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

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.**

   Improving the infrastructure which supports healthcare information communication is a goal all constituents in society share. Information infrastructure has often been characterized in transportation terms - the "information superhighway" being an accepted metaphor for the internet. Like the Interstate highway system, the government played the foundational role in the creation of the Internet. Once a foundation was present for both the physical and the metaphorical highways, many businesses and processes that depended on them flourished and grew organically without government support. However, unlike the highway system, the internet is maintained and upgraded by private funding and control, where the interstate highway system is supported on an on-going basis by state and federal funding. In addition, in both the physical and virtual world, completely private channels arose as special purpose conduits for traffic – the private toll-road and the ATM network might spring to mind. A fundamental question for the creation of a National Healthcare Information Network is whether its foundation and maintenance is more like the "high-control/high-involvement" physical highway system, like the "low-control/low-involvement" virtual super-highway which carries the majority of public information traffic, or instead more like the "low-control/medium-involvement" network of totally private yet regulated systems which carry financial transactions involving commercial banks, the central bank (Fed), and other business and consumer entities.

Fundamental transformation of this country's healthcare system is inevitable. Whether that transformation takes place as a matter of merely reacting to new resource realities or as a function of careful planning from this day forward depends upon overcoming the "entropy of uncertainty" and coming to a national consensus on an appropriate course of action. What role should the government play in transforming the way clinical information flows? Will the healthcare information technology industry accomplish some or all of this without the government's help? Does industry need guidance, standards and funding to create the necessary infrastructure or does government need to build or buy some or all of it as a national or a state procurement? Answering these questions requires that a balance be found between the needs of government, industry and the public, and depends on a framework for examining alternatives for governmental action in this matter.

High-Level Working Definition

The National Healthcare Information Network is assumed to be a set of secure networks, databases and functions used to connect appropriate and authorized personal health information to the appropriate persons, at the appropriate time and location to achieve the optimal health outcome. The value of this network is in the reduction of costs and the improvement of quality expected as we:

- Eliminate Errors through the access to complete and critical information a the point of care
- Eliminate Variance by the adoption of comprehensive, knowledge-rich HIT solutions by providers
- Eliminate Delay through improved access to quality information, regardless of when/where in the continuum of care, thereby improving overall efficiency
- Eliminate Waste by preventing duplication of testing and therapies
- Eliminate Friction – removing steps from the process that provide to value to care but drive costs higher

Evaluating Governmental Options for action

This framework will provide a filter through which any proposal for a series of governmental activities and actions can be examined in order to identify elements which align the incentives of the expected participants in such a transformation. These participants are assumed to be federal government, states, industry, healthcare providers and the public. Where immediate resource scarcity drives action, options may be limited. Those which can be undertaken by regulation and guidance may be the only options available when funding or political will is scarce. When costs must be immediately contained and time is scarce, government may be compelled to move more unilaterally without regard to the interests of other constituents. When operating prior to a crisis situation, the full range of governmental opportunities remains.

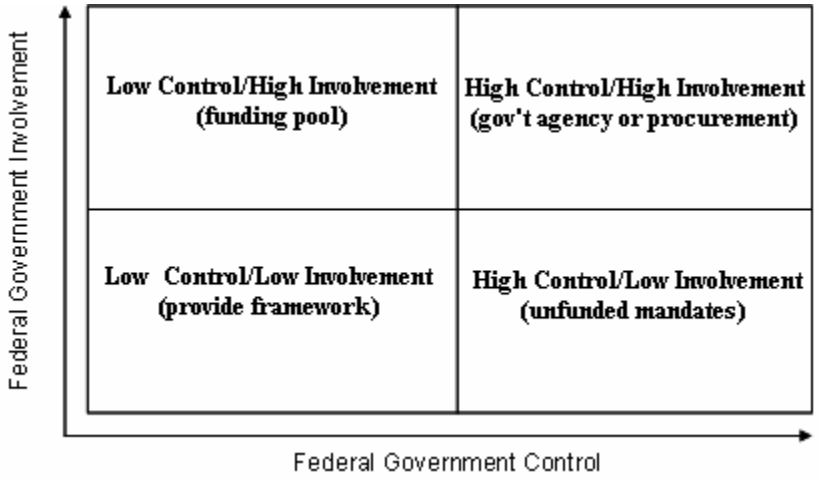
In order to evaluate options, we must establish a "roadmap" for our project of building a National Health Information Network.

