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Office of the National Coordinator Health Information Technology
Department of Health and Human Services
Attention: NHIN RFI Responses
Hubert H. Humphrey Building, Room 517D
200 Independence Avenue, S.W.
Washington, DC 20201

Re: National Health Information Network RFI

Dear Dr. Brailer:

Thank you for this opportunity to comment on interoperable health records and the National Health Information Network (NHIN). I am an Associate Professor of Anesthesiology and Neurosurgery at Yale University School of Medicine, and the chair of the American Society of Anesthesiologists Committee on Electronic Media and Information Technology (EMIT). I also represent the American Society of Anesthesiologists to Accredited Standards Committee X12. Although this report was prepared by the members of EMIT, this response does not reflect the opinions of the American Society of Anesthesiologists.

Widespread implementation and use of electronic clinical information systems, particularly electronic health records, provide a unique opportunity to improve the quality and efficiency of health care delivery. Anesthesiologists have a broad understanding of the health record. In principle, the pre-anesthetic evaluation covers the entirety of the relevant medical history. Anesthesiologists communicate with a variety of medical specialists at different institutions, request consults from nearly every medical specialty, and work with every clinical laboratory. Most of the medical devices used in the operating room and intensive care unit generate data that must be recorded in the medical

record. As a result, anesthesiologists are already working with other specialties and with equipment manufacturers to develop solutions that improve communication between medical devices. Any initiative that would create a universal electronic health record will benefit from the unique insights of practicing anesthesiologists.

This response answers only questions regarding the framework, technology, and acceptance of the NHIN. Numbers next to subheadings refer to the questions in the RFI.

1. Working definition of NHIN

The NHIN should allow any authorized health care professional involved in the care of a patient to access any medical information that had previously been generated for or on behalf of that patient. Any health care professional should also be able to add information to that patient's medical record.

The most difficult obstacle to overcome will be communication between medical devices and individual medical record systems and secure, third party, storage and retrieval systems. There are, however, several initiatives already underway that address these issues. SNOMED (www.snomed.org) started as a common language for pathology, but now serves as a data dictionary for multiple medical specialties and dentistry. The Data Dictionary Task Force of the Anesthesia Patient Safety Foundation has been developing a common language for anesthesiology; SNOMED and the Royal College of Anesthesiology of Great Britain will adopt this language. Health Level 7 (HL7) (www.hl7.org) is an ANSI accredited organization that is charged with developing standards for exchange and management of data that support clinical patient care. HL7 is currently developing a clinical document architecture that will describe the medical record. Accredited Standards Committee X12 (ASC X12) is charged by the American National Standards Institute (ANSI) to develop standards for electronic data interchange. Standards developed by ASC X12 have already been adopted by the Centers for Medicare and Medicaid Services and incorporated as part of the rules for health care insurance transactions under the Health Insurance Portability and Accountability Act of 1996 for electronic claims presentation.

2. NHIN Model

Several community health information network initiatives provide a potential framework for the NHIN. The NHIN could either adopt a model similar to a community health network, or be designed to link existing community health information networks into a larger group. One such model is the Massachusetts E-Health Collaborative (www.maehc.org). The goal of the Collaborative is to make medical information widely available to health care professionals in Massachusetts. The Collaborative preserves confidentiality through the use of secure information systems. The initiative is not limited to transmitting the medical record from place to place; it is designed to facilitate the use of decision support systems and may in the future be expanded to include reimbursement information as well.

Interoperability is critical in order to guarantee rapid adoption of the NHIN. Open standards promote both cooperation and competition among different sectors of the health care industry, and should be used throughout the system. The rapid growth of the Internet, and the development of new networking technologies not envisioned by the creators of the Internet Protocol demonstrates the value of non-proprietary standards.

