of modified or new CTEs, including by using surveys. Expert opinion from a small group is helpful to identify candidate standards, but must be supported by data from the field to inform decisions about when to require their use. In addition, it is especially important to ensure that pilot tests are independently evaluated to assess scalability and applicability across different settings. Evaluation results for these pilot tests should be widely disseminated before standards are adopted for national use. ONC should also use this approach to evaluate any initial set of CTEs.

Any use of standards is hard and requires providers to change information technology systems, change how care is provided, and conduct extensive – and ongoing – training of staff. All of this happens in a fast-paced, rapidly changing health care system where there is a strong emphasis on reducing costs. An effective transition to standards adoption needs to be supported by educational resources that are easy to find and understand. Therefore, we urge ONC to ensure that the NwHIN is supported by a single source of easily available and useable tools to support adoption of all standards that HHS puts forward in regulation, whether for meaningful use or the NwHIN. To be helpful, these resources should be made available sufficiently ahead of compliance dates so that end-users can make use of them as they implement and prepare to use the updated systems.

While the AHA agrees that establishing a robust, participatory process for modifying or adding CTEs is important to ensure that the governance structure of the NwHIN supports and reflects innovation in this space, the AHA also believes that it is equally important to the success of the NwHIN for HHS and ONC to coordinate among existing privacy and security standards for electronic health information activities to simplify compliance requirements. As we noted throughout our comments, many of the issue areas addressed by the CTEs discussed in the RFI, such as security requirements, patient access to information, and technical standards to support data exchange are also the subject of regulations promulgated by different agencies within HHS. For example, OCR oversees and enforces compliance with HIPAA while the Centers for Medicare & Medicaid Services establishes requirements for meaningful use, and ONC itself mandates certification standards for use in the Medicare and Medicaid electronic health record incentive programs. **To avoid imposing duplicative, or worse, contradictory, requirements on hospitals and other health care organizations that are likely to be subject to all of these different standards, we strongly urge HHS to develop mechanisms to closely coordinate across these efforts. Developing coordinated standards will reduce the regulatory burden on hospitals and other health care organizations that participate in health exchanges or do business with entities that facilitate electronic exchange and will help mitigate patient and provider confusion and distrust of such a complex system.**

Dr. Farzad Mostashari

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Thank for your consideration of these comments. We believe that ONC can facilitate the widespread adoption of the NwHIN by establishing a governance structure that builds on existing privacy and security standards and appropriately balances the importance of increasing patient and provider trust in electronic exchange with the need to avoid imposing unduly burdensome requirements on entities that facilitate that exchange. We welcome the opportunity to continue to work with ONC on these issues in the future.

Should you have any questions about our recommendations, please feel free to contact me or Chantal Worzala, director for policy, at cworzala@aha.org or Lawrence Hughes, assistant general counsel, at lhughes@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President