Roadmap

- Describe the System
  - Describe essential attributes and goals of the system
  - Describe the functional capabilities
  - Describe end-state technical requirements of the system
- Gap Analysis
  - Determine what assets are available and adopted already
  - Identify gaps between the end-state and currently in-use assets
  - Identify ways in which interoperability can be enabled through standards alone
- Finding Suppliers
  - Identify suppliers (or criteria for selecting suppliers) of technology filling the gaps
  - Identify potential independent buyers for parts of the system
  - Identify parts of the system which have no independent buyers
- Governmental role
  - Determine funding and governance mechanisms for creation and ongoing maintenance of the components of the system which have no independent buyers

A range of options exists for government action to enable such an infrastructure. A simple matrix which defines the characteristics of an action can be constructed and some constituencies can reliably be expected to favor one quadrant over another. Options which balance the axes of the matrix can be expected to align incentives of the participants generally. On one axis, **Federal Government Involvement** takes the form of funding, direct procurement and formal governance. On the other, **Federal Government Control** encompasses regulations, standards, mandates and incentives short of out-and-out financial support for an activity. For purposes of discussion, these quadrants can be referred to according to a somewhat simplistic set of labels.

- Low Control and Low Involvement - the "provide framework" quadrant. This sort of approach in its purest form is the support that government gives to industry self-oversight. An example might be the FDA's safety regulation approach.
- High Control and Low Involvement - "unfunded mandates". These are characterized by regulation without financial support for those who would be required to comply. An example could be the Americans with disabilities act provisions for accessibility in public structures.
- Low Control and High Involvement - "funding pool" where access to the available funding is managed by a set of guidelines but the use of those funds is less constrained. The SBA might be a good example of this quadrant. Government grants might fall into this category.
- High Control and High Involvement – "government agency or procurement". This model requires the government to build and maintain the component themselves.



Essential Attributes

- The NHIN is person centric and connects the person by providing virtual health system:
    - The health care information is owned by the person. The person may view and enter their own health information. The person determines who can view information and what information to share and what information is stored (in accordance with HIPAA).
    - Functionality allows a person to participate actively and responsibly in their care to the degree they are able to do so: Research, personal health surveys, medication information/interaction, preventive medicine alerts, personal diary, disease-specific monitoring, etc.
    - Additional information available will include quality reporting of health care providers
- The NHIN is secure from unauthorized activity
- The NHIN provides almost real-time, accurate information
- The NHIN will utilize national patient identifiers and national provider identifiers to ensure the correct persons/providers are identified.
- The NHIN is reliable, available, scalable…
- The NHIN enables population-based information for public health, bio-surveillance, research and quality management/benchmarking.
- The NHIN support care across the continuum of care (personal care, home care, complementary alternative medicine, ambulatory, inpatient, skilled nursing, psychiatric, long-term care, etc)
- The NHIN is connected to professional organizations such as (American Diabetes Association, American Heart Association, Academy Health (AHSR), etc.) as well as to disease registries.
- The NHIN will not replace provider's medical records, but health information from the NHIN may elect to be added to the provider's medical record.

Key Barriers

- Misaligned incentives, benefits, burden between stakeholders
- Funding of acquisition and maintenance of HIT in clinical settings

- Concern about privacy and security
- Resistance to adoption by providers
- Training of providers and consumers
- Competition does not lend itself to sharing of information
- Access by the elderly, rural, and poor
- Legal barriers such as Stark Laws
- State laws and licensing varies
- Concerns about liability

Key Enablers

- The formation and funding of ONCHIT
- Financial incentives for HIT acquisition and maintenance (public and private)
- The removal of legal barriers such as anti-kickback
- Consumer-driven health care – consumers want visibility into their own health information and information to make decisions
- Pay-for-performance and quality reporting
- The sharing of best practices – to promote the benefits of having a NHIN amongst providers and consumers. Demonstration projects across the continuum, etc.
- The increase visibility of HIT via rhetoric by the Administration and Congress
- Standards, policies from HIPAA (Privacy, security, patient identifier, provider identifier)
- Standards on medical terminology
- HIT solution certification -- provide minimum bar for providers
  Homeland defense and disease control benefits

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.**

Organizational and Business Framework

- Participation must be voluntary for the consumer and highly incentivized for the provider.
- Financial and non-financial incentives must be carefully crafted to increase adoption by providers and consumers. These incentives may include loans, grant funding, private investment and differential reimbursement.
- Standards and policies must be created, maintained and there should be penalties for non-compliance. Unlike HIPAA, some entity must enforce these penalties.
- All stakeholders groups need to have input in the process.
- Additional considerations include: security, confidentiality, authentication, integrity, length of time to keep records

Management and Operational Considerations

- The NHIN is built upon the RHIOs. Most of the management and operational issues are determined at the RHIO level.
- Private sector competition may be encouraged in the construction and implementation of a NHIN:
    - Mandated standards
    - Non-proprietary technologies or solutions
    - Encourages competition via innovation, cost
- Special attention must be given to elderly, rural and poor consumers. Subsidizing these populations and their providers via grant or additional reimbursement (DSH) may be necessary.

