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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Coordinator for Health Information Technology

Development and Adoption of a National Health Information Network

AGENCY: Department of Health and Human Services.

ACTION: Request for Information.

SUMMARY: Public comment is sought regarding considerations in implementing the President's call for widespread adoption of interoperable electronic health records (EHRs) within 10 years. On April 27, 2004, President Bush established the position of the National Health Information Technology Coordinator. On May 6, 2004, Secretary Tommy G. Thompson appointed David J. Brailer, MD, PhD to serve as National Coordinator for Health Information Technology. The Executive Order signed by the President required the National Coordinator to report within 90 days of operation on the development and implementation of a strategic plan. This Framework for Strategic Action entitled: "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care" (the Framework), was presented at the Health Information Technology Secretarial Summit II on July 21, 2004. The Framework is posted for reference at: *[http://www.hhs.gov/onchit/framework/]*. The Framework outlines an approach toward the nationwide implementation of interoperable health information technology in both the public and the private sectors.

In order to realize a new vision for health care through the use of information technology, the report called for a sustained set of strategic actions, embraced by the public and the private health sectors, which will be taken over many years. The Framework outlined four major goals: inform clinical practice with use of EHRs, interconnect clinicians so that they can exchange health information using advanced and secure electronic communication, personalize care with consumer-based health records and better information for consumers, and improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.

This Request for Information (RFI) addresses the goal of interconnecting clinicians by seeking public comment and input regarding how widespread interoperability of health information technologies and health information exchange can be achieved. This RFI is intended to inform policy discussions about possible methods by which widespread interoperability and health information exchange could be deployed and operated on a sustainable basis.

DATES: Responses should be submitted to the Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology (ONCHIT), on or before 5:00 P.M. EST on January 18, 2005.

ADDRESSES: Electronic responses are preferred and should be addressed to: NHINRFI@hhs.gov in the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services. Include **NHIN RFI Responses** in the subject line. Non-electronic responses will also be accepted. Please send to:

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

FOR FURTHER INFORMATION: On December 6, 2004, there will be a technical assistance conference call to answer questions from potential responders. More details will be provided on how to participate in this call on the ONCHIT website *[http://www.hhs.gov/onchit/]*. Additionally, a public, online Frequently Asked Question (FAQ) page will be provided to answer questions throughout the response period on ONCHIT's website.

Please direct email inquiries and responses to NHINRFI@hhs.gov. For additional information, contact Lee Jones or Lori Evans, in the Office of the National Coordinator for Health Information Technology at toll free 877-474-3918.

BACKGROUND: As the nation embarks on the widespread deployment of EHRs, a variety of concomitant challenges and barriers must be addressed. One of these is interoperability, or the ability to exchange patient health information among disparate clinicians and other authorized entities in real time and under stringent security, privacy and other protections. Interoperability is an essential factor in using health information technology to improve the quality and efficiency of care in the United States. Interoperability is necessary for compiling the complete experience of a patient's care, for maintaining a patient's personal health records and for ensuring that complete health information is accessible to clinicians as the patient moves through various healthcare settings. Interoperability is needed for clinicians to make fact-based decisions so medical errors and redundant tests can be reduced. Interoperability is also critical to cost-effective and timely data collection for biosurveillance, quality measurement and clinical research. In short, interoperability is essential for realizing the key goals that are desired from health information technology.

With the exception of a few isolated regional projects, the United States does not currently have meaningful health information interoperability capabilities. Moreover, the broad set of actions and tasks that are needed to achieve interoperability are not well-defined. It is known that interoperability requires a set of common standards that specify how information can be communicated and in what format. On this, there has been considerable effort and progress achieved by private sector organizations such as Health Level 7 (HL7), and by the American

National Standards Institute (ANSI), both of which are voluntary consensus standards setting organizations. Also, HHS and other federal agencies have advanced the adoption of standards through the Consolidated Health Informatics (CHI) initiative, as well as the Public Health Information Network (PHIN) and National Electronic Disease Surveillance System (NEDSS) under the leadership of the Centers for Disease Control and Prevention (CDC). With HHS participation, HL7 has also created a functional model and standards for electronic health records.

However more remains to be done to achieve interoperability and to determine the process by which these tasks should be pursued in the public and private sectors. Clearly needed are interconnection tools such as mobile authentication, identification management, common web services architecture and security technologies. Also needed are precisely defined implementation regimens that are specified at the level of software code. There is also a need for common networking and communication tools to unify access and security. Aside from this, mechanisms for ensuring the sustainable operation of these components on a widespread and publicly available basis must be defined. There are potentially other components that may not be known at this time. The collective array of components that underlie nationwide interoperability is referred to as a National Health Information Network (NHIN) in the Framework.

