Summary of Nationwide Health Information Network (NHIN) Request for Information (RFI) Responses

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Note: The following discussion is a summary of the 512 responses to the Request For Information (RFI) received by the Office of the National Coordinator for Health Information Technology (ONC) and does not reflect opinions of the Department of Health and Human Services or the Federal government. Examples, quotations, and tabulations are for illustration purposes only and should not be considered as the definitive range of options, recommendations, or issues regarding the creation and operation of a nationwide health information network. Our purpose in publishing this document is to illustrate the types of responses submitted to address the development of a nationwide health information network. This document is simply a summary of comments we received in response to the RFI. We attempted to restate the comments as they were expressed and not include any of the Department's views or analysis. As is the case with any attempt to summarize a diversity of opinions, the distillation process could not capture the rich detail of every response, nor is every viewpoint of the respondents represented. RFI responses will be made publicly available on ONC's website (www.hhs.gov/healthit) in accordance with Freedom of Information Act standards.

While this document includes both individual and organization responses, except as noted below, it primarily reflects the responses of the organizational respondents. Numerical references (e.g., most, many, few, etc.) used to describe responses throughout the report are based on the responses submitted from organizations only.

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Executive Summary

On July 21, 2004, the Department of Health and Human Services (HHS) released the Framework for Strategic Action, *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care*. The Strategic Framework outlined four major goals to realize the President's vision of health care that utilizes information technology to avoid dangerous medical mistakes, reduce costs, and improve care:

- Inform clinical practice with use of electronic health records (EHRs).
- Interconnect clinicians so that they can exchange health information.
- Personalize care with consumer-based health records and better information for consumers.
- Improve population health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.

On November 15, 2004, in an effort to gain broad input regarding the best mechanisms to achieve nationwide interoperability to meet the goal of interconnecting clinicians so that they can exchange health information, the Office of the National Coordinator for Health Information Technology (ONC) released a Request for Information (RFI). The RFI encouraged the public to explore the role of the Federal government in facilitating deployment of a nationwide health information network, or NHIN, how it could be governed, financed, operated, and how it could be supported by and coordinated with regional health information exchange projects.

Five hundred and twelve organizations and individuals provided nearly 5,000 pages of information. The responses have yielded a rich and descriptive collection of thoughts on interoperability and health information exchange. ONC created a Federal government Review Task Force (RTF) to review the RFI responses. For the purpose of the RTF process and to aid in producing this summary document, the RFI responses were categorized into two types: (1) individual responses, which were mostly concerned with a narrow set of issues and (2) organization responses, which included all other responses, most of which were comprehensive and detailed submissions. While this document includes both individual and organization responses, except as noted below, it primarily reflects the responses of the organizational respondents, and numerical references (e.g., most, many, few, etc) used to describe responses throughout the report are based on the responses submitted from organizations only.

Drawn from the respondents' unique perspectives, the comments offered a wide range of thoughtful suggestions. Among the many opinions expressed, the following concepts emerged from the majority of RFI respondents:

- A NHIN should be a decentralized architecture built using the Internet linked by uniform communications and a software framework of open standards and policies.
- A NHIN should reflect the interests of all stakeholders and be a joint public/private effort.
- A governance entity composed of public and private stakeholders should oversee the determination of standards and policies.
- A NHIN should be patient-centric with sufficient safeguards to protect the privacy of personal health information.
- Incentives will be needed to accelerate deployment and adoption of a NHIN.
- Existing technologies, federal leadership, prototype regional exchange efforts, and certification of EHRs will be the critical enablers of a NHIN.
- Key challenges will be the need for additional and better-refined standards; addressing privacy concerns; paying for the development and operation of, and access to the NHIN; accurately matching patients; and addressing discordant inter- and intra-state laws regarding health information exchange.

Beginning with Section 2, this document summarizes the comments we received in response to the RFI. We attempted to restate the comments as they were expressed and not include any of the Department's views or analysis. However, inasmuch as this summary necessarily leaves out some content, the RFI responses will be made publicly available on ONC's website (www.hhs.gov/healthit) in accordance with the Freedom of Information Act standards.

1. Introduction

On November 15, 2004, the Office of the National Coordinator for Health Information Technology (ONC) within HHS released a Request for Information (RFI) to learn how widespread interoperability of health information could be achieved through a nationwide health information network, or NHIN. Studies over the past several years point to health information technology as a tool for improving quality of care, reducing errors and delivering significant cost savings. Furthermore, the potential value of the interoperable exchange of health information among disparate entities is substantial. A recent study[1] that estimated a net savings from national implementation of fully standardized interoperability between providers and five other types of organizations could yield $77.8 billion annually, or approximately 5 percent of the projected $1.7 trillion spent on U.S. health care in 2003. Other studies estimate that between 20-30% of our health care spending, or up to $300 billion each year, is for treatments that do not improve health status, are redundant, or are not appropriate for the patient's condition.[2] Administrative inefficiencies (e.g., paper handling) have been separately estimated to be of similar magnitude.[3] While more work is needed to validate these savings estimates, all-available evidence suggests that implementation of interoperable health information exchange will result in significant savings.

The NHIN RFI stimulated substantial interest. Cumulatively, the 512 responses yielded nearly 5,000 pages of information. The responses have yielded a rich and descriptive collection of thoughts on interoperability and health information exchange.

Through the Federal Health Architecture (FHA) eGovernment initiative, ONC established a Federal government-wide RFI review task force (RTF) to review, summarize and analyze the RFI responses. The RTF consisted of more than 120 Federal officials from 16 agencies. A list of participating RTF agencies is provided in Appendix A.

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[1] *The Value Of Health Care Information Exchange And Interoperability: There is a business case to be made for spending money on a fully standardized nationwide system*. by Jan Walker, Eric Pan, Douglas Johnston, Julia Adler-Milstein, David W. Bates, and Blackford Middleton – Health Affairs: Web Exclusive, January 19, 2005 (http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.10v1)

[2] Wennberg et al. Geography and the Debate Over Medicare Reform, Health Affairs. 02/13/02. W96-W114; Wennberg et al. Use of hospital, physician visits and hospice case during the last six months of like among cohorts loyal to highly respected hospitals in the United States. BMJ. March 13, 2004; Fisher et al. The implications of regional variations in Medicare spending, Part 1: The content, quality and accessibility of care. Annals of Internal Medicine. 2003; 138:273-287; Fisher et al. The implications of regional variations in Medicare spending, Part 2: The content, quality and accessibility of care. Annals of Internal Medicine. 2003; 138:288-298.

[3] Woolhandler et al. Cost of Health Care Administration in the United States and Canada. New England Journal of Medicine. 8/21/03, 349(8):768-775

Over the course of six weeks in February and March 2005, RTF participants met in work groups to review the organizational responses.[4] The RTF participants first summarized the RFI responses and then identified the various themes and options expressed by the respondents.

This document is an summary of the RFI responses primarily from organizations, and does not attempt to analyze or discuss the relative merits of the responses, nor is it exhaustive or representative of the full content of the responses.

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[4] Responses by individuals were analyzed in a separate process.

1.1 Background

On April 27, 2004, President Bush called for most Americans to be covered by interoperable electronic health records (EHRs) within ten years, and in doing so, signed Executive Order 13335 establishing the position of the National Coordinator for Health Information Technology within HHS. The National Coordinator was charged with developing, maintaining, and directing the implementation of a strategic plan to guide the nationwide adoption of health information technology (health IT) in both the public and private health care sectors. The National Coordinator was also charged with delivering a report to the Secretary of HHS on progress toward a strategic plan within 90 days of appointment.

On July 21, 2004, HHS released the Framework for Strategic Action, *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care,* which presented 4 goals and 12 strategies to achieve the President's vision of health care that utilizes IT to avoid medical errors, reduce costs, and improve care.

The four goals are:

- 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.
- Improve population health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.

ONC believes that a key component of the goal to interconnect clinicians is to promote interoperability, that is, the ability to exchange patient health information among clinicians and other authorized entities in a timely manner and under consistent security, privacy, and other protections. Interoperability has many benefits for the various stakeholders involved in the delivery of health care. EHR interoperability can improve the availability of a consumer's medical information to his or her clinicians for treatment purposes. Consumers could consult clinicians more easily without fear of losing their records, repeating tests or having to recall complex histories for each clinician. Payers could benefit from the economic efficiencies, fewer errors, and reduced duplication of effort. Clinicians could benefit from having easier access to complete problem lists, procedure histories, allergies and medication histories at the point of service. Interoperability also may lead to meaningful public health reporting, bioterrorism surveillance, quality monitoring, and advances in clinical trials.

On November 15, 2004, ONC published a RFI seeking public comment and input regarding the development and adoption of a NHIN. The RFI asked respondents to explore the role of the Federal government in facilitating deployment of a NHIN, how it could be governed, financed, operated, and how it could be supported and coordinated by regional health information organizations (RHIO)[5]. ONC encouraged organizations to work together and submit joint responses.

The RFI asked 24 questions in the following six categories:

1. General Information
2. Organizational and Business Framework
3. Management and Operational Considerations
4. Standards and Policies to Achieve Interoperability
5. Financial and/or Regulatory Incentives and Legal Considerations
6. Other Considerations, Including Design Principles And Measures Of Success

Appendix B contains a copy of the RFI published in Federal Register Volume 69, No. 219, November 15, 2004, 65599–65601.

1.2 Scope of Document

A variety of health care entities representing a cross-section of the industry, as well as private citizens, submitted RFI responses to the National Coordinator. Collaborative responses from industry groups or consortia and major clinician associations were also submitted, and collectively they appear to present the views of different components of the health care industry on developing, deploying, or using health information technology.

ONC created a Federal government Review Task Force (RTF) to review the RFI responses. For the purpose of the RTF process and to aid in producing this summary document, the RFI responses were categorized into two types: (1) individual responses, which were mostly concerned with a narrow set of issues and (2) organization responses, which included all other responses, most of which were comprehensive and detailed submissions. A table showing the distribution of types of RFI respondents is provided in Appendix C. The RTF was asked to primarily consider the responses from organizations, while a separate process was utilized to analyze the responses from individuals.

This document is a summary of comments received in response to the RFI. The ONC attempted to restate the comments as they were expressed and not include any of the Department’s views or analysis. As is the case with any attempt to summarize a

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[5] For definition of the RHIO concept, see Framework for Strategic Action, *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care*, published July 21, 2004 from HHS (http://hhs.gov/healthit/frameworkchapters.html)

diversity of opinions, the distillation process could not capture the rich detail of every response, nor is every viewpoint of the respondents represented.

While this document includes both individual and organization responses, except as noted below, it primarily reflects the responses of the organizational respondents. Numerical references (e.g., most, many, few, etc.) used to describe responses throughout the report are based on the responses submitted from organizations only. A breakout of the individual responses is provided in Appendix D. Because most these comments addressed privacy and security issues, in Section 4.1.4 we more completely describe the range of comments received from these responders.

The document is organized in sections based on the six categories of questions from the RFI. Each section includes a brief description of the RFI category, an overview of the comments relevant to the category, and where appropriate additional detail to emphasize common themes from the responses. In some cases, we have combined similar topics into the most applicable sections because respondents addressed topics across multiple RFI categories.

RFI responses will be made publicly available on ONC's website (www.hhs.gov/healthit) in accordance with the Freedom of Information Act standards.

2. General

The General Information category of the RFI requested input on a working definition of a NHIN as well as the identification of barriers and enablers to interoperability. The respondents address what a NHIN could look like, who may be involved, and how health care may be affected by a NHIN.

Some respondents defined a NHIN at the most basic level as a concept or ideal that could be introduced into the market by the Federal government, encouraging industry stakeholders to take advantage of the opportunity to make health information interoperable. Other respondents included in their definition other requisite NHIN characteristics, such as: standards and policies, business rules and privacy protections, protocols, existing infrastructure, networks, software, hardware, storage mechanisms, security schemes, data models, architectures, and other purposeful distinctions that seek to fully address the potential scope of a NHIN.

Similarly, the roles described as being involved in the operation and use of a NHIN varied widely. Some of the respondents described operational scenarios including: clinician usage ranging from direct clinician-to-clinician communication, to various sorts of clinicians and providers sending and receiving health information on demand; patients controlling access to their health information and filling in personal health records from information made available by a NHIN; regional and national entities acting in various capacities to secure and facilitate the movement of information; and other entities filling a multitude of roles and functions in the value chain of health information exchange.