Standards and Policies to Achieve Interoperability

- All stakeholders must participate in developing standards and governance around interoperability
- Consideration of global standardization must be considered as health care is becoming global (N.B.: UK and Australia)

Financial and/or Regulatory Incentives and Legal Considerations

- The federal government and CMS must play a leadership role in incentivizing the NHIN
- Incentives must be at both the national and the regional level
- Must consider changes to legal barriers and the variation between state laws and licensure

Other

For more than 25 years, Cerner Corp. has been a visionary leader in providing information management systems designed to improve health care. A global company with more than 5,000 employees and $900 million in revenue, Cerner has over 50 clinical and financial applications that enhance the managerial efficiency and clinical effectiveness of healthcare delivery worldwide. The company has facilitated technology implementations for hundreds of client providers at the institution and community levels.

The following are a list of key guiding principles that Cerner uses in our community level Health Economy Architecture (HEA) Solution, and which are particularly applicable to a NHIN.

- *Person-centric*

  The EHR is meant to store, maintain and provide access to information for the foremost purpose of treating patients/persons and making patient/person clinical data available to authorized caregivers for the express purpose of caring for them.

- *Mass-customized views of all clinical data*

  Patients/persons as well as several types of caregivers and healthcare authorities will access the EHR in different contexts of care. Not withstanding the significant quantities of data amassed and the location of authorized requestors of

information, the EHR must be able to provide customized views of data aligned with each requestor's needs and purpose.

  - Mass-customization of data gives the user the ability to:
    - View the data they want
    - In the form they want
    - When they want it
    - With data that is presented and formatted in the context of the use case
    - Supporting the "what if" scenarios of the provider

- *Value add for the provider*

  The EHR must be architected with a constant focus on the added value that its data can bring to caregivers and caregiver organizations. The EHR must be ready to fulfill the requirements of today's and tomorrow's mission critical activities accomplished in the day-to-day delivery of care by healthcare professionals and their organizations.

- *Timely and accurate information*

  Patients/persons and healthcare professionals need to make decisions on an ongoing basis in the process of treating illnesses and other health related conditions. An EHR is expected to sustain any resource involved in the process of care with timely, complete and accurate information. The EHR is viewed as an authoritative and reliable source of clinical information.

- *Think, build and act at all levels (local, regional, national)*

  The development, implementation and operation of EHR solutions across different areas of the country may be enacted under a number of circumstances and contexts. The solution must allow for a maximized level of flexibility around the diverse approaches that may exist to implement it in whole or in part across different regions. First and foremost, it must support providers across the continuum of care in the local and regional regions. Interoperable and integrated EHR components will exist across different regions and different provider type and provider delivery settings. The architecture must insure the system's integration and systems interoperability of all the components. It must allow for gradual implementation paths in any given region.

- *Standards-based*

  EHR solutions require standards-based systems in which to operate. The solution must rely on recognized standards in the world of information technology and healthcare for the development of services-oriented architectures. These standards are fundamental to the successful interchange of information. Each domain system must be able to communicate with other key components of the solution. Currently there are many incompatible and non-interoperable systems and standards. There are also incompatible versions within the same standard that have been deployed across the country. Through the adoption of the EHR,

standardization must occur. Standardization also implies a common definition of the EHR solution. This will save costs on a national basis. Standards will enable cost effective systems integration and interoperability.

- *Replicable solution — patterns, components*

  The solution must be built to maximize the potential for reusability at all levels. It must be based on recognized industry practices that favor component designs and reusability driven by design patterns which support care delivery. This principle is expected to be vital in generating economies of scale in the development of a wide-area EHR.

- *Leverage legacy systems and solutions*

  The solution must take into account systems and solutions that exist as applications in healthcare organizations or as regional level solutions. It must leverage the established capabilities and information repositories of such solutions and allow for integration and added value to be provided by EHR data. Existing investments in information technology for any region or organization must be allowed to survive and prosper through their normal life-cycle. The solution must support integration strategies to support legacy and upcoming IT solutions in healthcare.

- *Design for a phased rollout with near term results*

  Different regions must be able to create rollout strategies that can be adapted to their existing planning strategies, capabilities, resources, systems and business objectives. The solution must provide sufficient granularity and flexibility in its design for initiatives to be put in place and succeed in small incremental steps, thus generating near term business results and return on investment.

- *Scalable*

  The solution must offer solutions that can be deployed in small operational contexts and sustain growth both in terms of geographical coverage, number of systems, number of users and concurrent transactions.

- *Extensible to support future growth*

  The solution must be built to handle today's healthcare practice needs and provide openness towards needs that may arise in the future. Healthcare and medicine are dynamic domains that sustain constant changes over time. The architecture must also provide flexibility towards business domains, such as social health, that it may not directly address today but may be called upon to address in the future.