The NHIN could be developed and operated in many ways. It could include state-of-the-art web technologies or more traditional clearinghouse architectures. It could be highly decentralized or somewhat centrally brokered. It could be a nationwide service, a collection of regional services or a set of tools that share common components. It could be overseen by public organizations, by private organizations, or by public-private consortia. Regardless of how it is developed, overseen or operated, there is a compelling public interest for a NHIN to exist.

Therefore, the National Coordinator for Health Information Technology is seeking comments on and ideas for how a NHIN can be deployed for widespread use. To begin this process, the National Coordinator is inviting responses about the questions in this RFI. We intend to explore the role of the federal government in facilitating deployment of a NHIN, how it could be coordinated with the Federal Health Architecture (FHA), and how it could be supported and coordinated by Regional Health Information Organizations (RHIOs). (For additional information on the FHA and the RHIOs, please refer to the report: "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care," at: *[http://www.hhs.gov/onchit/framework/]).*

There are many perspectives that can be brought to bear on this important topic. Health information technology organizations, healthcare providers, industry associations and other stakeholders all have important insights that will inform future deliberation. In the interest of having the most compelling, complete and thorough responses possible, we encourage interested parties to collaborate and submit unified responses to this RFI wherever possible. Comments from the public at large are also invited.

RESPONSE FOR REQUEST FOR INFORMATION:

From:

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Website: www.aventyn.com
Email: navin@aventyn.com

General

1. The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned, and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this RFI regarding interoperability.

Response: There are several barriers to interoperability starting with hardware platforms to operating system to applications that use multiple data formats. In order to achieve a class of interoperability that allows disparate systems, applications and transactions to materialize in near real-time fashion standardized data formats need to be established. Today and in future a reliable class of interoperability can be enabled for example by standardizing data formats around ASCII, XML, JDBC using SOAP messaging protocols for enterprises to share data seamlessly and be interoperable.

2. What type of model could be needed to have a NHIN that: allows widely available access to information as it is produced and used across the health care continuum; enables interoperability and clinical health information exchange broadly across most/all HIT solutions; protects patients' individually-identifiable health information; and allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives? Please include considerations such as roles of various private- and public- sector entities in your response.

Response: A service oriented architecture model, in other words a web services model can be architected for both payer and providers as well as administrators and several other players within the ecosystem benefit from accessing information. A model that allows data access anytime, anywhere and anyplace must be the mantra for the model. An SOA web services model for example will not only address the needs and roles of the private and public sector entities but will also provide transparency. A guideline for basic interoperability will be to limit the alienation of public vs. private sectors by drawing lines in the sand on how data is shared.

3. What aspects of a NHIN could be national in scope (i.e., centralized commonality or controlled at the national level), versus those that are local or regional in scope (i.e., decentralized commonality or controlled at the regional level)? Please describe the roles of entities at those levels. (Note: "national" and "regional" are not meant to imply federal or local governments in this context.)

Response: Patient care is a critical need and a problem that needs to be addressed by the NHIN. The core of the network must enable electronic patient records be available at the national level. That said, multiple aspects of privacy, security and workflow process at the back-end must be common at the regional level using a bottoms-up approach and flow from the edge to the core of the network. Regional, in this context would apply to all the players within the network ecosystem.

Organizational and Business Framework

4. What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Please describe the kinds of entities and stakeholders that could compose the framework and address the following components:
    a. How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?

Response: With the internet as the backbone a NHIN can be developed using relevant wired and wireless technologies such as Ethernet, Wireless Wide Area Network, Wireless Local Area Network, Wi-MAX, Radio Frequency Identification and Ultra Wide Band. An architectural approach that considers a model that is a combination of an EDI model for legacy applications and SOA based model for forward looking applications that recognizes wired and wireless technologies can be considered to be feasible.

    b. How could policies and standards be set for the development, use and operation of a NHIN?

Response: It is imperative that there be a single source i.e. entity that takes a leadership role and is nationally recognized to set general policy and standards in terms of the development, use and operation of a NHIN. This entity will work closely with existing federal, industry and private entities to address gaps, provide adequate coverage across the federal, private and technology industry standard bodies and regulatory bodies. The strategic objective of setting policies and standards must be to drive the development of specifications with consensus from key players and deliver the specifications to the implementers in a timely fashion

    c. How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?

