



June 29, 2012

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

Re: 45 CFR Part 171
Nationwide Health Information Network: Conditions for Trusted Exchange
Request for Information (RFI)

Submitted via: <http://www.regulations.gov/>

Dear Mr. Posnack:

On behalf of AMIA (the American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced request for information (RFI). AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of health information technology (health IT).

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health and healthcare. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

AMIA thanks the Department of Health and Human Services (the Department) and the Office of the National Coordinator for Health Information Technology (ONC) for issuing this RFI which seeks broad input on a range of topics. We appreciate ONC's ongoing efforts to conceptualize and implement the Nationwide Health Information Network (NwHIN) through various initiatives such as the Nationwide Health Information Exchange, the Direct Project, and the Standards and Interoperability Framework. We are pleased to see ONC propose a governance mechanism for the emerging NwHIN through public regulation and rule-making as we believe this is essential to protect consumers' privacy, promote interoperability across disparate health care system networks, and create operational, technical and financial standards for entities participating in the NwHIN.

However, we encourage ONC to continue to undertake activities to align and harmonize existing Federal and state rules, regulations and guidelines in order to help reduce barriers to appropriate

health data exchange. We urge ONC to continue to consider ways to balance the benefits and value of health data exchange and sharing with the need to address ongoing concerns about data privacy and security.

In providing input, we will provide general comments about the proposed approach, respond to the requests for specific comments included in the Federal Register, and discuss other proposed provisions for NwHIN governance. Our specific comments address the following topics:

- Definitions of Terms and Terminology
- Relationship with Existing Requirements
- (Selected) Conditions of Trusted Exchange (CTEs) and Embedded RFI Questions
- Self-Regulation and Governance

General Comments

We recognize that ONC is required by the Health Information Technology for Economic and Clinical Health (HITECH) Act, to address NwHIN governance. However, we believe that there are many unanswered questions. We note that the early health information exchange pilot programs such as those funded by the Agency for Health Care Research and Quality (AHRQ) were geared more towards technical feasibility rather than policy and governance evaluations. Thus, we caution that ONC should not assume that the technical models substantiated through the early research would operate as efficiently or effectively under alternative governance models.

One of our main observations is that the RFI does not appear to address uses of health information exchange outside of continuity of care and limited aspects of quality reporting. The RFI suggests that ONC plans to issue a Notice of Proposed Rulemaking (NPRM) about NwHIN governance. It appears that certain components of the RFI, if they were to proceed to the stage of an NPRM, may be perceived to add constraints to HIPAA privacy, security and confidentiality requirements, such as when patient consent is required for certain types of data disclosure and/or exchange. Such constraints may restrict and/or complicate current health information exchange practices that are already in use to support patient care, public health planning and operations, quality improvement initiatives, and research.

Definitions of Terms and Terminology

We suggest that ONC provide clearer articulation of the definitions for various terms and terminology, as well as the nature and scope of entities and processes described in the RFI. Based on our reading of the RFI, it appears that the intent of ONC is to encourage voluntary requirements for a class of entities to be known as Nationwide Health Information Network Validated Entities (NVEs). What is less clear is the definition of those entities to which the “validation” of a menu of prescribed standards, governance mechanisms and specific conditions of trusted exchange (CTEs) could ultimately apply. The RFI seems inconsistent, often equating

NVEs with existing health information exchanges (HIEs), while at other times suggesting application of the contemplated requirements to any entity which exchanges health data via the Internet. It is, therefore, not clear whether or how the proposed “voluntary” nature of the proposed NVEs and the CTEs relate to existing health data exchange concepts and entities.

Furthermore, several additional issues could be further clarified. These include the following:

- The extent to which the proposed requirements would apply only to entities exchanging health data via the Internet (as contrasted with organizations using other methods or mechanisms).
- The extent to which ONC intends that conditions of trusted exchange (CTEs) as proposed in the RFI apply to entities that are business associates (BAs) to HIPAA covered entities (CEs) and providing information exchange services related to healthcare delivery, such as State Health Information Exchanges (HIEs).
- The extent to which ONC intends to also apply CTEs to other entities that are engaged in the “transfer” or “sharing” of health information electronically, such as claims clearinghouses or entities that offer personal health records (PHRs) via on-line (Internet) patient portals. That is, it appears that the proposed requirements could easily apply to all entities that export or import data through NVEs.