- *Cost-effective*

  The solution must be defined to maximize the effectiveness of every dollar invested towards EHRs across different regions.

- *Secure and private*

  The creation of a wide-area EHR generates a new level of accessibility for health related information on individuals. The solution must provide for stringent,

rigorous and best-of-breed security and privacy policies and principles to be applied continually and throughout every aspect of any of its components.

- *Allow for innovation and competition*

  The creation of a wide-area EHR creates the potential for new classes of applications that may leverage health related information to provide better care or even change the way care is delivered. The solution must be vendor neutral and allow for innovation and competition from any organization or vendor who wishes to develop EHR-enabled solutions. The solution should be designed with "plug-and-play" in mind - with interface facades such that one vendor component may be plugged out and another plugged in.

- *Comprehensive*

  The solution must be comprehensive in covering all areas of business process, information, system services and technology to sustain the full scope of a wide-area EHR.

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.)**

National

- Security and Privacy procedures/policies
- A minimum set of medical record information (including images)
- National patient identifier
- National provider identifier
- A minimum set of authorization for viewing, adding information
- Detailed implementation guides
- Certification
- Training
- "Marketing of the benefits"
- Performance requirements
- Focus on rural, elderly and poor
- Population based research, public health, bio-surveillance…

Regional

- Value add functionality for provider
  - Messaging between providers
  - Messaging between consumer and provider
  - Order management
  - ADE alerts
  - Claim management
  - Referrals
  - Test results (lab/ radiology)

    - Telemedicine/telemonitoring
    - Access to evidence based medical information
- Value add functionality for consumer
    - Messaging between consumer and provider
    - Scheduling appointments
    - Prescription management
    - Claim management by consumer
    - Referral
    - Test results (lab/ radiology)
    - Telemedicine/telemonitoring
    - Consumer research on specific health concerns
    - Alerts/reminder for preventive medicine

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?

   A framework needed to develop, set policies, and standards for, operate, and adopt an NHIN include the following attributes:
   - The key focus should always be on the person receiving care – the ability to provide high quality care in an efficient manner should drive decisions regarding a NHIN.
   - A secondary key focus should be on state Departments of Health and on AHRQ and CMS – the ability to provide high-quality policy planning decision-support, health services research, and public health research.
   - Participation must be voluntary for the consumer and highly incentivized for the provider.
   - Financial and non-financial incentives must be carefully crafted to increase adoption by providers and consumers. These incentives may include loans, grant funding, private investment and differential reimbursement.
   - Standards and policies must be created, maintained and there should be penalties for non-compliance. Unlike HIPAA, some entity must enforce these penalties.
   - All stakeholders groups need to have input in the process.
   - A NHIN must support RHIO development and sustainment.

- Additional considerations include: security, confidentiality, authentication, integrity, length of time to keep records**.**

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.**

   Any financial model for building a NHIN must incorporate a certain level of federal government funding. The federal government has a role in:
   - General funding assistance (i.e., granting programs, etc.).
   - HIT investments.
   - CMS and other demonstrations incentive programs.
   - Funding assistance for continued development of data standards and interoperability requirements.

   In many community models, payers play a major role in the financing model – which could be extended to a national level.

   Whatever financial model is used, proper incentives must be properly aligned from each stakeholder's perspective. In addition, benefits must be seen immediately and not solely promised in the future.

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

   See answer to question 5 above. The ability to sustain a functioning NHIN includes many of the same elements needed to build a NHIN, including:
   - General funding assistance (i.e., granting programs, etc.).
   - HIT investments.
   - CMS and other demonstrations incentive programs.
   - Funding assistance for continued development of data standards and interoperability requirements.

   Other financial models include payment by stakeholders or users, but these will not be sustainable without federal support. It is worth noting that the NHIN is built on the success of regional (RHIO) initiatives, and that, regional financial and business models are different that a national financial model.

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?**

   Privacy and security is a critical component for the NHIN. In fact, the concept and existence of a NHIN will not be achievable unless security and privacy considerations can be accounted for, resolved, and implemented. It is also generally recognized that the technologies required to enable and insure appropriate privacy and security standards are

available today. So, the privacy and security issues needing addressed do not necessarily revolve around technologies and processes, but instead pertain to the absence of normalization of policies, laws, rules, and regulations. The primary problem centers around finding consistent answers to questions that span the different regions of our country. Some of the questions needing answers include:

- What information is needed?
- What will the information be used for?
- Who owns the data?
- Who will have access to this information?
- What is consent?
- How is consent expressed?
- Harmonization of the definition of roles?
- What needs to be audited?
- Trust relationships between regions and between information domains?
- Trust relationships between domains within a region?