Thirdly, some respondents expressed a strategy for developing a NHIN through the Federal government's encouragement and endorsement of a NHIN. Other respondents stated that the Federal government role could be expanded to include: facilitation, development or establishment of standards for interoperability; use of policies, regulation, and/or incentives to bring about change; certification of products, infrastructure, services, and/or entities that are a part of the NHIN structure; and other mechanisms to bring about a change to encourage the use of health IT in the delivery of care.

Many ideas were both suggested and challenged ranging from rejection of the entire NHIN concept through specific advice regarding specific aspects of a solution to creating a NHIN. Despite the variations on NHIN themes, however, there are some overarching concepts, which include:

- The Federal government is uniquely positioned to advance a NHIN.
- There is a need for some form of implementation and harmonization at a regional level.

- Cooperation between the public and private sectors is essential for successful realization of a NHIN.
- The NHIN should evolve incrementally and include appropriate incentives, coordination, and accountability to succeed.

The balance of this section illustrates some of the themes amassed from the responses around a NHIN definition and the corresponding enablers and barriers to its realization. The respondents also presented many detailed models of governance, operation and construction regarding a NHIN, which are discussed in sections 3, 5 and 7. The characterizations of the level of support for a given topic (e.g., many, most, some supported) are based on the number of respondents that commented on that topic, and not from the full set of responses.

2.1 Definitions of NHIN

Respondents were asked to define a NHIN in order to provide context for their overall RFI response. While some respondents defined a NHIN as a centralized national database, a more common NHIN definition was a "network of networks," built on the Internet, making patient health information available online to health care providers when and where they need it. Another expanded NHIN definition included a "system of systems" that included payer-related administrative information exchange as well as clinical health information exchange.

In many cases, the NHIN definition also included an infrastructure to define and support all necessary standards, policies, network services, and regulations and business rules. Respondents discussed the role of Federal regulation and the lessons learned from the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Some respondents stated that the government should be very judicious about using regulation to address these issues.

Some respondents stated that reconciliation of the variation in laws, business practices, and other security and privacy issues across regions would need to be addressed to achieve interoperability. One example cited is the variance in privacy laws across states. While a lot of attention was given to technical matters in the NHIN definitions, factors like these were acknowledged as vital to achieve interoperability. Some respondents indicated that HIPAA provided much needed flexibility to accommodate diverse state and business interests.

The NHIN definitions presented often recognized that technical, financial, legal, organizational and clinical considerations are necessary for interoperability, and therefore should be part of the makeup of a NHIN. In other responses, the definition included only the necessary set of transactions, protocols, and security/confidentiality standards required to support clinical and administrative processes.

Respondents typically described the overarching mission of a NHIN as a network to improve the quality and safety of care, reduce errors, increase the speed and accuracy of treatment, improve efficiency, and reduce health care costs.

Common themes emerged regarding the nature of interoperability and health information exchange:

- Information must be available nationwide, in real time, wherever health care is provided (e.g., emergency room, physician's office, hospital, laboratory).
- Information must be secure, exchanged in a patient-centric manner and governed by privacy and access control policies.

- Local or regional coordination of health information exchanges needs to support market variation.

The utility of the NHIN was seen by many to go beyond the provision of day-to-day health care delivery. Many respondents pointed to the importance of a NHIN in support of rapid translation of scientific knowledge into daily practice, the ability to help patients manage chronic disease, public health surveillance and reporting, response to bioterrorist activities, and the promotion of clinical research and scientific study.

2.2 Barriers/Enablers

Respondents identified a core set of challenges that need to be addressed while developing and adopting a NHIN: leadership, funding, clinician confidence, consumer control, aligning incentives, diffusion in rural and underserved areas, legacy system integration, coordination of standards development, patient identification, stakeholder education and legal and regulatory concerns.

Many respondents stated that leadership and commitment from the Federal government would be an essential enabler for the development and adoption of a NHIN. Respondents' proposed roles for the Federal government in developing and adopting a NHIN are discussed throughout this document.

The need for funding was cited by many respondents as a key enabler to build and implement the NHIN. Suggested sources of funding included the, payers, regional health information exchange efforts, consumers and Federal government. The misalignment of incentives across the health care industry was identified many times as a major challenge for widespread NHIN adoption and use.

Respondents emphasized the importance of user confidence in a NHIN. In particular, it was noted that clinicians must have confidence in the quality, relevance, and timeliness of health information exchange or adoption will not be achieved. Clinicians must also be able to identify their patients and obtain the information they need in real time and should not have to perform duplicate data entry in order to make information accessible through a NHIN.

Consumers must likewise, according to respondents, have confidence that their information is correct and protected from unauthorized use. Respondents considered the ability of consumers to opt in or opt out (in total or in part) of the NHIN an essential feature for establishing consumer trust and acceptance of the NHIN. Opinion was divided on whether an opt-in model (where consumers could explicitly agree to participate in NHIN) or the opt-out model (where consumers could be assumed to wish to participate unless they specifically stated otherwise) would be the best consumer minded approach. To build overall stakeholder confidence, several suggestions were made for the implementation of access logs, audit trails and robust security monitoring. A consumer education campaign was also recommended.

Perceived legal and regulatory barriers were frequently discussed, including challenges presented by the physician self-referral law (Stark), as well as the HIPAA privacy and security regulations overlaid with diverse state privacy laws. Some respondents stated that without the proper solution to address the different laws within and across states, full information exchange might be impeded.

Respondents stated that the use of existing health IT standards is helpful, but not sufficiently coordinated or specified to yield truly interoperable systems. The responses suggested creating several new standards coordination groups and implementations that could be referenced as models, to enable NHIN development. Some respondents noted that standards groups may have difficulty in reaching agreement, and that a new nationwide entity may have to facilitate standards convergence and mediate across the various stakeholder groups.

The integration of legacy systems with a NHIN was identified as a key issue to address. Some respondents expressed concern that legacy systems may not be designed to meet interoperability standards to the extent necessary to participate in a NHIN, and typically may not have the ability to manage information requests from external users, validate their authenticity, map the patient identification information provided to their own internal patient identifier, and securely package the requested data for transmission. Respondents suggested a backwards compatibility plan for all legacy system integration with a NHIN.

Responses discussed the issue of limited access to computer technology and broadband networks in rural areas and safety net providers as a key barrier to NHIN adoption. Some suggested that these barriers could be overcome by subsidizing provision of broadband communications to rural areas or through other technology-based solutions. In addition, some areas and some NHIN users will not have constant access to the network at any given time (e.g., first responders, home health workers, some clinics). Some providers will use technologies that are becoming increasingly pervasive in health care such as hand-held computers and the infrastructure should allow these users to synchronize with the overall network when connectivity is available.

Another key consideration for NHIN development and adoption was the perceived difficulty in correctly identifying patients and linking individuals to their information. There were three main perspectives presented by respondents that addressed this issue. One perspective involved the use of a unique national patient identifier to ensure that the NHIN always stored information in the right record and retrieved information for the right patient. With this approach, use of a national patient identifier was recommended as the most efficient technical solution. However, a second group strongly opposed the use of a national patient identifier due to concerns that such an identifier would threaten patient privacy. A third group supported a pragmatic approach where patients would agree voluntarily to participate in a national identifying system.

Respondents identified the following as critical enablers of a NHIN: Federal leadership, the growth of regional exchange efforts in communities across the country, existing efforts to define and certify EHRs, and rising consumers' expectations that authorized health information will be quickly, securely, and accurately exchanged. Another type of enabler mentioned was the creation of new services or products based on a NHIN. For example, disease management services could be provided for patients who agreed to share their clinical and prescription data. These opportunities may also lead to greater development, adoption and diffusion of NHIN-enabled technologies.

The number of perspectives articulated provides sources of ideas to address many issues, and the while emphasis any given response placed on an issue varied, the respondents presented very few issues as insurmountable.

3. Organizational and Business Framework

The Organizational and Business Framework section of the RFI asked respondents to explore the type of governance models and policy objectives, financial models and the privacy and security considerations to develop and adopt a NHIN. The discussion of privacy and security considerations has been included in Section 4: Privacy and Security.

Respondents described four governance and three financial models with a variety of hybrid components within each model. There was particular emphasis on the roles of the Federal government and the consumer in the governance and overall business aspects of a NHIN in order to ensure transparency and public accountability. Several governance principles and attributes recurred throughout many of the responses. Some of these principles and attributes are mutually exclusive, while others could be combined, in whole or in part. Some of the more prevalent themes include:

- Public and private sector collaboration, including consumer representation.
- A balanced top-down/nationwide and bottom-up/state or regional approach with opportunities for multi stakeholder partnerships.
- An allowance for the governance framework to evolve over time.
- A means for local input, oversight, innovation and process improvement.
- Standards for business, ethical, and technical behavior with clearly defined roles, responsibilities, and sanctions for violations.
- Business rules for data use and disclosure policies, secure health information exchange, patient and provider identification, authentication, and non-repudiation for patients, providers and other entities.
- Sustainable financial model.
- Consumer control over the exchange of their health information.
- An environment for continuous learning and quantification of success.
- Education and outreach for patients and all other stakeholders, to ensure that they understand what the system will provide, how it should be used, their rights, etc.

The balance of this section describes the ideas in this vein that were presented by respondents. The characterizations of the level of support for a given topic (e.g., many, most, some supported) are based on the number of respondents that commented on that topic, and not from the full set of responses.

3.1 Types of Frameworks

While some respondents who addressed governance considerations indicated that little or no NHIN governance was required, most indicated that a well-built governance model was needed to develop, set policies and standards for, operate, and promote the adoption of a NHIN. Respondents also expressed the need for the Federal government to play a role in a NHIN, however, the views regarding the level and type of involvement varied widely. Responses ranged from recommending that the Federal government have complete control and oversight of a NHIN, to a more networked approach with the private sector, to minimal or no federal involvement.

Four NHIN governance models emerged from the responses, each ascribing control and decision authority to the following stakeholders in varying ways:

- The Federal Government
- Federations of RHIOs
- State Government Sponsored Federation of RHIOs
- Public-Private Collaborative Entities

The roles and responsibilities of various stakeholders in each of the four models are discussed below.

3.1.1 Federal Government

According to the respondents advocating this approach, the Federal government should be the principal decision maker governing the NHIN in a centralized, top-down manner. Other stakeholders could be consulted, but they would have only advisory functions. The Federal government would create a health information agency and/or designate existing agencies and would be responsible for all aspects of governing, financing, and setting standards and policies including developing, operating, and maintaining a NHIN.

Respondents who proposed this framework stated that the Federal government is the best candidate to facilitate a nationwide consensus and serve as an impartial convener of a broad range of stakeholders

3.1.2 Federations of Regional Health Information Organizations

As opposed to a centralized, top-down approach, respondents advocated a bottom-up governance approach through regional organizations.

While some respondents envisioned regional and other community-based health information exchange efforts as wholly independent entities without any national coordination, many comments suggested a more coupled arrangement whereby regional health information exchange efforts or RHIOs address the variability inherent in local business and implementation issues, inform the NHIN governance process, and adhere to a common set of rules and policies established by a NHIN governance body. Some respondents specifically identified a federation of RHIOs as the oversight organization and principal decision maker governing a NHIN.

There were many potential roles assigned to RHIOs in the responses. With respect to governance, RHIOs were called to convene and foster relationships among stakeholders and ensure participants have a vehicle by which policies governing health information exchange are coordinated and enforced. Respondents expressed concern over the protection of patient health information and proposed that a regional governance structure could provide better information protections and respond to consumer needs.

Respondents noted that the challenges of current regional governance models include high variability in infrastructure development and the use of standards, lack of financial sustainability, and the potential to promote the self-interest of dominant stakeholders instead of promoting the public’s interest. Many respondents stated that financial models and a NHIN infrastructure in particular must be addressed if community and regional health information exchange projects are going to be successful and sustainable. Interoperability between regions was mentioned as a key criterion in implementing a regionally oriented NHIN to allow patients to switch between geographic regions and utilize the full benefits of a national framework.

3.1.3 State Government Sponsored Federation of RHIOs

As in the Federation of RHIOs model above, commenting respondents indicated that RHIOs could collectively govern and oversee a NHIN in this model. The RHIOs, however, would be state government based or sponsored organizations, and there would be one RHIO per state. According to respondents advocating this model, local governance of a NHIN would be conducted through the collection of state-established RHIOs.