Relationship with Existing Requirements

In discussing the statutory authority for ONC’s establishment of a governance mechanism for the NwHIN, the RFI relies heavily upon provisions of the HITECH Act, in addition to the existing HIPAA Privacy and Security rules. We urge ONC to clarify to what extent the “voluntary” requirements undertaken for “validation” apply to entities which operate within the current framework of HIPAA Covered Entities (CEs) and Business Associates (BAs) and/or whether the Department is proposing standards for all entities that may engage in the electronic exchange of health information via the Internet.

It is not clear how the proposed governance mechanisms and processes might relate to current regulations and laws, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules and the Patient Safety and Quality Improvement Act of 2005 (PSQIA) Patient Safety Rule, which address protecting the privacy and confidentiality of consumers’ health information and establishing procedures and fines for unauthorized or inappropriate access, use, or disclosure.

We urge ONC to consider refinement or enhancement of current regulations and laws to apply to the emerging NwHIN rather than establishing separate privacy, security and confidentiality requirements for data exchanged via the NwHIN.

Conditions of Trusted Exchange (CTEs) and Embedded RFI Questions

We appreciate the efforts underway to establish CTEs as part of the governance of the NwHIN. However, as described the CTEs appear narrowly focused on the exchange of patient information for treatment purposes. Several existing organizations, such as the State HIEs, support a wide range of processes and services, including quality improvement, health services reporting, research, and public health surveillance.^{1 2}

Furthermore, some existing state organizations were created and expanded within existing laws such as HIPAA, and typically without additional regulation from the state or federal governments. It is possible that their success at supporting patient care processes, quality outcomes, and public health operations would have been slower and more difficult if the proposed CTEs and their governance as described in the RFI were enacted. National (federal) statutory regulations on top of state regulations of exchange practices could impede the progress of health information exchange.

When HIPAA was enacted, it included strict standards for de-identified data because of the importance of protecting patient privacy while allowing for the myriad ways in which aggregated or anonymized data can be used to advance healthcare quality, safety, efficiency and innovation. We believe that sound policy choices should favor the appropriate uses of de-identified data, and not unnecessarily prohibit it.

We have concerns about the potential negative impact of several of the 16 CTEs proposed in the RFI. These include what we believe would be the potential significant burdens and limited benefits of CTEs S-3 “meaningful choice,” S-8 “access to,” and S-9 “correction/annotation of” aggregated and unique individually identifiable health information (IIHI) datasets, as well as S-6, which prohibits the use/disclosure of de-identified health information for commercial purposes. Our concerns are further described in the following discussion.

CTE S-3 and S-10. It appears that CTEs S-3 and S-10 would have the effect of requiring consent for uses/disclosures via an NVE, including uses/disclosures for treatment, payment and healthcare operations (TPO). Existing entities have spent a significant amount of time and effort developing their own approach to choice, based on current legal standards and additional elements specific to their own operations. There are ongoing operational challenges to consent policy with HIEs today which may not be resolved by the proposed CTEs.^{3 4 5}

¹ Shapiro JS, Mostashari F, Hripscak G, Soulakis N, Kuperman G. Using health information exchange to improve public health. *Am J Public Health*. 2011 Apr;101(4):616-23. Epub 2011 Feb 17.

² Shapiro JS, Genes N, Kuperman G, Chason K; Clinical Advisory Committee H1N1 Working Group, New York Clinical Information Exchange, Richardson LD. Health information exchange, biosurveillance efforts, and emergency department crowding during the spring 2009 H1N1 outbreak in New York City. *Ann Emerg Med*. 2010 Mar;55(3):274-9. Epub 2010 Jan 15.