In general, these questions, and others, need to be addressed at the national level. Although answers to theses questions are not readily available, the following list provides guiding principles that should be used when privacy and security decisions are being made:

- Voluntary participation by the person.
- Person/patient rights regarding access control of their own clinical data, i.e., authorization required for access by a family member.
- Clinical data should be managed by the providers directing the care given to the person.
- Stringent, rigorous, and enforced privacy and security policies.

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

One of the most important attributes of a NHIN is that it promotes a vision that healthcare organizations and stakeholders can use to determine a shared definition for the interoperability of electronic health records across provider organizations and communities. A common understanding of the desired future state allows for a more coordinated effort where each region can act locally while sustaining the objective of a wide-area interoperable set of EHR solutions.

Much of the discussion on the subject of a NHIN and EHRs will occur within regions, involving provider organizations, healthcare professionals and technology vendors. Although those participating in these initiatives will have different perspectives and interests in relation to the EHR, the NHIN should provide a common framework to better enable stakeholders to express their visions and requirements and to identify and resolve issues.

Any framework to develop an interoperable infrastructure must be developed by a governing body that is:

- independent and neutral;
- transparent; and
- multi-stakeholder.

Management and Operational Considerations

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

The development of a NHIN creates the potential for new applications that leverage health information that may ultimately change and improve the way care is delivered. In addition, existing applications and technologies are ever evolving and must have a role in the NHIN. In that vein, the NHIN should be:

- Vendor neutral.
- Allow for innovation and competition from any organization or vendor who wishes to develop NHIN-enabled technologies.
- Designed with "plug-and-play" features in mind.
- Designed with economic incentives for interoperability and standards use.

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 public domain;
c. achieves country-wide interoperability; and
d. fosters market innovation

- The NHIN is built upon the RHIOs. Most of the management and operational issues are determined at the RHIO level.
- Private sector competition may be encouraged in the construction and implementation of a NHIN:
  - Mandated standards
  - Non-proprietary technologies or solutions
  - Encourages competition via innovation, cost
- Driven by balanced, multilaterally-aligned incentives.
- Special attention must be given to elderly, rural and poor consumers. Subsidizing these populations and their providers via grant or additional reimbursement (DSH) may be necessary.
- Multi-stakeholder influence and input

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?

All parts of the world want their healthcare systems to offer the highest levels of care possible to their rural populations. No one should be deprived of certain services because they are not living in or close to an urban area. Telehealth and all the applications that revolve around this concept stand to make a big difference in better enabling clinicians and patients/persons in rural settings to have access to all available and leading edge services. The EHR being delivered via a NHIN is a key structural component of any telehealth solution and by itself stands to better enable clinicians and patients/persons in rural settings in the management of care for individuals.

In addition to the telehealth applications discussed above, a number of other items need to be considered in order that lower income rural and urban areas are sufficiently served. These items include:

- The NHIN must be developed in a way that it is able to be "turned on" with a limited investment from the providers in these areas.
- The NHIN must not require existing health information technologies be replaced by new technologies.
- The NHIN must account for lower technical expertise.
- Providers must be able to connect to the NHIN via the Internet – which should lead to a lower initial capital investment
- Federally financed technical support.
- Increased leverage from grants and loans.

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?

The success of a NHIN is reliant upon the success of community and regional initiatives (RHIOs); therefore, it is imperative that they are not affected in a negative way. Ideally, the effects would be positive and include:

- Regional providers able to deliver higher quality care due to a more complete picture of the person's medical history.
- Improved efficiencies through reduced medical record transfers, etc.
- Reduced costs by the ease of use of ePrescribing-like applications.

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?

The implementation and broad adoption of a NHIN will certainly have an effect on the health information technology market. At the point that clinical data sharing is aligned

with proper financial incentives, the ensuing market opportunities are significant enough to merit investment in a NHIN by the industry. The following issues must be considered to properly incent the health information technology industry:

- Design, development, implementation, and support of the components that make up the NHIN should be performed by clinical application vendors, in collaboration with their partners and clients.
- Must not create barriers for entry.
- Must encourage innovation and competition.
- The deployment of a standards-based, interoperable NHIN creates exciting opportunities for greater reusability of existing systems and for creating new, high value-add solutions.
- If done right, there is opportunity to reduce vendor development and implementation costs incurred in the current, non-standards based environment.

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?

It makes no sense for the NHIN program to reinvent, or for the NHIN program to commission the reinvention of, existing interoperability standards for healthcare information by creating totally new standards development organizations (SDOs). Existing independent standards groups (e.g., HL7, ASTM E31 CCR, ANSI-HISB, CDISC, etc.) are appropriate and vital co-contributors to the successful development of interoperability in NHIN and RHIO implementations. However, the ONCHIT leadership must be mindful that these disparate SDO organizations have been perennially plagued by adversarial give-and-take that seeks to advance the power of each respective standards organization and the member stakeholders of each. The standards processes have been characterized by frustratingly slow progress toward consensus standards over periods of many years and excessively many iterations and review cycles. The thought-leader experts in each SDO technical committee – industry participants and academics alike – invariably have serious conflicts of interest that cannot be mitigated adequately. And the SDO standards bodies have never up to now been accountable to produce standards deliverables on a timetable such as is required for timely implementation of the NHIN. They are totally incapable of delivering on time, and ONCHIT must be cognizant of this fact.