State and local governments were recognized by some respondents as potentially having an important role to play in NHIN governance, especially with respect to the public health aspects of information exchange, change management, provision of incentives or sanctions based on NHIN participation, and auditing considerations through states’ insurance commissions. Some respondents suggested that the Federal government could monitor state-level management of NHIN operations with a tiered-grievance process to address issues. Others suggested that State governments participate in the following activities:

- Establish the framework and architecture for NHIN operations.
- Impose policies for public health departments to utilize a NHIN for surveillance and reporting.
- Appoint representatives to be on a national board of governors to oversee a NHIN.
- Set local implementation and auditing requirements.
- Measure and report particular types of information at the state level.
- Provide incentives for NHIN participation or confer other benefits for NHIN adoption.

Respondents expressed concern that outdated state laws such as those requiring handwritten signatures are an impediment to a NHIN. Some also expressed the concern that state laws governing privacy, data use, and disclosure policies vary greatly across states and are stricter than the HIPAA regulations. Some of these respondents noted policy solutions must address the variation in Federal and state laws in order to achieve nationwide interoperability. Other respondents indicated that this variation was needed to accommodate divergent interests across states.

3.1.4 Public-Private Collaborative Entities

Respondents recommended the creation of a NHIN oversight body comprised of public and private stakeholders, including physicians and other providers, federal and state government, payers, industry vendors and associations, RHIOs, public health, and consumer privacy and patient advocate representatives. In this model, a new public-private collaborative entity could be created to oversee, finance, develop, set policies and standards for, and deploy a NHIN. In contrast to the previous models, each key stakeholder would have an equal voice in the governance process.

These respondents thought the proposed public-private entity would determine NHIN standards, establish a software and hardware framework for interoperability and develop the policies and business rules for the operation of a NHIN not only to ensure the public's interest, but to stimulate the formation of a private market for health information exchange that does not exist today. New entities could also set regional guidelines, such as security conventions and paradigms, to ensure standardization for state-based or regional NHIN implementation and adoption through RHIOs.

Respondents suggested that a public-private collaborative governance model could be a not-for-profit, self-sustaining organization governed by a Board of Directors comprised of all health care and health IT stakeholder groups, and include representatives from the Federal government, a set of independent directors, and an appointed executive leader. This governance framework could also oversee NHIN standards setting.

Many respondents called for the Federal government to share equal governance and provide support to the private-public collaborative entity or entities to manage the direction, development, and implementation of the NHIN. In this context, it was suggested that the Federal government consider the following roles and responsibilities:

- Set in motion market forces that will drive NHIN development and adoption.
- Ensure that the NHIN governance is managed in an open and transparent manner and that patients' rights are protected.
- Take a leadership role to establish business policies for information sharing in a trusted environment and reduce obstacles regarding Federal and state regulations.
- Educate the public to ensure understanding of a NHIN.
- Identify required NHIN standards and work with other stakeholders to articulate and codify standards, and defer or minimize the creation of regulatory standards.
- Certify NHIN standards compliance and manage a compliance grievance process.
- Recognize certified RHIOs to ensure a minimum level of business and technical conformance to permit interoperability.
- Leverage influence as a purchaser and not as a regulator.

Many respondents advocated a central role for the consumer with respect to a public-private collaborative approach to NHIN governance. Specific recommendations included:

- Ensure significant representation of consumer and patient advocates in the governance and advisory structures of all national and regional NHIN authorities, including standard-setting and operational entities.
- Ensure that consumer and patient interests are fully represented in the development and implementation of the NHIN at all levels.

3.1.5 Other Governance Concepts

Other organizational and business frameworks mentioned by respondents included:

- Health Information Banks. A few respondents recommended the creation of entities that would maintain people's health information in much the same way banks manage customer's financial accounts. The "health care banks" would allow people to store their health data, authorize "wire transfers" of their health data to specific providers, and provide a central repository for health providers to send updates.

- International Models. Respondents suggested that the United States could learn from other countries' experiences with health information exchange including existing systems in Australia, Brazil, Scotland, Sweden, and emerging systems in Great Britain (National Health Service) and Canada (Canada Health Infoway).
- Models from other Industries. Governance could be modeled after other commercial sectors, such as the airline, transportation, telecommunications, power, or the financial and banking systems.
- Communities of Interest. Some respondents proposed that groups of stakeholders with common interests, values, needs, or organizational affiliations could come together to govern information exchange for specific purposes. For example, a community focused on a specific disease, like cancer, may form to enable information exchange. Another example might be academic medical centers enabling data exchange for research purposes.

3.2 Financial Models, Mechanisms and Incentives

Respondents offered a wide range of recommendations regarding NHIN financial models, including the use of incentives to ensure widespread adoption. The funding models, the mechanisms and uses by which funds could be allocated and managed, and the sources of initial and ongoing funding are summarized in this section.

The key financial principles across many responses and their proposed models include the following:

- A compelling business case is required to ensure buy-in from all health care and health IT stakeholders.
- The type of financial models and sources of funding will evolve over time and change as a NHIN matures and becomes self-sustaining.
- Targeted financial and other incentives may be needed to ensure widespread NHIN adoption.
- Stakeholders that could most benefit by widespread NHIN adoption should contribute financially to its development.
- Some respondents stated that Federal funding is required to get a NHIN started.

3.2.1 Financial Models

Most respondents who addressed financial considerations called for funding to support the development and adoption of a NHIN. The funding could come solely, or in a shared fashion, from: the Federal government, regional health information exchange efforts, private industry, consumers and other NHIN participants. While there was no uniform consensus on who should pay, there was significant support for a model whereby stakeholders that could most benefit from a NHIN would contribute financially to its development and operation.

Respondents generally identified three main sources of funding needed to support the creation and implementation of a NHIN, with varying initial and ongoing funding responsibilities. The three sources of funding identified by respondents were:

- Public and Private Sector Partnership
- Private Sector
- Federal Government

Varieties of funding mechanisms by which funds are allocated and managed are discussed briefly below and then further in subsection 3.2.2. It was also expressed strongly that a NHIN should not create unfunded mandates, burdening the state/local governments and the private sector with expenses needed to implement a NHIN without clear benefit to those incurring the costs and a stable health information exchange market in which to participate.

3.2.1.1 Public and Private Sector Partnership

Respondents who mentioned this model suggested that the Federal and state governments, RHIOs, and the private sector share investment in the development and operation of a NHIN. Many respondents indicated that a shared funding model could reflect a phased approach, with varying levels of support from a range of stakeholders occurring at various stages of NHIN deployment. It was also suggested that a new public-private entity would need to manage and track the financial activities of a NHIN to promote the public interest.

In the initial NHIN development and implementation stage, many respondents recommended that the Federal government contribute to the funding of the governance entities required for NHIN development and operations. According to many respondents, the Federal government could also authorize the creation of revolving loan programs, grant programs, and refundable tax credits for physicians and/or regional exchange projects to support NHIN deployment.

In the NHIN operations stage, however, a variety of responses suggested that the private sector could support a sustainable financial model if the business case were clearly defined and properly aligned with health care payment, and if a private market for health information exchange were realized. Further, depending upon the state of health services reimbursement through Medicare and private insurance companies, incentive payments to physicians could be required for NHIN adoption until a foundation is set for paying for quality, so physicians can manage the risks associated with being paid based on the quality of the treatment they render.

3.2.1.2 Private Sector

Respondents suggested that a financial model based on free market principles to foster innovation and avoid government intervention could be manifested through a variety of private sector resources. In particular, the initial investment for the NHIN could be achieved through venture capital or capital investment from industry purchasers, payers, providers, and vendors in the private sector. For the most part, respondents who proposed this model indicated that the NHIN revenue model could be a set of value-based fees whereby those that derive value from improved efficiencies and quality of care pay accordingly for its use.

3.2.1.3 Federal Government

Some respondents suggested the Federal government should finance the development and adoption of a NHIN. Initial funding could be provided through grants or loans and ongoing operations and maintenance funding through tax revenues, reimbursement differentials, and/or user fees.

Respondents who proposed this model were concerned that other models could not provide the financial infrastructure necessary to support a NHIN and could impose user fees that could inhibit broad participation in and widespread adoption of a NHIN. Some respondents also said that until the benefits of a NHIN are proven, user fees should not be assessed. Other respondents recognized that federal financing would necessarily be limited.

3.2.2 Financial Mechanisms

Some respondents thought the financial models above could utilize a variety of financing mechanisms or vehicles including grants, loans, bonds, taxes (such as refundable tax credits for physicians and/or regional health information exchange projects to support NHIN deployment), user fees and reimbursement differentials.

The funding mechanisms discussed by respondents for initial NHIN development and implementations were primarily grants and loans, but tax incentives and reimbursement differentials were also proposed. The Federal and state governments were mentioned as the predominant grant and loan providers. Loan programs in particular could be structured to offer low-interest loans along with previous borrowers' return on investment information to entice potential borrowers. Recipients of loans and grants could be RHIOs establishing key business and governance building blocks for a NHIN, low-income, rural and safety net providers, local community service organizations to seeding RHIO development, industry consortia executing NHIN pilot tests, and private sector vendors constructing software for use in a NHIN that complies with standards for health care technology. Respondents also noted that capital investment from large providers, purchasers, and payers could be instrumental in NHIN development.

In discussing the funding mechanisms for NHIN operations and maintenance, a number of respondents favored user or service fees collected through transactions, subscription or public utility methods. Their premise is that those who use the information could bear the financial burden of maintaining a NHIN. Various approaches to this were suggested, including varying the charges in accordance with the value that the requestor would gain from the data. The determination of value might be predicated on cost savings or could be calculated based on benefits. According to respondents, a benefit of this approach is that fees are relatively easy to adjust as economic conditions change and could be collected at the time of service, providing an efficient revenue stream.

Respondents identified the following specific users or service fee methods or method components:

- RHIO-based subscription fees, where RHIOs are paid fees that account for the value the data bring to the end-user or requester of the data. Examples of subscription types might be disease management or payment by researchers to obtain de-identified information.
- An individual provider user fee based on subscribed or transacted usage rates or value-based rates, and/or type of information.
- Consumer fees--akin to those of a public utility or subscription–to allow consumers to review, contribute to, and amend their records and see who has accessed their information.
- A NHIN subscription fee paid by purchasers and payers, including the Center for Medicare & Medicaid Services (CMS).
- A certification fee charged to companies for product certification for NHIN compliance that would cover the costs of NHIN governance.

3.2.3 Financial Incentives and Other Uses of Funds

A number of respondents viewed financial incentives as a critical component in the development of a sustainable business model for a NHIN. Since the health care market has not widely adopted interoperability to date, respondents thought that incentives were required not only to advance NHIN adoption, but also to set a foundation for health care payment based on quality of care versus volume of services. Numerous responses discussed the use of financial incentives, by payers in particular, to promote the development and adoption of a NHIN. Pay for use and pay for performance programs in particular were also seen as key drivers for NHIN adoption.

Many respondents viewed the use of financial incentives as a driver for health care reimbursement changes from volume to quality that could transform health care from siloed, episodic, and reactive care to proactive, interconnected, and continuous care. Once this paradigm shift is enabled through reimbursement reform, respondents suggested that no further financial incentives will be needed for interoperability. Some respondents suggested that the maximum benefit for least investment would result from redesigning current reimbursement by both public and private payers to include a significant proportion of payment tied to use of interoperable EHRs in a NHIN, validated health outcomes, or evidence-based process measures.

A number of respondents expressed ideas for how financial incentives could be used for NHIN prototype development tied to NHIN adoption and use. Public and private purchasers and payers could create incentives and disincentives in payment systems using reimbursement differentials and in contracting through inclusion in preferred listings. Some respondents thought CMS in particular could provide incentives for the development of a NHIN by leading the payer industry in pay-for-use and pay-for-performance programs. They also suggested that CMS provide incentives for use of a NHIN by committing to more rapid turnaround of claims dollars. Other respondents suggested that funding for incentives could be achieved in part through the redirection of resources from multiple Federal government agencies and state governments that may be spending money to develop competing solutions for their own needs. A few respondents stated that funding incentives was as part of malpractice tort reform, having a percentage of all attorneys' fees or awards be set aside in a trust account that is transferred to the government to provide financial incentives for a NHIN.

Many responses noted that small physician offices in particular would respond to financial incentives to adopt interoperable EHRs as well as assistance with implementation. Some responses noted that vendors should be encouraged to offer EHRs that are NHIN compatible and scalable to any size clinical practice.

Many responses proposed that the Federal and state government consider tax credits, income tax, consumption tax, tax-free savings accounts, and tax deductions for payers, clinicians, providers, RHIOs, and other organizations that purchase hardware and software and other services for NHIN adoption. Another idea proposed by a few responses was a tax-free savings account that could be established as a special account owned by a physician group practice, where contributions to the account would pay for current and future health IT expenses. Unspent account balances would accumulate and accrue interest from year to year.