³ Genes N, Shapiro JS, Kuperman G. Health Information Exchange Consent Policy Influences Emergency Department Patient Data Accessibility. <http://proceedings.amia.org/127j1s/1>

⁴ Genes N, Shapiro JS, Kuperman G. Health information exchange consent policy influences emergency department patient data Accessibility. ACEP 2010 <http://webdoc.nyumc.org/nyumc/files/nyclix/attachments/Consent%20ACEP%20AMIA%2048x72%20poster%20v3.pdf>

CTE S-6. The RFI proposes (S-6): “An NVE must not use or disclose de-identified health information to which it has access for any commercial purpose.” We request that ONC clarify the definition of the term “commercial.” For example, since it appears that many entities (potentially NVEs) are inherently or could be for-profit entities, it is not clear whether this blanket prohibition applies to core activities and services that a for-profit organization conducts or provides (with full disclosure to its members and participants), or whether this CTE would apply to any entity that would seek to use or disclose data (“sell”) for “commercial purposes.” We understand that there are for-profit as well as non-profit organizations including hospitals and public sector entities (e.g., the VA) that are developing HIEs. Additionally, we encourage ONC to provide additional clarification about what NVEs can/cannot do with the data that they obtain, collect and/or process via the NwHIN (as contrasted with data that they obtain, collect, and or process directly to/from their data providers).

In our view, the prohibition of “commercial” use of de-identified data could potentially interfere with or compromise the development of a sustainable business models for electronic data interchange and potentially, stifle various types of research, including health services research, outcomes research, clinical and translational research, population health, and comparative effectiveness studies. Thus, we believe that ONC needs to further clarify under what circumstances various entities would be eligible to function as NVEs and to more clearly delineate the functions that can be undertaken.

Further, we question the extent to which a prohibition on commercial use of data by NVEs would sufficiently or successfully address all existing and potential future concerns about inappropriate re-identification of health data. To the extent that de-identified health data exist, a ban on “commercial” use by NVEs would likely not prevent attempts to re-identify health data by bad actors for inappropriate uses.

While HIEs could, in theory, continue to be supported by government appropriations in perpetuity, they have been envisioned as self-sustaining entities, especially as money for new government programs has diminished. If HIEs are not allowed to generate revenue in exchange for the data they collect and process, they may not be able to function.

State HIEs as well as other data nodes require resources; absent sustainable financial incentives or other business models for the electronic exchange of health data, data fluidity may be compromised and the aggregation and use of large datasets for clinical research and discovery may be disincentivized. We believe that HIEs possess de-identified information that can potentially provide great value for research without jeopardizing the privacy of identifiable individuals.

⁵ Ancker JS, Edwards AM, Miller MC, Kaushal R. Am J Prev Med. 2012 Jul;43(1):76-80. Consumer perceptions of electronic health information exchange.

Examples of the value of using de-identified data are becoming increasingly evident. One recent example of the power of de-identified health data is reflected in a study published in June 2012 in the Centers for Disease Control and Prevention's Preventing Chronic Disease that describes the establishment of the largest, most comprehensive diabetes registry in the U.S. The SUPREME-DM DataLink utilizes de-identified data from nearly 16 million health plan members who were enrolled in 11 participating plans between 2005 and 2009 in 10 states, and provides a unique and powerful resource for the conduct of population-based diabetes clinical trials, outcomes, quality and other research.⁶ Another example, the Cross-Institutional Clinical Translational Research project, explored a federated query tool and looked at how this tool can facilitate clinical trial cohort discovery by managing access to aggregate patient data located within unaffiliated academic medical centers.⁷

We urge ONC to review prior and ongoing work related to data uses, de-identification, and stewardship undertaken by the National Committee on Vital and Health Statistics (NCVHS), AMIA and others.^{8 9 10 11 12} For example, AMIA has focused several of its annual policy meetings on the use and re-use of health data and has previously offered recommendations regarding the implementation of appropriate data stewardship principles to address many of these challenges.