Extensible Markup Language (XML) is used to create documents that contain structured information. It is a cross-platform, hardware- and software-independent tool for exchanging data. XML is widely used to describe and identify specific kinds of data, and makes it possible for two companies using independently developed programs running on incompatible systems to share information such as inventory or order status. These characteristics make XML a flexible and efficient way to define the structure of the information within the network. Within the health care industry, the HL7 clinical document architecture project makes use of XML to define each item in the medical record. Using XML to exchange information can potentially allow software to determine the structure of a newly added database and extract needed information.

3. Scope of NHIN Individual Elements

One possible structure for the NHIN would be a centrally managed network of community health information networks. Standards for the language and architecture of the data dictionary must be common among all segments and should be managed at the national level by a single organization. This organization could also offer a suggested

structure for community health systems; systems that use that structure would be guaranteed maximal utility from the NHIN. Using this model, the NHIN would link statewide or communitywide health information networks that would in turn link individual physicians offices, clinical laboratories, and hospitals. Individual communities could enter into contracts with corporations in the private sector to store and transmit health care information. Institutions and health care providers could choose their own equipment, which would then communicate with the community health information network through the standards mentioned above.

7. Privacy and Security

Security becomes a significant issue any time large amounts of protected health information (PHI) are aggregated, stored, and transmitted. Most of the requirements for storage and transmission of PHI are covered under HIPAA. Moreover, any provider of services to a health care organization that handles PHI becomes a business associate as defined by HIPAA.

In order to ensure privacy and security of PHI, the medical record should be encrypted and stored on secure servers. A “smart card” carried by the patient would contain a key that permits access to the medical record. Providing the smart card would allow access to specific areas of the record for a defined period of time as defined by the type of encounter. For example, a clinical laboratory worker would be granted one-time, write-only access to the record unless a specific test required additional privileges. If the patient is admitted to the hospital, read and write access would be granted to hospital workers for the duration of the stay. A primary care provider could be granted unlimited read and write access for the duration of his or her relationship with the patient. Records of encounters with mental health professionals would be in a separate, highly confidential category and require specific permission to access. The patient could also choose to restrict access to specific portions of the medical record. In the event of a medical emergency, information would be made available to the clinician through the use of a third key that would be administered at the regional or national level.

8. Public policy objectives for broad participation and interoperability

Open standards and early participation by the users of the NHIN are crucial to its successful implementation. It is critical that the database architecture, transmission protocol, and interface to the NHIN remain open; all of the technology discussed in this RFI is nonproprietary. This report has referred to the importance of open standards. From a public policy standpoint it would be inadvisable to allow any health care software vendor to achieve a position of control of health care information standards or domination of the market. Open source software, which has been rapidly adopted by corporations in the private sector and by many governments around the world, may have an especially important role in NHIN. There should at minimum be an equal playing field for vendors of proprietary and open source solutions during contracting for the NHIN.

Health care workers approach technology differently than most other professionals, and work best when information is presented in the way it is used in the patient care setting. All too often, however, information technology solutions are designed by software developers with little or no experience in the clinical environment. These systems are frequently put into clinical settings without consulting the workers who will ultimately use them. The result is a system that is difficult or impossible for health care providers to use. Health care workers, especially physicians, are highly motivated, enjoy working with new technology, and understand the problems unique to the environment in which they work. Involving health care workers early in the development of the NHIN will result in a system that is readily accepted by the health care community.

14. Agencies to diffuse interoperability standards

Several standards groups currently develop and maintain standards for interoperability of health care information systems. One successful model is ASC X12, which currently works with the Centers for Medicare and Medicaid Services to develop standards for electronic insurance transactions mandated by HIPAA. This group works with the National Uniform Billing Committee and the National Uniform Claim Committee. Standards must be submitted for public comment and approved by the Designated Standards Maintenance Organization prior to being adopted as a rule. Such a

model could easily be adopted by the NHIN, which would work with existing standards committees to develop standards for interfaces and data architecture.

Conclusion

Thank you for your consideration of these comments. I would be pleased to work with your office as the NHIN progresses. The American Society of Anesthesiologists would be happy to provide any assistance that you may require. If you have any questions, please contact me at keith.Ruskin@yale.edu, or (203) 785-2802.