A number of respondents also suggested that Federal funds could be important during the start-up phase of a NHIN, especially with respect to support of pilot or demonstration projects that demonstrate the feasibility and benefits of a NHIN.

4. Privacy and Security

Due to the number and length of comments on privacy and security aspects of a NHIN across multiple categories of RFI questions, this section was created to summarize these topics as presented by the respondents who commented on them.

In contrast to other sections of this RFI Summary document, this section describes responses received from both organizational respondents (sections 4.1 through 4.1.3), and individual respondents (Section 4.1.4). As previously mentioned, all responses to the RFI will be made publicly available on ONC's website (www.hhs.gov/healthit) in accordance with Freedom of Information Act standards.

The topics that follow below are HIPAA and local privacy and security considerations, a summary of leading privacy and security issues identified by respondents, including the use of a national patient identifier, opt-in or opt-out models for consumer participation, role-based access to information, and consumer education. The RFI responses discuss recommended roles of various NHIN stakeholders to ensure patient privacy and a secure NHIN.

The legal, policy, and operational aspects of privacy and security discussed in the RFI responses are summarized below. (For a discussion of the technical considerations of privacy and security, see Section 7.)

Nearly every RFI response addressed patient privacy and reiterated that the American public must feel confident that their health information is secure, protected, portable, and under their control. While some respondents expressed strong concern about whether a NHIN could ensure patient privacy, others said that it would only be as strong as its security features. A key principle conveyed by many responses was that privacy and security should be viewed as fundamental business and technical requirements of a NHIN in developing the architecture, data access and control policies, business rules and governance models, and not viewed as constraints or trade-off elements. State-of-the-art and stringent security features were identified as a critical component of a NHIN if privacy is going to be preserved.

The characterizations of the level of support for a given topic (e.g., many, most, some supported) are based on the number of respondents that commented on that topic, and not on the full set of responses.

4.1 HIPAA and State Variation

Almost all of the responses discussed the manner in which covered entities implement the HIPAA privacy and security regulations and how this would impact and introduce challenges to implementation of a NHIN. Some respondents noted that exchange of information could be impeded both within and across states due to a lack of uniformity and consistency of Federal and state privacy and security laws. Some of these respondents recommended Federal preemption of state laws to simplify and standardize the implementation and use of a NHIN.

Respondents noted a variety of options with respect to the privacy and security provisions of HIPAA, including not altering them, repealing them, expanding the definition of covered entities to include a NHIN and RHIOs and/or broadening them to make sure they are the same or that they do not conflict with regulation across all levels of government. Some respondents also argued that Federal field preemption of state laws would facilitate the implementation and use of a NHIN, by simplifying the adoption of standards.

Many respondents proposed that the state and regional variation in privacy, security and other information sharing laws be addressed by RHIOs in each state. Many respondents also noted that the HIPAA privacy and security rules allow two compliant hospitals within a region or state to employ different methods for electronic security, patient identification, and user authentication, and that this variation in business practices would need to be addressed across organizations both within and between states to allow for interoperability.

Many respondents proposed that RHIOs create an infrastructure for privacy and security compliance within and across states that uses intermediaries (possibly RHIOs themselves) to negotiate differences in security policy. This was thought to require the implementation of an inter- and intra-state business and legal framework. In order to guard against the potential for privacy and security breaches, respondents also recommended a RHIO accreditation or certification requirement. The rationale often given for accreditation was that it could ensure adherence not only to HIPAA regulations, but also to more uniform business policies and procedures, interoperability standards, and other harmonized standards. Some respondents indicated that certification could increase public confidence and provide an enforcement mechanism for NHIN policy.

4.2 Leading Privacy and Security Concerns

A leading privacy concern discussed by many responses was the use of a national patient identifier in a NHIN. According to respondents, the risk of accidental and intentional privacy and security breaches is heightened with the existence of a national patient identifier. Some respondents opined that, from a technical perspective, a national patient identifier was not needed, as there are combinations of matching algorithms, neural networks, and/or heuristic methods that can accurately identify patients without a national identifier.

An almost equal number of responders supported using a national patient identifier. Those who supported the use of a national patient identifier indicated that only a unique patient identifier or a strongly enforced standard for local identifier-assignment schemes would provide the level of integrity needed to identify patients accurately and link them to their health information. With an algorithmic patient identifier instead of a national patient identifier, respondents said that the management of false positive identifications (i.e., where the wrong patient record is provided) and false negatives (i.e., where the patient's record exists, but is not found) could be extensive and difficult to manage.

Others, in contrast, stated that the benefits of convenience and access must be weighed against the risks of disclosure and personal intrusion.

Respondents raised other major privacy considerations for a NHIN:

- Health record ownership – The responses highlighted that there is little agreement regarding who owns or should own the patient health record (e.g., the patient, various providers, health plan), who maintains it, what constitutes it, and which medical providers or payers should have access to the record in whole or in part.
- Consumer opt-in versus opt-out model for NHIN adoption – Respondents discussed an opt-in model, which means that the patient would have to actively consent to having his or her information available via a NHIN. They also discussed an opt-out model that presumes patient consent to participate until the patient specifically files an opt-out request. Respondents noted that the implication for the opt-in model is that the volume of records available would grow much more slowly as patients learned about a NHIN and decided whether or not to participate. The opt-out model would require less overhead, but could lead to patients' perceptions that their information was shared without their consent. Some respondents suggested that consumers should have the ability to selectively opt-in or opt-out portions of their health information.
- Disclosure limitations – Some respondents discussed the need for new limitations on the disclosure of health information. For example, consideration should be given regarding the duration of the rights of disclosure, instances when the ability to garner consent may be difficult (i.e., an unconscious patient in an emergency room), and consumers' ability to change or modify consent over time.
- Role-based user access features – Some respondents advocated role-based access mechanisms that would allow patients to grant permission to classes of providers at a given institution to view certain portions of their records while screening information from other users. The most frequently cited example in this regard was a feature to shield mental health related information from all users except certain mental health professionals. Other examples could include a role-based access granted to all nursing staff in a clinic or to all house staff. This would prevent other staff (e.g., pharmacy technicians) from accessing certain data.
- User authentication – A number of respondents indicated that authentication of NHIN users (e.g., physicians, providers, payer staff, researchers, patients

themselves) is an important NHIN security element. It was often recommended that various forms of authorization be required before a user could view, change, or add data to specific patient records. Some respondents suggested that patients should have tokens or cards, similar to ATM cards, which could be used to grant authorization to various users to see their medical records.

- Consumer education – Some respondents stated that public awareness campaigns about NHIN participation rights and the benefits of health information exchange are needed to educate consumers about the privacy considerations.
- De-identified data – The use of de-identified data was discussed in several responses, with general agreement on its usefulness for biosurveillance, public health, and clinical research.

4.3 NHIN Participant Roles in Privacy and Security

The roles and responsibilities of various industry participants with respect to NHIN privacy and security considerations were discussed by many responses. In this context, the NHIN participants that many RFI respondents deemed to have the most influence and responsibility for privacy and security considerations are: a NHIN governing body, RHIOs, physicians and other health care providers, public health officials, consumers, vendors and standards development organizations.

Responses suggested that a NHIN governing body or privacy board could:

- Confirm policies that ensure patient access to their health information, the right to review and annotate electronic health information and to review a log of who accessed their records. Some respondents also suggested that the governing entity could also establish procedures for patients' acknowledgement of the potential impact on the quality of care they receive if they choose to withhold information, as well as an explicit patient waiver of right of redress for adverse consequences due to patient withholding of information.
- Establish policies enabling a multi-tiered authorization structure to meet different requirements. One tier could be for categories of information for which different authorizations may be permitted (e.g., sensitive reproductive, behavioral, psychological health information; infectious diseases and other reportable conditions; medications; emergency medicine information; continuity of care information). A second tier could be for categories of users for which different levels of access may be authorized. The combination of user privileges and data restrictions would then determine access.

Respondents also noted possible roles of the other NHIN participants, such as:

- RHIOs could enforce national policies regarding access, review, and amendment of provider records and differential authorizations (by category of information and user).

- Physicians and other health care providers could remove barriers to a patient's ability to electronically access, review, and annotate provider records; implement EHR systems that interoperate with Personal Health Record (PHR) systems; and educate and inform patients of authorization rights and responsibilities at the point of care.
- Public health entities could contribute expertise to policy development regarding differential authorizations by developing solutions to national and state public-health barriers.
- Consumers could control access to their health information.
- Vendors of clinical EHR systems and PHR systems could incorporate functionality that: enables patients' electronic access, review, and annotation of provider records; allows interoperability of EHR and PHR systems; and enables differential authorizations. Vendors could also incorporate other value added functionality to strengthen consumers' ability to make sound health decisions and manage their health care: messaging between consumer and provider, scheduling, prescription management, claim management, referrals, test results, telemedicine, monitoring, alerts/reminders for preventive medicine.
- Standards development organizations could develop the necessary standards to identify categories and/or items of information that will enable the mapping of standards to one another. These organizations could also develop standards for PHR systems, interoperability of PHR and EHR systems, and consumer-oriented vocabularies.

4.4 Concerns on Privacy Expressed by Individual Responders

The RFI encouraged responses by groups of stakeholders, though it was open to all. More than half of the responses were from individuals. The responses of organizations and groups of organizations tended to attempt to answer the specific RFI questions, and thus are the primary focus of this summary document. The individual responses tended to make general statements about the NHIN concept, without addressing the specific RFI questions. Because the overwhelming majority of these individual responses were in some way concerned with privacy and /or security, a brief summary of these responses is included here.

Most of these individual respondents, which included clinicians and private citizens (see Appendix C for a breakdown of responses), expressed the strong sentiment that health data are private and needs to be secure. Some respondents were opposed to the use of health data repositories and expressly opposed the establishment of federal or state government databases. Some respondents indicated that if a national health information network was to be established, patient consent should be required for participation, and the type and level of detail of health information to be exchanged should be specified and limited. Further, many respondents indicated that patients should have the right to opt-in or opt-out in whole or in part, and that patient consent and control over the dissemination of health information should be required.

Some of these respondents expressed deep concerns about the ability to maintain appropriate patient confidentiality within any type of NHIN construct. This sentiment was usually passionately expressed, and sometimes pointed out the unknowns associated with an NHIN as grounds to proceed cautiously if at all. Specific concerns varied, with unauthorized access to patient records being a primary scenario these respondents sought to avoid. Some respondents also expressed opposition to the use of a national health patient identifier. Respondents also expressed concern that the potential benefits of health information exchange did not outweigh the risks of privacy violations.

This large group of individual respondents clearly expressed significant reservation, and often direct opposition to a NHIN being pursued as an endorsed strategy of the Federal government.

5. Legal Issues

The responses identify perceived legal obstacles for nationwide implementation of interoperable health information technology, and some proposed changes to federal and state self-referral, anti-kickback, antitrust, tax, and licensure laws.

Respondents often used HIPAA as a blanket term, but from the given context, it appears that only the privacy and security aspects were being referenced.

5.1 Legal Considerations

The responses noted a plethora of Federal and state statutes surrounding current practice and the confusion of interpretation and interrelationships they encountered. There were no fewer than 25 specific Federal laws cited as potentially applicable to the implementation of a NHIN, including the following:

- Americans with Disabilities Act (ADA)
- Anti-kickback law
- Antitrust laws
- Clinical Laboratory Improvement Amendments (CLIA)
- Drug Enforcement Agency (DEA) regulations
- e-Government Act of 2002
- Employee Retirement Income Security Act of 1974 (ERISA)
- Federal Education Rights and Privacy Act (FERPA)
- Federal income tax laws regarding private inurement, private benefit, and unrelated business income
- Freedom of Information Act
- Gramm-Leach-Bliley Act (GLBA)
- Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- Intellectual property and copyright protection
- Medical malpractice
- Medicare Modernization Act of 2003
- Medicaid payment
- Physician self-referral law （Stark)

Some respondents from the mental health community cited additional regulations and case law that mandated strict privacy for patients so that treatment was not compromised. The most often cited case was the U.S. Supreme Court decision, Jaffee

v. Redmond, 116 S. Ct. 1923, (1996), but numerous other federal, state, and local cases were cited as well.