Recent illustrations of the persistent and serious dysfunction among existing SDOs can be found in interactions between HL7 and ASTM. The ASTM E31.28 work group recently refused to sign the HL7 harmonization memorandum of understanding (MOU). There has been no agreed framework for co-development of the CCR and EHR standards, including procedural rules as well as outcomes. Different financial models of the different standards entities' stakeholders and a clash of cultures between the different

entities are well known. Because of persistent disputes, consensus, when reached, is frequently of a low-value lowest-common-denominator sort, which serves no one particularly well and which also gives rise to a high rate of non-standard "extensions" beyond the standard, on the part of suppliers whose products offer features far beyond the lowest-common-denominator and "legacy" features. On account of the foregoing issues, Cerner therefore believes that direct federal involvement and ONCHIT oversight would be required in commissioning and supervising the engagement of these organizations for the purposes contemplated for the NHIN program, to insure an on-time specification of acceptable standard NHIN features and to prevent suppliers' convenience and competitive pressures from unduly influencing the standards process. It is plausible to us that ONCHIT could delegate the contracting and oversight role to another appropriate office, such as Michael Fitzmaurice's team at AHRQ. Without such authority and operational ability to establish and enforce deadlines and functional requirements-specifications, the NHIN interoperability standards formulation process would be predestined to fail.

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.**

    Cerner believes that the policies and administrative procedures that have characterized the recent HIPAA 837 and X.12 transaction standards-setting process have been reasonably effective and congenial and free from proprietary bias. NHIN should attempt to emulate those, to the degree applicable in this new context.

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

    Please see responses to items 14 and 15 above.

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?**

    - Harmonization of definitions and standards need to take place between all RHIOs so they can interoperate.
        - RHIOs must be able to communicate by way of exchanging messages between each other across any number of regions;
        - Applications must be able to communicate by way of exchanging messages with an data sharing utility within a given region;

    - Semantic, security, privacy, transactional, policy and administrative meta-data must be exchanged and interpreted similarly between utilities;
- Interoperability needs to be instantiated between the core components of a RHIO for them to participate together in the accomplishment of the mission of the NHIN.
- Standards need to be in place for all participants to agree on the semantic meaning of the information deposited in the utility and accessed from there.
- Policies and agreements need to be in place between all regions that maintain and operate a utility.
- Funding incentives for interoperability and standards use.

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?

One role of the federal government is to assist in funding standards development and interoperability requirements. However, we also favor active involvement by HHS (possibly via Michael Fitzmaurice's office within AHRQ) in supervising and performing project management of the standards process, as suggested above.

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?

Provider Incentives -- Clinician acceptance is critical to the success of a NHIN implementation because of its ramifications on other factors, including implementation risk, customization requirements, and cultural change. An implementation can sink or swim with the position of clinicians, particularly physicians. To support a technology implementation, a physician must trade-off time that could be spent attending patients. Often their expectation is that this investment of time, at best, has no direct benefit (quality or financial) to them or their patient and, at worst, has the potential to disintermediate them from care delivery if the technology "works." Finally, expected cost avoidance from diminished errors and overall system quality does not necessarily accrue benefits to the physician.

Other incentives that could be put to broader use include pay for performance and grant incentives. In addition, CMS demonstration pilot models should be fleshed out further to appropriately judge their validity.

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?