Further, we urge ONC to harmonize NwHIN governance with relevant Federal efforts (such as the Big Data Research and Development Initiative) that aims "to advance the core scientific and technological means of managing, analyzing, visualizing, and extracting useful information from large and diverse data sets"¹³ and the Health Data Initiative (HDI), "that encourages innovators to utilize health data to develop applications to raise awareness of health and health system performance and spark community action to improve health."¹⁴ Furthermore, organizations

⁶ Nichols GA, Desai J, Elston Lafata J, Lawrence JM, O'Connor PJ, Pathak RD, et al. Construction of a Multisite DataLink Using Electronic Health Records for the Identification, Surveillance, Prevention, and Management of Diabetes Mellitus: The SUPREME-DM Project. *Prev Chronic Dis* 2012;9:110311. http://www.cdc.gov/pcd/issues/2012/11_0311.htm

⁷ Nicholas Anderson, Aaron Abend, Aaron Mandel, Estella Geraghty, Davera Gabriel, Rob Wynden, Michael Kamerick, Kent Anderson, Julie Rainwater, Peter Tarczy-Hornoch. FOCUS on clinical research informatics: Implementation of a deidentified federated data network for population-based cohort discovery *J Am Med Inform Assoc* 2012;19:e1 e60-e67 Published Online First: 26 August 2011 <http://jamia.bmj.com/content/19/e1/e60.full.pdf+html>

⁸ Safran C, Bloomrosen M, Hammond WE, Labkoff S, Tang PC, Detmer DE. Toward a national framework for the secondary use of health data: an American Medical Informatics Association white paper. Expert Panel. *J Am Med Inform Assoc* 2007;14:1-9. Epub 2006 Oct 31. <http://jamia.bmj.com/content/14/1/1.full.pdf+html>

⁹ Bloomrosen M., Detmer D. White Paper: Advancing the Framework: Use of Health Data—A Report of a Working Conference of the American Medical Informatics Association *J Am Med Inform Assoc* 2008;15:6 715-722 <http://jamia.bmj.com/content/15/6/715.full.pdf+html>

¹⁰ National Committee on Vital and Health Statistics. Report to the Secretary - Enhanced Protections for Uses of Health Data: A Stewardship Framework for "Secondary Uses" of Electronically Collected and Transmitted Health Data, December 2007. <http://www.ncvhs.hhs.gov/071221t.pdf>

¹¹ National Committee on Vital and Health Statistics. The Community as a Learning System Report. December 2011. http://www.ncvhs.hhs.gov/111213_chip.pdf

¹² National Committee on Vital and Health Statistics, "Health Data Stewardship: What, Why, Who, How—An NCVHS Primer," September 2009. <http://www.ncvhs.hhs.gov/090930lt.pdf>

¹³ http://www.whitehouse.gov/sites/default/files/microsites/ostp/big_data_press_release_final_2.pdf

¹⁴ <http://www.hdiforum.org/page/show/462516-history-of-the-health-data-initiative>

such as the Patient-Centered Outcomes Research Institute (PCORI) are exploring relevant activities such as options to create a “national data infrastructure to support high quality patient-centered outcomes research.”¹⁵

CTE S-8 and S-9. CTEs S-8 and S-9 would impose direct obligations on the NVEs in connection with individual patients. We do not believe that this is an appropriate role for the NVEs. We believe that patients should continue to act directly and primarily with their own healthcare providers and health plans/payers. These providers and health plans/payers will be the creators of most (and likely all) of the data held by an NVE, and will be the appropriate parties to maintain and assure the accuracy of these data and provide access to it. We do not believe that the NVEs should be required to provide notices directly to individual patients or to otherwise directly provide “individual rights” to patients. We believe that such proposed requirements could create significant additional administrative burdens on HIEs, which already are struggling to meet their obligations consistent with a sustainable business plan, and that any notifications can be provided through existing channels.