The most frequently cited law was HIPAA, as noted in the previous section. The physician self-referral prohibition or “Stark law” was the second most frequently discussed law. Some respondents stated that the Stark law impedes the establishment of arrangements that could promote the adoption of a NHIN and related health IT services. Respondents noted that the Stark “Phase II” regulation, effective July 26, 2004, promulgated an exception to the prohibition for “community-wide health information systems,” but did not define “community-wide health information systems.” Some respondents stated that the exception had unrealistic requirements for the availability of the community-wide system to all patients and providers, with no accommodation for initial pilots and overall incremental implementation. Respondents requested further clarification of the community-wide exception as well as relevant anti-kickback safe harbors. The potential for liability under Stark was also a major concern of provider groups that may want to use the community-wide exception and was cited as a potential barrier to adoption of a NHIN.

Additional comments from respondents touched on international laws, state law disparities, and liability as follows:

- Respondents feel that international laws may have a potential effect on a NHIN.. In particular, the need to address both non-residents seeking health care and access to medical records for American citizens traveling overseas. Examples cited were medical information requested by an overseas physician and physician encounters via telephone.
- Other areas cited in which state laws are particularly disparate and could pose challenges to a NHIN include licensing (definition of “provider”), disclosure, minors, long-term care, HIV and AIDS, substance abuse, and alcohol abuse, as well as the requirement for “wet” (pen-and-ink) signatures.

Some respondents were concerned that there was the potential for increased liability for practitioners because of modifications to the patient record. Incorporation of information from other sources may impose a duty of review and create additional liability.

6. Management and Operational Considerations

The Management and Operational Considerations RFI section addressed private sector competition, technical implementation, and operational considerations.

A number of respondents suggested that successful operation of a NHIN depended on the ability to sustain participation of all the required stakeholders. The strategies for maintaining participation varied by stakeholder group, but should be closely aligned with their expected benefits of a NHIN. For patients, many respondents indicated that a NHIN should enhance high quality care and maintain the privacy of personal health information. Respondents warned that any privacy breaches would severely affect consumer confidence in, and acceptance of, a NHIN. For providers, accessing a NHIN should be easy and reliable. Many respondents recommended the use of subsidies, discounts, loans, or grants to sustain access for providers in lower income rural and urban areas. Some payers stated that access to health data through a NHIN is valuable because of the information it provides regarding health care delivery. However, access to health data comes at a cost because it must be documented and tracked on an ongoing basis. Responses from public health organizations and clinical researchers articulated the need for a NHIN to provide convenient access to accurate, de-identified information.

In addition to the comments above, there were several themes that emerged in reviewing responses in this section including promotion of competition, a gradual rollout of a NHIN in phases, and the roles of regional entities in sustaining operations.

The balance of this section describes the ideas in this vein that were presented by respondents. Quantitative characterizations of the level of support for a given topic are stated relative to the number of respondents that commented on that topic, and not from the full set of responses.

6.1 Private Sector Competition

Respondents provided many comments on the role that the private sector could play in implementing a NHIN. Typically, the private sector was viewed as the most appropriate source of the applications and systems that will support a NHIN. Many respondents indicated that a minimal, but necessary, set of national standards would allow vendors the fullest range of competitive opportunities and spur innovation. Respondents cautioned, however, that competition should be based on companies' ability to present and capture health information, not on the information itself.

Many respondents suggested the use of open, non-proprietary systems as an important mechanism to ensure the broadest private sector participation and competition. The Internet, created around a minimal suite of open standards and technology, was often cited as the appropriate operational model for a NHIN. The benefits of an open systems approach were stated to be:

- Reduced cost of entry for developers.
- Availability of open, international standards for data content.
- Connectivity.
- Mitigation of limitations of being tied to proprietary systems.

Other suggested strategies to facilitate competition included:

- The Federal government should avoid creating barriers to entry in the marketplace.
- Widespread adoption of a NHIN would increase flow of dollars into this market segment, which would encourage increased competition.
- Rewarding technology usage through payment policies, in order to help influence private-sector competition, should leverage the influence of health insurance companies.
- Private industry should be included in the planning process.
- Vendors should be encouraged to compete based on the quality of service.
- RHIOs could create competition by seeking multiple bids for local contracts
- Use of web-services technology could encourage competition.
- Use of a decentralized model (local or regional) would generate competition.

6.2 NHIN Rollout and Operation

When discussing operational considerations, many respondents recommended that a NHIN follow an evolutionary path, with a gradual rollout. Many respondents stated that an incremental approach that integrates existing networks and builds momentum around early successes is more likely to succeed due to the nature of the U.S. health system. This approach offers opportunities to make adjustments as the system evolves, mitigates the costs of wholesale replacement of existing systems, and recognizes the time required to work with stakeholders to make the necessary financial, legal, and regulatory changes.

Advocates of a phased approach offered a number of suggestions on how to get started, including:

- Initiate pilot projects to prove the various architectures and interface concepts and to test scalability. Many respondents called upon the Federal government to provide funding for pilot projects or prototype demonstrations.

- Seed a NHIN with “starter” records that include a set of data, such as hospitalization dates, prescription drug histories, etc., with additional provider data being added as the provider systems are enabled. Some suggested the creation and exchange of a document to transfer health information across settings of care. The point of using the starter records would be to pilot various connectivity and interface functions and to provide information of immediate clinical utility as a more robust capability is being prepared for full implementation.
- Roll out electronic prescribing as part of the initial functionality.
- Implement document-based data exchange architecture immediately (e.g. using the Clinical Document Architecture (CDA)), with a gradual rollout of a more structured, code-driven architecture at a later time. Other respondents suggested that both document-oriented and code-driven architectures should be rolled out simultaneously, with the more structured data being exchanged by the NHIN-affiliated organizations that have the technical framework available to handle it. In this approach, both document driven and structured data would be used throughout the NHIN’s implementation, simply because both types of data are appropriate in communicating about a patient’s condition.

After a period of initial investment, many respondents indicated that the ongoing operations of a NHIN could be financially self-sustaining once a business case is identified for participants. Optimistic that the marketplace will eventually determine the costs and benefits of health information exchange, these respondents recommended that those who benefit financially from the widespread adoption of interoperable EHRs should bear the operational costs of a NHIN. These suggestions are discussed in more detail in the Financial Section.

Other considerations for operating a NHIN included the need to:

- Create a standard for reliability and availability of the systems that are part of a NHIN.
- Develop, test, and implement continuity of operations and recovery plans for emergency situations.
- Maintain and update standards.

6.3 Regional Health Information Organizations

Respondents’ predictions about the effects of an operational NHIN on regional exchange efforts were greatly influenced by their proposed technical and governance architectures. For those advocating a centralized repository for health information, a single entity could be responsible for maintenance and support, with local providers and consumers responsible only for data entry and retrieval.

On the other hand, most respondents who discussed technical considerations envisioned a NHIN as a decentralized network built around regional exchanges of information through the RHIO. In a decentralized architecture, RHIOs could handle the day-to-day operations of regional health exchange and facilitate integration into a NHIN. Others recommended approaches that did not require RHIOs included a centralized NHIN architecture and data storage.

For those responses that supported the notion of RHIOs, the following are operational considerations that RHIOs would need to address in relation to the NHIN:

- Harmonize authorization and security regimes among partners within the RHIO.
- Work with other RHIOs to address variations in laws and regulations across jurisdictions.
- Comply with national priorities.
- Maintain accreditation.
- Share implementation lessons with other RHIOs.
- Assist local providers with EHR implementation.
- Offer services directly to providers, especially in the case of RHIOs in rural areas.

Other comments addressed the anticipated effect a NHIN could have on existing and emerging RHIOs, with existing technical infrastructure. Some of these comments were:

- Existing exchange projects may feel threatened by rapid advance of a standards-based NHIN that would undermine many of their current infrastructure development activities.
- Future regional exchange projects should emphasize education and implementation facilitation and have much more limited infrastructure roles than activities today.
- A NHIN would not impair the efforts of existing community or regional health information exchanges; in fact, it could be designed to augment and enhance such entities. A NHIN could function to help existing health data exchange infrastructures become more effective. The design principles of inclusive and encompassing participation make it imperative to incorporate successful local and regional efforts that currently enable and govern health data exchange between organizations.

7. Standards and Policies to Achieve Interoperability

The “Standards and Policies to Achieve Interoperability” section of the RFI focused on standards and policy requirements, including the roles of various organizations in standards development. For a NHIN to exist, many respondents stated that standards would be needed to facilitate interoperability. Beyond a consensus that standards were needed, there was great variety of opinion regarding who should create standards, how they should be created and maintained, and which standards should be considered to achieve interoperability. Despite this variation, there was some agreement on the primary participants in the standards process, namely the standards development organizations (SDOs) and the Federal government. The topics that follow in this section examine the responses as they pertain to the role of standards and policy in achieving interoperability; the process of developing standards for a NHIN; and two of the principal players involved in NHIN standards (the SDOs and the Federal government). Quantitative characterizations of the level of support for a given topic are stated relative to the number of respondents that commented on that topic, and not from the full set of responses.

7.1 Achieving Interoperability Through the Use of Standards

Many respondents said that interoperability is critical to realizing the widespread deployment of EHRs that share information. As was seen in Section 2, the concept of interoperability had various meanings among the RFI respondents, and therefore many standards were seen as enablers. Some of the concepts of interoperability noted were:

- Uniform business processes.
- Controlled medical terminology and commonly accepted business transaction definitions.
- Communication protocols that comply with security requirements.
- Reference implementations, open specifications, and software interoperability “workbench” (e.g., centralize monitoring and integration tools).
- Data standards allowing data exchange via standardized data streams among entities with software systems that are not integrated.

Respondents mentioned that many existing standards could support interoperability. In addition to the standards named that are commonly used in the United States, several respondents strongly suggested that international standards should be incorporated into a NHIN.

Many respondents stated that standards were seen as the critical element in any kind of interoperability. The following groups of standards illustrate some of the interoperability dimensions that were presented in the responses:

- Terminology / coding standards – nomenclature used to describe medical concepts using restricted terminology and/or coding schemes. These address common vocabularies and data interoperability primarily.
- Markup standards – information about the data characteristics enabling descriptions of how to represent data items in a relational and definitional way, showing structure and applicable nomenclature involved in describing various data elements. These address common vocabularies, software, and data interoperability primarily.
- Security standards – information about data characteristics and security protocols that allow representation of data in protected forms. These address communication and software interoperability primarily.
- Network-interaction standards – protocol for inter-application communication and dynamic service integration. These address communication and software interoperability primarily.

7.1.1 Terminology/coding standards

The responses discussed the need for one set of standards that are applicable industry-wide. In particular, many respondents stated that vocabulary and coding standards need to have a national controlling baseline for what constitutes the national standard. Some thought this would then guide all future health information technology applications and exchanges. Others thought this master set of standards would be the bridge between custom implementations of other standards, where translations to/from the master set would facilitate health information exchange among health applications. Many standards were held up as candidates for the master set, including the following list:

- Current Procedural Terminology (CPT-4)
- Health care Common Procedure Coding System (HCPCS)
- International Classification of Diseases (ICD-9, ICD-9-CM, ICD-10)
- Logical Observation Identifiers, Names, and Codes (LOINC)
- Medical Subject Headings (MESH)
- National Library of Medicine’s (NLM) RxNORM
- Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)
- Veterans Administration’s National Drug File Reference Terminology (NDF-RT)

Some respondents noted that there might be holes in the standards, possibly requiring new standards to be created to complete the master set of authoritative NHIN standards.

7.1.2 Markup standards

The responses commented often about the pervasiveness of technologies like XML, and the value they have contributed toward structuring data across the industry. Because of their effectiveness and prevalence, markup languages were seen as key components in representing health information electronically, and several options were suggested as candidates for incorporation into a NHIN architecture:

- eXtensible rights Markup Language (XrML)
- eXtensible Markup Language (XML)
- eXtensible Access Control Markup Language (XACML)

Respondents noted that there has already been significant adoption of this kind of technology, and many of the mainstream standards are already being expressed using them.

7.1.3 Security standards

Security was a common refrain across the responses. In order to build a convincing case that a NHIN can adequately protect privacy, respondents indicated that the technologies used to enable secure transactions must be exceptional. Many security issues were spoken about generically, but relatively few data protection technologies were specifically identified. Some that were mentioned are:

- American Society for Testing and Materials (ASTM) E31.20 Data and System Security for Health Information (Security and Privacy)
- OASIS Security Services (Security Assertion Markup Language - SAML)
- Public Key Cryptography Standards (PKCS)
- XML Encryption

7.1.4 Network-interaction standards

Web services and service-oriented architectures (SOA) were fairly popular among respondents that gave comments about the technical architecture of a NHIN. A number of them stated that the ability to make services available incrementally and in an ad-hoc manner was a way to avoid monolithic software and large switching costs.