Response: The adoption and use can be accelerated by automation and coordination of the technology available today within the healthcare industry. In addition, providing mainstream education to develop a culture to broadly take advantage of people skills for clinical transformation is a requirement.

d. How could the NHIN be operated? What are key considerations in operating a NHIN?

Response: The combined effort of a network that is operated at the national level with regional interconnects would be a suitable model, relatively quick to implement and modular enough to administer and manage. The key is to ensure interoperability, integration, accuracy, timeliness and security not necessarily in that order. A test bed that is driven by a national network provider and a chosen local provider in a large metro area would be practical.

5. What kind of financial model could be required to build a NHIN? Please describe potential sources of initial funding, relative levels of contribution among sources and the implications of various funding models.

Response: Federal and Venture Capital funding with a majority of the capital from the VC community. A model that allows a business to pay for itself is feasible rather than a service based model.

6. What kind of financial model could be required to operate and sustain a functioning NHIN? Please describe the implications of various financing models.

Response: A model that allows a business to pay for itself is feasible rather than a service based model. By driving a pay for itself model it is possible to contain costs, optimize the network and manage the network services. The service provider model while feasible has the potential to charge royalties, develop proprietary solutions and pass the costs on to the end user. At the end of the day, regardless of the preferred model, a requirement would be to implement a model that is pay on demand.

7. What privacy and security considerations, including compliance with relevant rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are implicated by the NHIN, and how could they be addressed?

Response: Privacy concerns can be addressed by maintaining status quo at the very minimum. In other words the privacy level cannot be compromised from present day levels. Allowing the end user options for disclosures is a requirement. It is the ultimate responsibility of the end user as well as the network provider to maintain extremely high levels of security starting from the individual information, to medical records to business transactions.

8. How could the framework for a NHIN address public policy objectives for broad participation, responsiveness, open and non-proprietary interoperable infrastructure?

Response: This request for information process is a good start and a reasonable model that can be used to develop a framework. By architecting a framework that is built using a modular approach can address several issues within a framework and provide an opportunity for broad participation.

Management and Operational Considerations

9. How could private sector competition be appropriately addressed and/or encouraged in the construction and implementation of a NHIN?

Response: By enabling free and timely access to policy changes, standards development, specifications and implementing a free enterprise policy that is not burdened by taxes and capital expenses it is possible to engage the private sector effectively.

10. How could the NHIN be established to maintain a health information infrastructure that:
    a. evolves appropriately from private investment;

Response: By the creation of national and regional private investment consortiums dedicated to incubating NHIN solution providers

    b. is non-proprietary and available in the public domain;

Response: Establishing appropriate policies and standards bodies, developing lucrative business models and ensuring high level of federal engagement.

    c. achieves country-wide interoperability; and

Response: By utilizing standard platforms, data formats, communication protocols and manageable network providers

    d. fosters market innovation.

Response: Incubating and encouraging small business to deliver solutions both at the regional as well as national level. Eliminating proprietary implementations, royalties and lock-in of vendor specific platforms intended to stifle innovation.

11. How could a NHIN be established so that it will be utilized in the delivery of care by healthcare providers, regardless of their size and location, and also achieve enough national coverage to ensure that lower income rural and urban areas could be sufficiently served?

Response: Every healthcare provider inclusive of public and private, as well as labs etc. must be mandated to be recognized and have a presence on the NHIN. Existing models that provide coverage for lower income rural and urban areas must be reviewed and enhanced. Federal and private initiatives to address gaps within the system must be setup to periodically assess and fix the gaps identified.

12. How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?

Response: It is possible that at the time of or immediately after the implementation of a NHIN there may be a rise in care costs that could adversely affect projects. It is also possible that there could be a significant spike in loss of productivity. Both these critical issues can be addressed by capturing requirements and validating potential issues with a fix at the test bed or pilot deployment

13. What effect could the implementation and broad adoption of a NHIN have on the health information technology market at large? Could the ensuing market opportunities be significant enough to merit the investment in a NHIN by the industry? To what entities could the benefits of these market opportunities accrue, and what implication (if any) does that have for the level of investment and/or role required from those beneficiaries in the establishment and perpetuation of a NHIN?

Response: The impact of a NHIN is highly significant ensuring a high level of patient care, significant level of security for high risk disease control, controlling costs, reducing adverse drug effects and optimizing various levels of clinical care starting from sick care to wellness to preventing break outs. There are several market opportunities for service providers, application developers, platform providers etc. The implementation of a NHIN can develop an ecosystem that provides benefits to all of those players mentioned above.