CTE S-10. We are concerned that the text of the RFI around CTE S-10 (Question 44) seems to focus only on treatment as a legitimate goal of health information exchange, and therefore by implication other types of activities which are not covered by this CTE (or any other) are not recognized. We note that HIPAA stipulates treatment, payment and operations as legitimate reasons for health information exchange (subject to law). HITECH itself identifies a whole host of reasons why health information exchange should be undertaken and considered. We also urge ONC to assure that any NwHIN regulations will allow health information exchange for population and public health purposes.

Questions 40 and 42. We request that ONC provide additional clarification about the individually identifiable health information (IIHI) sets that may be assembled by an NVE as contemplated in the RFI (Questions 40 and 42). The rationale for why patients should have access to such datasets is confusing. It may be sufficient for an NVE to audit and provide on demand (and based on a verified identity) the organizational sources of information in a patient’s record for direct follow-up by the patient. We are also concerned about the NVE becoming the authoritative source of health data; we believe that the electronic health data supplier is the more appropriate source (with the exception perhaps of IIHI actually entered into any interactive application provided solely by the NVE).

We believe that the patient should pursue correction of the data with the original source of the data and not the NVE. That being said, we believe that NVEs could be expected to be informed about and possibly track patient queries or questions in such a way that subsequent viewers of queries which might include that data understand that a question has been raised.

¹⁵ <http://www.pcori.org/meetings-events/event/national-workshop-to-advance-use-of-electronic-data/>

Self-Regulation and Governance

Some might argue that governance and interoperability of HIE is best left to the emerging industry itself using established practices of self-regulation. Self-regulation is an arrangement, involving formal or informal procedures, rules and norms, that is widely recognized as having the purpose of constraining the conduct of a set of private actors, and where the procedures, rules and norms are shaped to a significant degree by some or all of these actors through private rule-making. An example of self-regulation with private rule-making is NACHA - The Electronic Payments Association (<http://www.nacha.org>). In addition to NACHA, there are other models for self-regulation including the American Financial Accounting Standards Board (FASB).¹⁶ These examples are relevant since the adoption and growth of e-health information systems and HIE has often been compared with the adoption of e-commerce and the exchange of financial information across a wide array of banking and other financial institutions. Another example of a governance approach undertaken by the Federal Government relevant to administrative data exchange is the implementation and oversight of mandatory operating rules for HIPAA transaction standards (such as the Committee on Operating Rules For Information Exchange (CORE®)).¹⁷

Health information exchanges operate in a rapidly changing technical landscape, and deep technical and organizational expertise is needed to achieve the vision of a nationwide network that effectively, efficiently and seamlessly exchanges health information required for improvements in individual and population health. The need for such expertise and rapidly changing technical and regulatory landscape could therefore be seen as a rationale for ONC to consider delegating rule- and decision-making authority to a public-private sector entity.¹⁸

Concluding Comments

AMIA thanks ONC for its comprehensive activities to establish an approach to governance for nationwide electronic health information exchange. We recognize that the development and proliferation of different types of and approaches to health information exchange has resulted in yet another set of entities involved in handling health data. We are optimistic that stakeholders will ultimately benefit from an established set of “rules of the road” that govern the emerging NwHIN.

As a source of informed, unbiased opinions on policy issues relating to the national health information infrastructure, uses and protection of clinical and personal health information, and

¹⁶ Porter T and Karsten R. Self-regulation as policy process: The multiple and cross-cutting stages of private rule-making. *Policy Sciences*. 2006;39(1):41-72.

¹⁷ Council for Affordable Quality Healthcare (CAQH) www.caqh.org.

¹⁸ Mattli W and Büthe T. Global private governance: Lessons from a national model of setting standards in accounting. *Law and Contemporary Problems*. 2005; 68(3/4):225-262.

public health considerations, AMIA appreciates the opportunity to submit these comments. Again, we thank the Department for issuing this request for information. Please feel free to contact me or Meryl Bloomrosen, AMIA's Vice President for Public Policy at any time for further discussion of the issues raised here. With kindest regards, I am...

Sincerely,

A handwritten signature in black ink on a light pink background. The signature is cursive and appears to read "Kevin Fickenscher, MD".

Kevin Fickenscher, MD
President and CEO