The SOA may be important to a NHIN’s ultimate structure, according to the respondents.

7.2 Collaborative Standards Development Process

Respondents suggested many approaches to the development and diffusion of interoperability standards and policies. The common refrains tended to revolve around whom the stakeholders are, with many of the respondents giving the government and SDOs prominent roles in the process. Some proposed roles for the Federal government included:

- Take the lead in developing interoperability standards and policies.
- Sponsor the development of interoperability standards and policies.
- Play no role at all in the development of interoperability standards and policies.
- Require that the initial implementation of a NHIN include only data communications standards, not content standards, to speed implementation and adoption.
- Focus on minimum sets of standardization.
- Leverage HIPAA-established transaction standards (e.g., ANSI-Accredited Standards Committee X12N).
- Provide an open source reference implementations of standards.
- Make government systems interoperable before deciding how to implement interoperability across the rest of the clinical community.
- Facilitate activities undertaken by the states to enable regional health information organizations to implement standards.
- Facilitate work by the states with national organizations to manage and coordinate regulation, standards adherence, and implementation.
- Enforce regional level policies, resolve issues, and manage governance.
- Fund initiatives where SDOs are not making appropriate progress in the development of standards and policies.
- Have CMS dictate the standards for claims and other payer records.
- Publish an open specification so that vendors can build to it.

To ensure that fully informed groups develop standards and policies, respondents suggested that many types of stakeholders be included in the standards and policy development process. These include SDOs; Federal, state, and local governments; software and hardware vendors; systems integrators and consultants; payers; patient advocate organizations; RHIOs; ancillary health care providers (including home care agencies, hospices, home infusion companies and medical equipment dealers); representatives from academic medical centers and universities; physicians and other health care providers; and public health organizations. A standards control group could consider the requirements and concerns of all stakeholders in the decision-making process.

As for the role of SDOs in the standards development process for a NHIN, some respondents were concerned that the existing SDOs may be biased in favor of a given set of vendors, so they wanted to see the government establish a mechanism to filter bias from the standards setting process. To minimize proprietary bias, some respondents suggested that standards be in the public domain (unless it was necessary to use a proprietary standard) and that access to standards be made available free of charge. Some respondents stated that vendors should be allowed to adopt standards voluntarily, but others suggested that use of standards be mandatory, especially when conducting transactions with the government (Federal, State, regional, or local). A number of respondents felt that vendors would continue to create systems that are not interoperable, until strong standards and certifications are in place.

A small number of respondents warned that SDOs' parochial interests may impede the development and promulgation of standards. Many respondents said that SDO participation was critical, even with the establishment of a standards control group, to coordinate the many different types of standards and policies required for a health informatics environment to support NHIN (e.g., clinical data standards, network standards, security standards, privacy policies). Some respondents mentioned that the HIPAA Program acknowledged and incorporated SDOs in its implementation. Analogously, these respondents recommended that SDOs be active participants in NHIN standards and policy activities, as well.

Several respondents suggested the importance of RHIO participation with SDOs. In this way, the SDOs get a better sense of regional needs. One area of RHIO participation could be in the development of compliance tests. Other respondents stated that participation should include many of the stakeholders, including other governmental agencies, health care providers (including physicians), and consumer/patient advocacy groups.

In addition to developing, harmonizing, selecting, and promulgating standards, testing and certification of systems that use interoperability standards were recurring themes among many responses as key aspects of a mature process for standards development. A number of respondents expressed the belief that if vendors were required to certify their systems as compliant with NHIN-identified standards and policies, adoption of these systems by health care providers, including physicians, would be accelerated. Some thought that the Federal government should have the responsibility for certifying products and systems, others felt it within the purview of the SDOs.

7.3 Role of the Standards Development Organizations (SDOs)

In looking at the role of the SDO more narrowly, there was a wide range of opinions regarding the development and diffusion of interoperability standards. On one end of the spectrum, some respondents stated that the current approach with existing standards organizations developing and promulgating standards was adequate. In this scenario, existing SDOs and market forces would shape interoperability standards, and the role of the Federal government could be minimized. Using this model, some of the SDOs and conveners of SDOs seen as having a role with standards for interoperability are:

- Accredited Standards Committee (ASC)
- American Dental Association (ADA)
- American Society for Testing and Materials (ASTM)
- American National Standards Institute (ANSI) Health Informatics Standards Board (HISB)
- Health Level 7 (HL7)
- Java Community Process
- National Council for Prescription Drug Programs (NCPDP)
- Object Management Group (OMG)
- Open Geospatial Consortium (OGC)
- World Wide Web Consortium (W3C)

Many respondents expressed the need to have a coordinating body for health informatics SDOs. Sometimes a respondent named a particular existing SDO, private sector entity, or government organization (e.g., National Institute of Health National Library of Medicine) to be the coordinator, but more often respondents urged the creation of a new entity, often referred to as a Standards Control Group or Standards Control Body, that would be chartered to coordinate the development and use of interoperability standards and policies. This single authoritative entity would link together relevant SDOs.

The respondents identified many potential roles for this type of new entity. There were varying opinions among respondents on the roles and responsibilities of such an entity, and SDOs were sometimes stated as sharing these responsibilities. Some of the proposed responsibilities of this new entity include the following:

- Represent both public and private interests to harmonize redundant standards and identify missing standards.
- Ensure that standards are open.
- Manage a portfolio of interoperability standards.
- Define standards and policies.
- Provide oversight of SDO standards activities.
- Monitor SDO standards activities as they relate to health informatics.

- Certify implementations.
- Designate mandatory minimum standards for system components.
- Issue contracts and charter work on specific problems, as well as approve and certify results of the work.
- Integrate and govern all federal health care IT.
- Assess existing standards with respect to visibility, maturity, timeliness, and relevance to ONC's mission.
- Create information exchange standards for RHIOs.
- Collect and disseminate best practices.
- Endorse and encourage IT providers to comply with standards.
- Leverage federal resources to foster innovation.

A few respondents suggested that the new entity be a new trade organization (modeled on an entity such as The Electronic Payments Association [National Automated Clearinghouse Association - NACHA]), but many suggested that the entity be a not-for-profit group or public-private partnership. The Internet Corporation for Assigned Names and Numbers (ICANN) was often referenced as a model..

Respondents sometimes described the role and responsibilities of a new entity as being partitioned across multiple new entities. Some respondents described a second type of new organization, which would report to ONC to market the benefits of standards implementations to vendors. A third entity, a Federal Health Information Authority, was mentioned by some respondents, and would primarily diffuse standards throughout the health care marketplace.

Many respondents felt that the use of standards should promote interoperability, there was a vocal minority who felt that it was unrealistic to standardize on a NHIN scale, or that requiring interoperability could be intrusive to the practice of medicine.

7.4 Role of the Federal Government in Standards Development

There was a range of opinions concerning the role of the Federal government (or sometimes ONC in particular) in the development and use of standards across a NHIN. The following were major themes:

- The Federal government should lead by example, implementing important standards across various federal health systems, and bringing the knowledge and expertise gained by this activity back into the NHIN effort.
- The Federal government should charter standards development organizations to develop or enhance standards needed to implement a NHIN architecture.

Comments included suggestions that there be new standards organization(s) established to coordinate and manage standards and/or that federal agencies play this role. Other respondents stated that the Federal government should allow industry to solve any needed selection, reconciliation, and development of standards. Although there were variations on how to accomplish it, the need to harmonize standards for interoperability was commonly cited by respondents.

A few respondents stated that the Federal government should have no permanent, ongoing role in standards or policy development. However, many respondents said that the Federal government should have some form of ongoing role in standards development. The suggested roles varied significantly, and were sometimes contradictory. The following list illustrates some of the areas where government may have a role, according to the RFI respondents:

- Set the standard for the collection and use of de-identified data.
- Provide guidance and direction to the SDOs.
- Establish a minimum floor for standards, allowing rapid incorporation of updated standards.
- Require the implementation of standards for payment (by CMS).
- Encourage the development of architectural platforms and provide standards that integrate clinical and research data.
- Develop open-source tools that allow a reference implementation of a RHIO to be developed.
- Develop benchmark performance standards for all NHIN components.
- Reconcile differences among federal, state, and local laws.
- Establish a NHIN Program Manager responsible for the development and dissemination of policies regarding standards relevant to NHIN and guided by a NHIN Executive Board.
- Establish SDOs' roles for the development of a NHIN.
- Standards from the Consolidated Health Informatics (CHI) initiative and the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) should be considered in identifying standards for a NHIN, to make sure they are the same or that they do not conflict.
- Avoid the actual development of standards.
- Provide implementation guidelines for HIPAA.
- Federally mandate NHIN participants to implement standards to help ensure compliance and eliminate any proprietary formats.
- Promote organizational knowledge that elicits specific subject matter expertise (e.g., encourage groups with immunization expertise to work on the specification use cases or scenarios).

- Develop a strategic plan for NHIN, mandate specific standards, and coordinate public and private activities supporting a NHIN.
- Develop a model to facilitate interoperability.

8. Other Considerations

The “Other” section of the RFI sought comments on the major technical design principles and on measuring NHIN success. Each of these topics is discussed in the two sections below. Additionally, questions in the “General” section of the RFI prompted many respondents to present technical architecture concepts in response. These technical architecture elements are presented in this section in order to align them with the related principles that were espoused for a NHIN in the responses to question 23 of the RFI.

The balance of this section describes the ideas that were presented by respondents related to the above topic. The characterizations of the level of support for a given topic (e.g., many, most, some supported) are based on the number of respondents that commented on that topic, and not relative to the full set of responses.

8.1 Major Design Principles-Technical Models

The RFI asked for design principles for a NHIN technical architecture, and the respondents interpreted this in different ways. Many of the respondents noted design principles such as being patient focused, vendor independent, and having a service oriented architecture. Others noted the importance of ensuring an open source approach. Some described mechanisms for implementation or identified roles/responsibilities of specific stakeholders. For example, it was suggested that security technologies should be defined and implemented in all vendor products that were intended for use in a NHIN. Another example of this kind is one implementation design concept that espoused that all providers create a test gateway, which could be used in a uniform and predictable way by other NHIN participants to test their ability to interoperate and exchange data. Other implementation suggestions did not specify responsible stakeholders, and were more general in nature. One example that was mentioned numerous times is the use of the Internet as the basic infrastructure for a NHIN. Other suggestions include the use of existing public health systems, such as patient registries and vital records systems, as a foundation for a NHIN, and the use of publicly sponsored National Health Patient Index (NHPI), a National Health Provider Registry (NHPR), and National Health Patient-Provider Encounter Registry (NHPPER) to manage patient, provider, and record tracking.

A number of respondents suggested that a key design principle should be that a NHIN be patient-focused. This was often discussed in terms of availability of information for the patient (e.g., personal health record) and in terms of providing tools for patients to manage permissions for various NHIN stakeholders to view their records.

Respondents also mentioned the concept of a NHIN being vendor-independent (i.e., should work with a variety of legacy systems and should not be tied to any proprietary technology). Some respondents recommended open systems, while other respondents recommended that the architecture be flexible enough to allow legacy solutions and new proprietary systems to be integrated into a NHIN infrastructure.

Concerning the technical design of the proposed system, one of the items frequently mentioned was Service Oriented Architectures (SOAs). Respondents said SOAs support better integration with business processes and improved interoperability. SOAs are specific types of systems architectures that contain components that are designed to offer reusable services (such as authentication) that can be executed in a predictable way throughout the architecture. For example, this architecture could allow policies for authentication to be managed uniformly throughout a NHIN, and discoverable by all who needed to use them.

In addition to these and other guiding principles, more specific technical architecture ideas are summarized below.

8.1.1 Architectures

Architectures for complex systems are comprised of several interdependent layers, traditionally represented as the business layer, the application layer, the information/data layer, and the technology layer. Therefore the architectural elements presented by respondents for a given layer implied, assumed, or specified the related elements from other layers to varying degrees. Sometimes, the layers were mixed in a description, and other times they were orphaned. Even though these elements may have significantly differing contexts, the summary that follows attempts to categorize common elements across responses. While not ideal, this approach facilitates comparing and contrasting of major paradigms articulated for a NHIN architecture. Consequently, the items presented here are not full or true architectures, even though they are referred to as such for convenience. The respondents' options for a NHIN technical architecture are grouped and summarized below.