Standards and Policies to Achieve Interoperability
(Question 4b above asks how standards and policy setting for a NHIN could be considered and achieved. The questions below focus more specifically on standards and policy requirements.)

14. What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

Response: Standards can be diffused through existing technology industry standards driven by IEEE, World Wide Web, 3GPP, IETF, CHIME, HIMSS etc. Newer entities within these bodies can be created either in the form of working groups or development groups to address the NHIN standards and policies.

15. How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA? How can these standards be protected from proprietary bias so that no vendors or organizations have undue influence or advantage? Examples of such standards and policies include: secure connectivity, mobile authentication, patient identification management and information exchange.

Response: As stated earlier in 4.b the requirement is that there be a recognizable body that is solely responsible for proposing and driving standards and policies. This body would be recognized as being in a leadership role and proposing the strategic objectives for NHIN policies and standards as well as bridging with HIPAA. This body would not only be observers on the standards bodies mentioned in 14 but also work towards contributing to the

standards development and specifications. By ensuring the standards and specifications are in public domain will limit the proprietary advantage.

16. How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

Response: By gaining early access and insight that relate to SDO's can help mitigate the diffusion to a certain extent. By structuring and positioning the afore mentioned NHIN standards entity to provide NHIN presence in existing SDO's, build relationships and start contributing to the development of specifications must happen early.

17. What type of management and business rules could be required to promote and produce widespread adoption of interoperability standards and the diffusion of such standards into practice?

Response: By following established best known methods it is possible to provide widespread adoption.

a. Identify applicable dimensions, aspects and specific elements of the NHIN to be standardized
b. Identify and fill appropriate gaps in standards
c. Develop a top 10 list of elements to standardize within a timeframe
d. Develop and drive a success strategy to a well defined tactical plan
e. Identify the standards and working groups
f. Prepare the proposal for the standards group review
g. Develop partnerships with appropriate federal and private fellow travelers to drive standardization

18. What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

Response: The federal government should take a leadership role to drive the standards and policies proposal and refrain from the practical implementation and the imposition thereof. The role would be to ensure laws are drafted and followed within the scope of the relationship

Financial and/or Regulatory Incentives and Legal Considerations

19. Are financial incentives required to drive the development of a marketplace for interoperable health information, so that relevant private industry companies will participate in the development of a broadly available, open and interoperable NHIN? If so, what types of incentives could gain the maximum benefit for the least investment? What restrictions or limitation should these incentives carry to ensure that the public interest is advanced?

Response: Yes, financial incentives in the form of flexible tax codes, labor laws that benefit private industries, access to federal policy makers, federal regulators are a few that are required.

20. What kind of incentives should be available to regional stakeholders (e.g., health care providers, physicians, employers that purchase health insurance, payers) to use a health information exchange architecture based on a NHIN?

Response: A reliable, secure and stable network is incentive enough. However, for widespread adoption in a regional context a requirement would be to ensure incentives for patient care tools at a subsidized price. A gives / gets incentive model that delivers a tangible return on investment is a requirement for all stakeholders.

21. Are there statutory or regulatory requirements or prohibitions that might be perceived as barriers to the formation and operation of a NHIN, or to support it with critical functions?

Response: Yes, for the wider adoption of wireless technologies, telecommunications statutory and regulatory requirements need to be flexible, more wireless spectrum be made available and frivolous operational, administrative taxes abolished.

22. How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g., data privacy and security, antitrust constraints and tax issues)?

Response: Dedicated entities within the federal and private sectors must be encouraged and structured to work with each other to address these requirements. An example would be to enable and empower individuals and teams within the sectors to drive the above issues

Other

23. Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.

Response: Modular architecture based approach.

- Standards based for interoperability
- Support for multiple operating systems
- Support for multiple data formats
- Support for multiple wired and wireless communication protocols
- Support for multiple hardware platforms
- Interfaces to couple and /or decouple hardware, software, data management, communication, presentation and back-end applications and services.
- Modular, several elements that can be added, deleted and /or tested and validated independently
- Scalable across several platforms with complex to very simple capabilities and features

24. How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?

Response: Success can be measured by the definition, development and measurement of benchmarks. For example health care providers can measure care efficiency by enabling payers to report out after care on a measurable benchmark. It is important that part of the standards activities and architectural definitions, benchmark models must be established to measure success against actual solutions and real world situations.

Sincerely

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