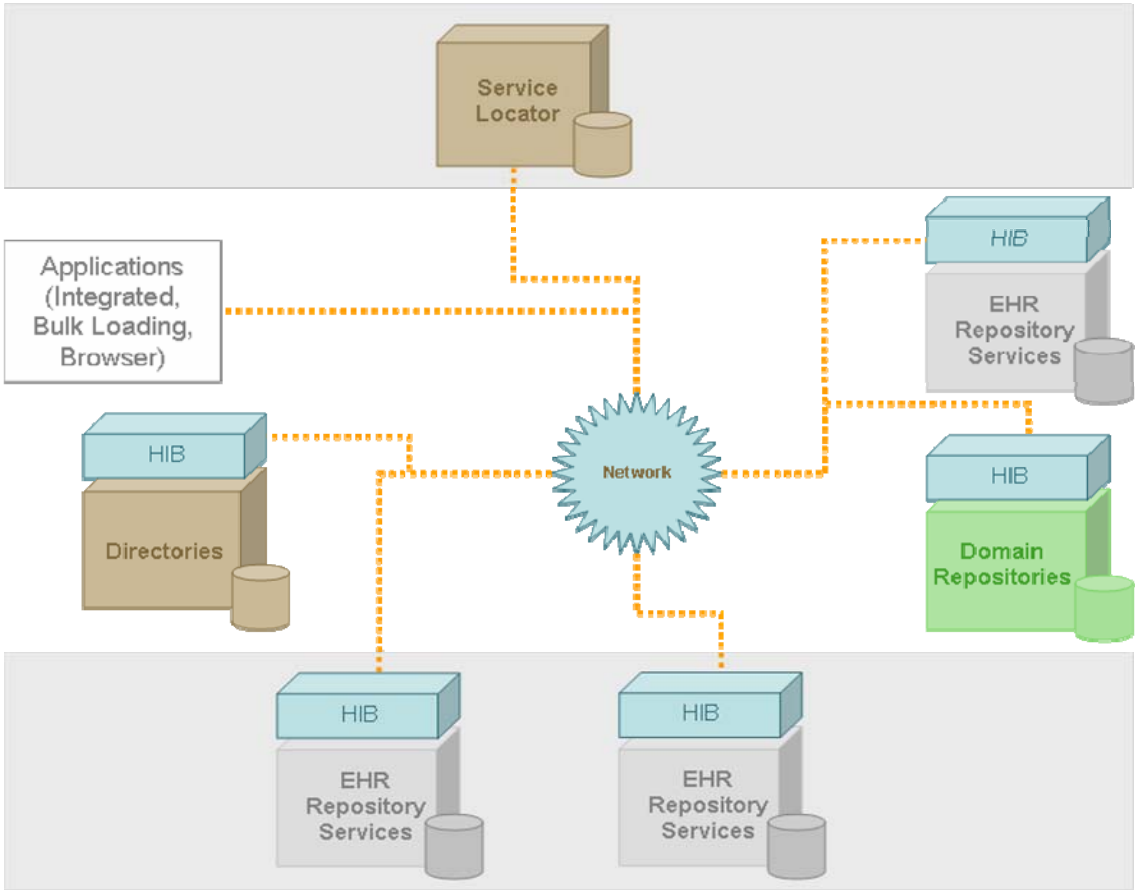
HIPAA and individual state laws provide certain challenges related to data sharing – and there is a needed harmonization of state and federal laws. In addition, the removal of legal barriers such as the anti-kickback and stark laws need to continue to be expanded.

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.

The following picture is an example of a possible technical architecture.



The EHR, as shown, can be accessed in any of three ways: via a standalone provider application, an integrated provider application, or through the bulk data loading approach. A standalone provider application may be a browser based or other application that provides EHR presentation functionality. An integrated provider is a provider application that exists today as part of a hospital information system, a physician management system etc. that is retrofitted to connect to and use the functionality provided by the EHR.

Users can access the EHR through a virtual private network (VPN) connection or through a firewall. The HIB provides the interoperability and connects to the directories and repositories. The Service Locator provides the location where data is stored for a selected patient/person.

Bulk loading of data results in files being periodically and automatically transferred into a server. The data is then automatically picked up by an "extract-translate-and-load" (ETL) software application, which interacts with the ETL service in the EHR Services. The ETL service can be used to load anonymized or de-identified data into surveillance and research-based data repositories.

EHR

The EHR is the central component that stores, maintains and manages clinical information about patient/persons. The extent of the clinical information sustained by the

EHR component may vary based primarily on the presence or absence of Domain Repositories in any given region. The EHR holds data replicated from feeder or application systems. Hence, it is an operational data store for the Cerner Solution. It is not an online transaction processing (OLTP) store for the feeder or application systems.

Domain Repository

A Domain Repository is a component that stores, manages and persists a specific clinical subset of data, typically at a regional level. These may be domain-level operational systems for the given region as well. The key data domains recognized as part of an EHR are medications, laboratory and diagnostic imaging results, diagnoses and conditions, procedures and services history, admissions/visits/venues history, and providers/roles history. Some of these data domains may be already deployed as regional level systems. An EHR infostructure must be able to assemble information transparently from these Domain Repositories in order to provide the complete clinical picture of a patient/person. Domain Repositories represent the notion of these systems that need to become part of an HEA Solution and be interconnected with EHR services to provide the full clinical picture of any given patient/person.

Directory

A Directory is a system that focuses solely on managing data pertaining to one conceptual entity. Directories store, maintain and provide access to peripheral information not categorized as clinical in nature but required to operationalize an EHR. The primary purpose of a Directory is to respond to searches using one or more pre-defined parameters in order to find and retrieve a unique occurrence of an entity. Examples of directories include: Person Directory, Provider Directory, Organization Directory, and User Directory.