8.1.1.1 Centralized Network with Centralized Repository

This architecture would accumulate and manage all NHIN data into a centralized repository. Security, privacy, authentication, and system management would be centralized. Local providers would submit data to, and request data from, the central site and would provide the data in either a document format (e.g., XML document or .PDF) or structured (and/or coded) response format.

This architecture could provide availability 24 hours per day, 7 days per week (24/7) and a single source for all patient data. A single set of interface standards, security policies, etc., could be defined and enforced, simplifying the technical and operational requirements for the system. A large volume of data would have to be shipped to this central site, however, which could cause network bottlenecks. Some respondents commented that it would be a major technical challenge to develop and operate a system this large.

8.1.1.2 Federated Architecture with RHIO Repositories

This architecture would empower regional organizations (RHIOs) to develop networks and manage the privacy, security, and authentication issues for their region. Local users would send their data to the regional network repository. A national directory of regional record locator pointers would be maintained so that patient records could be located across regions.

This architecture could allow 24/7 availability of the clinical data, respondents commented, while retaining the capability of tailoring the system to meet local technical and regulatory requirements.

8.1.1.3 Federated RHIOs Coordinate Exchange of Locally-Held Data

This architecture would involve creation of a peer-to-peer network of providers, who would store the data on their local systems. The regional broker (RHIO) could maintain pointers to records stored at the local provider level. When authorized users needed patient information, they would contact the RHIO repository, which would identify the known locations where the patient had records stored (e.g., the local hospital, clinic, and an outpatient radiology center). The user would then contact the various providers via a defined peer-to-peer technology, authenticate himself to each, and request the records identified in the RHIO pointer repository. The RHIO would manage communication of patient data in accordance with its state laws and regional requirements. It would also work with local providers, payers, and other stakeholders to develop infrastructures that responded to enterprise-to-enterprise variations. See peer-to-peer discussion below for some comments regarding local data storage.

A variation on this architecture is to allow the RHIOs also to broker the access and exchange of information instead of allowing that final step to happen in a peer-to-peer fashion. In this scenario, RHIOs do not store information, but are the trusted agent for all exchange in a region. This has advantages in that RHIOs are the only entity ever requesting information directly of a provider, thus decreasing the number of vectors into a given health enterprise.

The responses described this architecture as advantageous because the providers would store the data on their own legacy systems. There would not be a requirement to ship large quantities of data to central or regional repositories; only the identifiers and pointers to the local data would be transmitted until a valid request for information from an authorized user was received.

8.1.1.4 Non-Federated Peer-to-Peer Networks

Some respondents suggested that a NHIN provide standards to allow providers and other data holders to communicate directly with each other, without requiring any intermediation from a regional or national hub. This model requires the information provider (e.g., a clinic, radiology center, or a hospital) to be able to accept requests for data, authenticate the requestor, identify the patient, and package the requested data securely for transmission. Some respondents stated that if the local provider were not online when the data were needed, the information would not be available. Some respondents preferred this model because it was considered to provide strong access control for patients and providers. There would be no central or regional repositories of patient identifiers and pointers in this model. Thus, some sort of search mechanism would be needed to find locations that held records for a given patient.

8.1.1.5 Intermittent or Pervasive Communications

This model would be used in combination with one of the other models. It would allow rural users, first responders, etc., to connect to a NHIN intermittently and access necessary information. Use of this architectural component would place additional requirements on the architecture to support remote synchronization of data from intermittently connected users and will also require provision of various presentation models to allow the formatting of data in a form suitable for the remote users' hardware (e.g., handheld computers with low graphic resolution capabilities).

8.1.1.6 Consumer-Controlled Data Repositories

Some respondents suggested implementing an architecture that allowed patients to download information from their provider at the time of their encounter to their own personal device (a handheld computer or portable disk drive). This would give the patient increased access to and use of his/her data. Some respondents recommended an architecture that would allow providers to access and update a consumer's health information through a third party on behalf of the consumer. This consumer health information repository would be controlled and owned by the consumer could be managed by a third party. This would give the patient control of, and access to, his/her data.

8.1.2 Data Structures for a NHIN Record

Many respondents discussed the structure of a proposed NHIN health record itself. One such structure could be the concept of a PHR. Patients could use the PHR as a summary document, including data such as lab test results, histories of hospitalizations, allergies, and demographics and could add their own information (e.g., family histories). The EHR was the other predominant form of health record referenced. The EHR would contain details of interest to clinical providers. Respondents discussed the relationship of a NHIN EHR to the PHR. Some respondents stated that patients should have access to the entire EHR, while others did not. Some respondents stated that the PHR should be updated by the EHR; others did not agree or did not specify whether they feel this should occur. The discussion of the forms of the health record was a natural outgrowth of the interoperability discussions, and had implications for the architectural elements presented.

It appeared that some respondents think the data types stored as a part of the health record would be decided upon in the design of the NHIN architecture. Most of the architectures presented by the respondents could accommodate either the EHR or the PHR. Use of personal media, such as portable disk drives, would necessarily limit the amount of data that could be stored, and how exchange was facilitated.

The content of the data structures selected will have a great effect on items such as the volume of data that would have to be transmitted; the utility of the data base for clinical analysis or alerts; and the amount of effort that would be required to interface to legacy systems. Therefore, the following discussion of the responses regarding the structure and representation of data is presented below.

8.1.2.1 Document-Oriented Versus Structured Information

Several respondents suggested that the NHIN implementation be designed to use electronic documents instead of coded data values. For example, if an emergency room physician required laboratory results from another hospital, the results could be encapsulated in a .PDF file, a secure email, or an XML document and forwarded to the requesting physician. The benefit to this, according to some respondents, is that it would be relatively straightforward to specify and implement, and the physicians would receive the information in a form that is very likely to be displayable on their existing equipment (as a sort of lowest-common-denominator approach). The downside, some respondents said, to the document-oriented approach is that the data would not be sortable, coded, or otherwise compiled into a database. As use of a NHIN grew, the volume of documents that would need to be managed for a given patient could become unwieldy. It would be very difficult for physicians to track trends (e.g., blood pressure values or glucose) to find the results of a previous radiological exam quickly, and to use the data in clinical decision support functions.

The coded, structured data approach would provide data structures that could be used to produce reports, summaries and trends for specific patient care and for public health purposes. However, several respondents pointed out that there would have to be major changes made to legacy data systems to accommodate provision of structured information with or without shared vocabularies. In addition, the existing standards for structured data are, in some areas, incomplete or unclear, and various vendors have interpreted them differently. The consensus of respondents appears to be that the structured, vocabulary-driven approach may take longer to implement and be more technically complex, but will yield much greater information-processing flexibility.

Some respondents indicated that both the document-oriented and the structured approaches should be used throughout the life cycle of a NHIN. Some users would be ready to exchange coded data immediately because they have the appropriate infrastructure in use in their own facilities. Others would be able to handle a document approach. Also, some respondents commented that some data are best expressed in a document format and that this should be supported throughout the life of the system.

8.1.3 Network Organization and Infrastructure

The responses contained several conceptual structures for implementing the overall network. These are described below.

8.1.3.1 Current Internet Network

The majority of respondents recommended use of the current Internet network as the carrier for the NHIN data, no matter which of the architectures is ultimately chosen. The Internet was recommended because it is widely available, many potential NHIN users have access to it, and it is well understood by technologists.

Data security was a concern raised in the responses. Respondents often suggested using Virtual Private Network (VPN) technologies to address security concerns.

Movement of large volumes of data was a concern raised in some responses, especially in regard to the use of a central repository. This consideration led some to favor use of the federated RHIO model as an alternative architecture, because it would spread the bandwidth volume load.

A number of respondents expressed concern that users from rural areas or from certain socio-economic groups would not be able to obtain broadband access to the Internet and would thus be disadvantaged as a NHIN rolled out. They recommended a variety of solutions to this problem, some involving subsidizing broadband connectivity in selected areas.

8.1.3.2 Internet2 Network

Several responses recommended consideration of the Internet2 network as a vehicle for a NHIN. The Internet2 is a next-generation high-speed network that is currently in limited use.

8.1.3.3 Private Network

A few responses suggested use of a private network, which was considered to be easier to make secure. A private network in this context is not virtual, but segmented through hardware and/or separate infrastructure from public networks like the Internet.

8.1.3.4 Peer-to-Peer

Some responses suggested that no national network or backbone needed to be created at all; that users could communicate directly with each other in a peer-to-peer arrangement, possibly over the Internet. Each peer-to-peer arrangement would handle its own security protocols.

8.1.4 Privacy and Security Technologies

The issue of privacy was a pervasive theme throughout the responses. There was strong concern expressed about preserving patient privacy. The key issues raised in the responses in this regard had to do with patient identification and security.

8.1.4.1 Patient Identification

Several techniques for managing the patient identification infrastructure were provided, as shown below.

8.1.4.1.1 Master Patient Identification Repository

Some suggested that a master patient identification repository be provided, either at a centralized location or at the regional level. These repositories would be connected directly to a stored patient record that was also located in that repository. In other words, the patient identification and the record itself would be managed by the same central or regional entity. This was seen as an efficient and manageable way to handle identifications, particularly in regard to ensuring that the patient identification is connected to the proper records.

8.1.4.1.2 Patient Record Pointers

This approach to storing patient identifications was commonly suggested for architectures that stored the patient records at the local level. In this model, the patient identifiers would be stored in a directory at the national or regional level. This directory would also contain pointers to where the actual patient data were stored.

A user could access the directory to find the patient identifier needed, then follow the pointers to reach the repository for the patient’s records. There could potentially be several repositories in which information about the patient is stored, depending on the architecture ultimately developed. For example, if the federated RHIO architecture is used, a patient living in Maine with a vacation home in Florida, could have active records in two different RHIOs.

8.1.4.1.3 Patient Controlled Identification with Access Cards

This model would provide patients with smart cards or Radio Frequency Identification (RFID) tags that would be used to store their health data and/or unlock their health records. The respondents identified this approach as providing strong patient control over access to data, but also noted that this approach would require that the patient be present and/or have physical access to the card to release data. This may or may not be practical and could inhibit use of a NHIN in clinical emergencies, for clinical and health services research, and for public health purposes. Several respondents suggested that the patients could use the devices to authenticate themselves from a remote location (such as their home) and then grant access to specific data for specific time periods to designated providers.

8.1.4.1.4 User Authentication

A strong concern for security and privacy was evident throughout the responses. However, very little advice was offered concerning an architecture or methodology for authenticating users (e.g., providers, payers, or others who wished to view NHIN-held data). Rather, a number of issues and challenges to be addressed in a NHIN implementation were presented.

8.2 Measurement of Success

Many respondents discussed potential methods to measure the success of a NHIN. Some respondents suggested that measures be tailored to specific phases of NHIN implementation, with short-term measures tied to process activities (i.e., number of users, volume of transactions), and longer-term measures tied to outcomes (i.e., improved patient health status and safety, increased value of health care). Suggested success measures included:

- NHIN participation levels and frequency of use, particularly by providers and patients. Provider participation can be measured across specialties, regions, locus of practice, etc.
- Volume and accuracy of messages successfully transmitted via a NHIN.
- Clinician and patient satisfaction.
- Improved efficiency in care provision (i.e., quicker provision of responses/ results in diagnosis, treatment, lab and radiology results)
- Participation by vendors in a NHIN, particularly in terms of incorporating NHIN-ready features into their products and/or becoming NHIN certified.

- Number of (or total revenue derived from) new services enabled by the existence of a NHIN.
- Documented improvements in outcomes or cost of care based on value received.
- Documented improvements in public health due to ability to identify potential problems (e.g., flu epidemic).
- Reduction in adverse events due to insufficient or inaccurate patient information.
- Reduction in repeated diagnostic procedures, etc., due to information available via NHIN.
- Response time metrics for common queries.

Respondents also stated that the measures be evaluated for clinical relevance and field-tested before being promulgated for widespread implementation. Concern was also expressed that the measures of success not be limited to reductions in cost or in tests/prescriptions avoided.

9. Conclusion

The RFI was the first step along the path to informing policy decisions for the development and adoption of a NHIN. This summary report represents a valuable collection of in-depth thinking on the topic of a NHIN: what it could be, how it could be achieved, and who could be involved in various stages of its development and operation. HHS will continue to study and analyze the suggestions offered, and use them to shape the strategic plan for interoperable electronic health records.

