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.

REQUEST FOR INFORMATION:

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.

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.

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 <u>not</u> meant to imply federal or local governments in this context.)

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?
   b. How could policies and standards be set for the development, use and operation of a NHIN?
   c. How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?
   d. How could the NHIN be operated? What are key considerations in operating a NHIN?

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.

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

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?

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

Management and Operational Considerations

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

10. How could the NHIN be established to maintain a health information infrastructure that:
    a. evolves appropriately from private investment;
    b. is non-proprietary and available in the public domain;
    c. achieves country-wide interoperability; and
    d. fosters market 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?

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?

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?

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?

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.

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?

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?

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?

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?

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?

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?

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

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?

Signed November 9, 2004

David J. Brailer, MD, PhD
National Coordinator Office of the National Coordinator for Health Information Technology

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