HIB: The Healthcare Information Bus

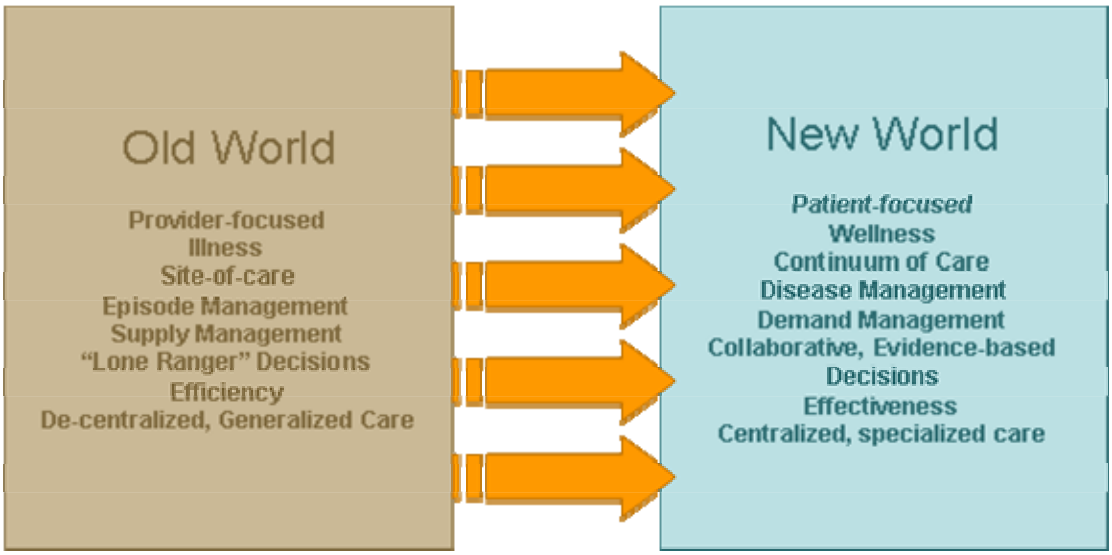
The Healthcare Information Bus (HIB) is an architecture (OSI Layer 7) that defines service components, service roles, information models and messaging standards required for the exchange of EHR data and the execution of interoperability profiles between EHR Services. The HIB is broken down into two layers of services: the common services and the communication bus services. The common services layer is an aggregation of services that accomplish generic functions potentially reusable for any Directory, Domain Repository or EHR system available in a given RHIO. The communication bus services layer is an aggregation of services that pertain specifically to enabling communication capabilities in a peer-to peer, highly distributed network of RHIOs. This layer handles the receiving and sending of messages between any two systems in a utility.

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?

Success will be measured by quantitative factors such as, improved quality and safety outcomes, lowering of healthcare spend per capita trend, number of users and daily transactions, fairer and more equitable access to health services with reduced disparities

among ethnic and socioeconomic groups, improved preventive medicine capabilities, enhanced public health surveillance and decision-support, support for, deep involvement of both public and private sectors, and HIPAA-conformant protection of patient rights and confidential data.

The primary determination of success should be measured by the complete shift from the old world of healthcare to the new world of healthcare. One does not have to look very far to see the fundamental changes that are occurring in the health care industry. Economic, social and many other drivers are forcing changes to the focus of health care. First and foremost, health care is becoming a more patient-driven industry. There is a palpable commitment to building a foundation that is grounded in the principles and values of patient/person and family focused care. Similarly, there is a demonstrated understanding of the need to shift the focus of health care efforts from the management of illness to the maintenance/promotion of wellness. As a result, we are seeing increased emphasis on the management of diseases across the continuum of care and along the lifecycle of the disease. To support this, the industry is experiencing a significant shift in how clinical decision making occurs. Specifically, we are replacing the "lone ranger" decision-making practices of the past with truly collaborative, interdisciplinary, and evidence-based approaches. We are also seeing a move from decentralized and generalized care to more centralized and specialized care.



While many of these changes are driven by advances in technology, they also require a capability from a NHIN – a capability that does not exist today. In the new world, we require access to health information not only across different systems but across different regions and domain boundaries. We require the ability to view clinical information from all sources and to use the infostructure to initiate orders and referrals to a broader range of care and service providers than is currently available through traditional mechanisms. This happens by extending the capabilities of our monolithic and even integrated but

tightly coupled information technologies to work within a framework of interoperability. Through a national, interoperable EHR-network we can extend, expand, and harmonize the sources of information available to clinicians in their work.

Healthcare professionals make clinical decisions based on knowledge. Access to relevant and reliable clinical information is a critical input for the process of knowledge creation. In fact, information is the lifeblood of an effective health care system. To ensure the best possible care, the information must be accurate, up-to-date, available, and accessible whenever those who provide health care services need it.