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Appendix A. Representatives from the following Federal Agencies and Offices participated in the review of RFI responses

Department of Agriculture
- Food Safety and Inspection Service
- Office of the Chief Information Officer

Department of Commerce
- National Institute of Standards and Technology

Department of Defense
- TRICARE
- U.S. Air Force Medical Service
- U.S. Army Medical Research & Materiel Command

Department of Energy
- Office of Environment, Safety, and Health

Department of Health and Human Services
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- Office of the Secretary

Department of Homeland Security
- Federal Emergency Management Agency

Department of Housing and Urban Development
- Office of Healthy Homes and Lead Hazard Control

Department of Justice
- U.S. Bureau of Prisons
- U.S. Marshals Service

Department of State
- Office of Medical Services

Department of Veterans Affairs
- Veterans Health Administration

Environmental Protection Agency
- Enterprise Architecture Program
- Office of Environmental Information

National Aeronautics and Space Administration
- Ames Research Center
- Johnson Space Center

National Coordination Office for Information Technology Research and Development

National Science Foundation
- Directorate for Computer & Information Science and Engineering

Office of Management and Budget
- Office of E-Gov and IT
- Health Division
- Office of Information and Regulatory Affairs

Social Security Administration
- Office of Disability Programs
- Office of Strategic Management

Appendix B. RFI Text

Federal Register/ Vol. 69, No. 219, November 15, 2004, 65599–65601

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 (EHR) 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 the ONCHIT 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 (RHIO). (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 not 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 (SDO) 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

BILLING CODE: 4150-24

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Appendix C. RFI Respondent Summary

The following table indicates the distribution of respondents by type.

Table 1. Types of Respondents

Type of Respondent	Count	Percent
Individual Consumers	174	**34%**
Individual - Health Professionals	108	**21%**
Vendors - Software, hardware, system integrators	95	**19%**
Associations - Medical, Patient Interests, Vendors	54	**11%**
Multistakeholder Respondents	16	**3%**
Provider Organizations (Hospitals, clinics, labs, homecare, hospice, pharmaceutical firms, etc.)	16	**3%**
Research Org (think tanks, non-hospital Universities, etc.)	15	**3%**
RHIOs	10	**2%**
Payers (HMO, PPO)	9	**2%**
Standards Development Organizations	7	**1%**
Federal, State, Local Government agencies	4	**1%**
Foundations	4	**1%**
Total	**512**	**100%**

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Appendix D. Responses from Individuals

Most of the individual responses focused on a single aspect of a NHIN. For example, approximately 85 percent of responses from individuals expressed strong concerns about the potential loss of privacy in the context of a NHIN. These privacy concerns included, for example, issues with the implementation of a national database, a national patient identifier, and informed consent. Many respondents expressed strong concerns about Federal control of a NHIN and had concerns regarding privacy and security regulations implemented under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). For example, one respondent indicated:

> As a consumer and private citizen I object to the proposed mandate of putting medical records on a database. My rights to privacy are already compromised and this requirement would further infringe on any remaining privacy. Please do not proceed with this proposal.

Fifty-three percent of health professionals responding to the RFI also expressed concerns about the potential loss of privacy that could occur through a NHIN. For example, one respondent indicated:

> As a clinical psychologist, I urge you to vigorously protect the mental health records of all citizens. Mental health records should not be placed in an electronics database unless there can be any benefit shown to the patient and only with the patient having provided clear, written informed consent as to the possible uses, and potential misuses of their records due to privacy violations. For the privacy of my clients (many of whom have been victims of incest), I keep all records on paper only, locked, and not to be released to anyone unless the client understands the full risks and implications. I would not agree with the federal government dictating to me how I can best protect the privacy of my patients. I certainly would not agree with mandatory requirements for electronic records. This is a professional, ethical decision best left to the professional judgment of the psychologist and patient.

Seventeen percent of health professional respondents shared their experiences and insights with the implementation of their own EHR systems. These responses typically concerned fears of an unproven system, anxiety about Information Technology (IT) security, or concerns about system cost with respect to either money or time. For example, one respondent indicated:

> I am aware of the number of times clinicians draw inaccurate conclusions and make inaccurate diagnoses based upon incomplete or inaccurate information. As a person who has seen her own medical records, and the medical records of family members, only to discover substantial inaccuracies in those records, I am

> fully aware of the likelihood that the NHIN will only serve to further entrench unreliable information. I also am aware of how difficult -- if not impossible -- it is to expunge inaccurate information from a record once it has been placed there. To deluge practitioners with unfiltered, inconsistently obtained, non-standardized, and at least in part inaccurate information is not good medical practice.

Nearly four percent of the individual responses expressed enthusiasm for the creation of a system that would facilitate interoperability. For example, one respondent indicated:

> “I am a practicing primary care physician, in general internal medicine for over thirty years. Although there might be many ways to approach a problem at any given point in the system, it is necessary for all points to have an understanding about what is happening to the patient at the other points. In my specialty of primary care internal medicine, I have understood this systems approach and enjoyed my position in the system not only as diagnostician but as planner and coordinator of care, in a collaborative role with the patient and other parts of the system.
>
> The situation that leads to medical errors just goes on and on. An orthopedist will prescribe an ulcerogenic drug to a patient who has had a bleeding ulcer. A patient with an acute myocardial infarction goes to the emergency room where nobody has access to important information such as the list of medications the patient is taking, the last electrocardiogram, the coronary arteriogram the patient had a week earlier at another hospital. Each of these, the other hospital, the cardiologist's office, the primary care office, may have expensive information systems, but their ability to intercommunicate is impeded by proprietary differences based on piecemeal marketing. Faxing information back and forth is archaic. We need true information exchange that would only be made possible by standards. This situation has gone on too long. “

Appendix E. List of RFI Responses Available On The Internet

The following RFI responses have been made available to the public on the Internet by their authors. This list is provided as a convenience to readers, and ONC does not have any responsibility for the web sites cited. The authors may choose to move or remove their responses at any time.

Respondent Organization	URL
Academy of Managed Care Pharmacy	http://www.amcp.org/data/legislative/analysis/ONCHIT%20%2D%20RFI%20Comment%20Letter%20%2D%20AMCP%20letterhead%2Epdf
American College of Emergency Physicians	http://www.imedi.org/docs/Azyxxi/6.%20Misc/American%20College%20of%20Emergency%20Physicians%20letter%20to%20David%20Brailer.htm
American College of Physicians	http://www.acponline.org/hpp/nhin.pdf
American Geriatrics Society	http://www.americangeriatrics.org/news/AGSNHITComments3.pdf
American Hospital Association	http://www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/agencyletters/content/050118RFI.pdf
American Society of Anesthesiologists Committee on Electronic Media and Information Technology	http://www.asahq.org/news/NHINRFIResponse.pdf
Apelon	http://www.apelon.com/news/misc/Apelon%20NHIN%20Response%20Extract.pdf
Association of American Physicians & Surgeons	http://www.aapsonline.org/confiden/nhincomments.htm
Booz Allen Hamilton	http://extfile.bah.com/livelink/livelink/145598/?func=doc.Fetch&nodeid=145598
CapTech Ventures	http://www.captechventures.com/news/current/CapTech_Ventures_Response_to_Electronic_Health_Record_Interchange_RFI.pdf
Center for Health Transformation	http://www.healthtransformation.net/content/getfile.cfm?FamilyID=778&filename=CHTResponseRFIFINAL1-18-05.doc
Cerner Corporation	http://www.cerner.com/public/filedownload.asp?LibraryID=10899
Citizens' Council on Health Care	http://www.cchconline.org/pdf/NHIN_public_comments.pdf

Respondent Organization	**URL**
Claredi	http://www.claredi.com/public/NHIN_RFI_Response.pdf
Confidentiality Coalition	http://www.hlc.org/FINAL.pdf
Connecticut Association for Home Care	http://www.cthomecare.org/NHINRFICAHCAnswersPDF.pdf
Connecting for Health-Collaborative Response	http://www.connectingforhealth.org/resources/collaborative_response/collaborative_response.pdf
Electronic Frontier Foundation/World Privacy Forum	http://www.worldprivacyforum.org/pdf/NHIN_final_EFFWPF.pdf
19. FasterCures	http://www.fastercures.org/sec/nhincomments
Federation of American Hospitals	http://www.fahs.com/issues/comment_letters/2005/CL%201.18.05%20BrailerRFI.pdf
Hawaii HIPAA Readiness Collaborative Steering Committee	http://www.hhic.org/hipaa/documents/NHIN_RequestForInformation_Final-HAWAIIFINALRESPONSES..pdf
Health Level Seven	http://www.hl7.org/Library/General/HL7Q14-18_final.pdf
Health Privacy Project	http://www.healthprivacy.org/usr_doc/NHIN_RFI_Response.pdf
HIMSS Electronic Health Record Vendor Association	http://www.himssehrva.org/docs/EHRVA_Response_to_ONCHIT_RFI-FINAL1.pdf
HLN Consulting	http://www.hln.com/noam/ONCHIT-RFI-HLNConsulting.pdf
Internet2	http://health.internet2.edu/files/NHINResponseInternet2.pdf
Interoperability Consortium	http://www.accenture.com/xdoc/en/industries/hls/healthplans/insights/leaders_respond_nhin.pdf
Joint Response SureScripts and RxHub	http://www.rxhub.net/pdf/Final%20RxHub%20Surescripts%20NHIN%20RFI%20Response%20jan18%2005%20joint.pdf
Liberty Alliance Project	https://www.projectliberty.org/resources/LAP_ONCHIT_RFI_Response_1172005165359.pdf
Massachusetts Health Data Consortium	http://www.mahealthdata.org/ma-share/20050118_ONCHIT-RFI%20Response.pdf
McKesson	http://www.mckesson.com/pdf/NHIN_RFI_Response_01_18_05.pdf

Respondent Organization	URL
Minnesota e-Health Initiative Steering Committee	http://www.health.state.mn.us/e-health/rfiresponse.pdf
Mt. Washington Expeditionary Force	http://www.intersystems.com/mt_washington_vision.pdf
National Association of Health Data Organizations	http://www.nahdo.org/news/NAHDO%20Response%20to%20NHIN%20RFI.pdf
National Consumers League	http://www.nclnet.org/advocacy/health/letter_national_health_network_01182005.htm
NetMesh, Inc	http://netmesh.org/papers/nhin-rfi/NetMesh-NHIN-RFI-Response.pdf
NCHICA	http://www.nchica.org/FinalNHINResponse.doc
Ontolog Community	http://ontolog.cim3.net/file/work/health-ont/NHIN-RFI/NHIN_final-ontolog-rfi-response_20050118.doc
Open Health Records Exchange Project	http://www.openhre.org/local/NHIN_RFI_OpenHRE.pdf
PrivacyActivism	http://www.privacyactivism.org/docs/EHR-PAandPRC-050118.htm
UNYPHIED Project	http://www.unyphied.org/content_files/documents/unyphied%20rfi%20response.doc

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Appendix F. Acronyms

ADA	American Dental Association
ANSI	American National Standards Institute
ASC	Accredited Standards Committee
ASTM	American Society for Testing and Materials
ATM	Automatic Teller Machine
CDA	Clinical Document Architecture
CHI	Consolidated Health Informatics
CMS	Centers for Medicare and Medicaid Services
DEA	Drug Enforcement Agency
EHR	Electronic Health Record
FAQ	Frequently Asked Question
FHA	Federal Health Architecture
HHS	Department of Health and Human Services
HIMSS	Health Information and Management Systems Society
HIPAA	Health Insurance Portability and Accountability Act
HISB	Health Information Standards Board
HL	Health Level
HMO	Health Maintenance Organization
ICANN	Internet Corporation for Assigned Names and Numbers
ICD	International Classification of Diseases
ICD-9-CM	International Classification of Diseases-9-Clinical Modification
ID	Identification
IT	Information Technology
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
NCPDP	National Council for Prescription Drug Programs
NDF-RT	National Drug File Reference Terminology
NHIN	National Health Information Network
NIH	National Institute of Health

NLM	National Library of Medicine
OGC	Open Geospatial Consortium
OMG	Object Management Group
ONC	Office of the National Coordinator for Health Information Technology
PHR	Personal Health Record
PPO	Preferred Provider Organization
RFI	Request for Information
RFID	Radio Frequency Identification Device
RHIO	Regional Health Information Organizations
RTF	RFI Task Force
SAML	Security Assertion Markup Language
SDO	Standards Development Organizations
SNOMED	Systematized Nomenclature of Medicine
SNOMED-CT	Systematized Nomenclature of Medicine-Clinical Terms
SOA	Service Oriented Architecture
VPN	Virtual Private Network
W3C	World Wide Web Consortium
WSDL	Web Services Definition Language
XACML	eXtensible Access Control Markup Language
XML	eXtensible Markup Language
XrML	eXtensible rights Markup Language