Hawaii Health Information Corporation
HIPAA Readiness Collaborative Steering Committee

Response to the

Office of the National Coordinator for Health Information Technology
Request for Information

January 18, 2005

Dr. David J. Brailer
National Coordinator, Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Washington, D.C.

Dear Dr. Brailer

Hawaii Health Information Corporation (HHIC), a collaborative including over sixty organizations ranging from hospitals, health plans, state government, laboratories, physician groups and associations among its membership, is submitting this response to your Request for Information (RFI) on developing and adopting a National Health Information Network (NHIN) on behalf of its members.

This response represents feedback from the HIPAA Readiness Collaborative, through its Steering Committee, as well as representatives of two recently-funded Agency for Healthcare Research and Quality grants dealing with the planning and implementation of health information exchange: the Holomua Project, "Improving Patient Hand-Offs in Hawaii" and the Quality Health Alliance, "Quality Focused Connectivity". Numerous Hawaii hospital systems, payers, clinical laboratories, the primary care association, state of Hawaii departments, and other Hawaii health care stakeholders contributed to the collective Hawaii response, including:

- HIPAA Readiness Collaborative Steering Committee
- Hawaii Health Systems Corporation
- Hawaii Medical Service Association (HMSA) - Blue Cross Blue Shield of Hawaii
- Hawaii Pacific Health
- The Queen's Medical Center
- Rehabilitation Hospital of the Pacific
- Saint Francis Healthcare System of Hawaii
- State of Hawaii Department of Health

Our attached responses to the RFI's specific questions represent varied opinions and experiences of Hawaii's covered entities and other stakeholders.

Members represented in this RFI Response are supportive of a health care system that can assure greater patient safety, improved quality of care and increased efficiency. This initiative has lofty goals that will bring great benefits and great challenges to providers, payers, consumers and government. As you review our attached response, to ensure information will be interpreted in the same context, we would like to draw your attention to the following key points and assumptions used by the participating members:

- The system will not pay for itself. There needs to be federal funding and/or other incentives for the initial NHIN build-out. The business case to initiate the network still has to be made.
- Providers must be financially supported and allowed time to modernize existing systems (including manual systems) to build electronic medical records (EMR) for NHIN participation. A standard indexing method must also be determined early in the process for interoperability to occur.
- The system must be patient-centered and scalable. There needs to be minimal or no economic and technology barriers to participate (i.e., non-proprietary and open source-based). Large multi-facility systems, private practice physicians, pharmacies, clinical laboratories, and individual patients alike must be able to participate equally.

- Information accessed via NHIN must be secure, timely, and accurate. Stakeholders (patients, providers, payers, clinical laboratories, pharmacies) will not participate otherwise
- Medical record data repositories must remain decentralized and controlled at the provider level. A minimal set of nationally defined data elements and indices for interoperability should be maintained at the NHIN. No central databases or repositories at either national or regional levels.
- Existing interoperability models and related standards must be leveraged. It is unnecessary to build from scratch or to not benefit from "lessons learned" previously paid for by others. The Credit Bureau Reporting Network and the "BluesNet" developed and used by the Blue Cross and Blue Shield System are examples.
- Legal inconsistencies across statutory and federal law in areas such as privacy must be resolved. Consider indemnification early; covered entities will not participate if higher risk is perceived in NHIN participation.
- Availability of information does not replace the human elements such as patient input and professional judgment at the point of care.
- Issues related to opting in and opting out of NHIN participation must be addressed. The individual consumer (patient) needs to retain control over access to their own health information. Consumers will not participate in the NHIN otherwise.
- Potential NHIN profit ventures to maintain ongoing operations; such as for marketing purposes and healthcare operations (service line development) must be balanced with individual privacy protections. NHIN/RHIO funding for ongoing operations must be market-based – i.e., funded by participants
- NHIN must have the ability to certify and enforce RHIO adherence to standards. Standards implementation and oversight are critical for interoperability success. Do not link to international databases.

We welcome the opportunity to have continued interactions with your office. If you are interested, we would be pleased to have a more detailed discussion of the response submitted.

If you have questions about comments submitted, please contact Brenda Kumabe (808.534.0288 or BKumabe@HHIC.org)

Sincerely,

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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.

Working Definition – A national secure network (NHIN) of RHIOs for sharing a minimal set of patient data elements for the purpose of timely exchange of patient information to support current health management and continuity of care for the patient. The minimal data set include patient identifying information, medications list, immunizations, allergies/adverse reactions, recent diagnostic and lab results, and problem list. The NHIN serves the public interest by facilitating and promoting the interoperability between regional networks. The NHIN provides the leadership, sets the vision, and sets the standards for messaging, security, accreditation, and certification which the RHIOs adopt if they are to connect to other RHIOs through the NHIN.

A Regional Health Information Organization (RHIO) is a local or regional entity comprised of multiple enterprises which establishes a local secure network and infrastructure for the health care organizations and consumers in that region. The RHIO should be inclusive, with transparent and open governance, and utilizes national standards, seeking certification from the NHIN.

A working NHIN should have the following attributes:

NHIN Attributes	Enablers	Barriers
Public Support	- The promise that sharing information will lead to better coordinated health care, better use of health care resources, increased availability with improved quality - People generally trust their health care providers – if provider support can be ascertained through ethical persuasions - Potential consumer empowerment – ability to obtain information to make better (informed) decisions - Strong government backing – use government programs as pilot to include information for all covered by federal and state covered individuals – including the President – to demonstrate commitment	- Providers are in competition with each other - Proprietary practices that enabled businesses to gain strategic advantages - Existing businesses that support proprietary electronic health records systems - Privacy and security issues that may expose individuals to exploitations that will alienate others for their own gains - Consumers may not see the incentives since they are not the direct bearer of associated health care costs
Enable transition instead of transformation	- Begin with medical information and network within the public sector with private partnership – enabling businesses that might be impacted to transition to new businesses that the RHIN may create - Automation of the medical record is necessary for ensuring that relevant health	- Significant disruption of how businesses are being conducted - Potential increase in bureaucracy from necessary administrative controls

NHIN Attributes	Enablers	Barriers
	information is timely and accessible to clinicians as the patient moves through various health care settings. - The Federal government needs to provide the initial funding and sufficient time for the industry to transition, i.e., providers' and clinicians' medical records modernization by using IT tools. - Tax credits or tax breaks can be used as motivators - Partnership with insurance companies to provide Errors &Omissions (E&O) insurance breaks	
Create value	- Must be patient-centric - Demonstrate values "the right thing to do" with health information (how the data is appropriately used), such as Department of Health demonstrating more leadership in helping industry to improve, other than statistical reporting - Eliminate or reduce existing regulatory reporting requirements (since information can be extrapolated by regulatory agencies from NHIN)	- Needs by provider to protect information; even to protect their patient from their own information such as in psychotherapy notes, communicable disease information, family planning information - Costs associated with standardizing information to meet the goals of RHIN - Extensive changes in how business is conducted - Not all health information accessible at a national level will encourage usage or create value
Self-sustaining through revenue generation	- Generate revenue from entities that can gain from the information. For example, pharmaceutical companies for research, medical schools for research, consumers and providers for medical treatment and outcomes improvement, payers and employers for improved efficiencies in health care services utilization, various stakeholders for drug interactions information and laboratory results - Provide services with commercial value such as facilitating recruitment of patients to participate in clinical trails based on medical conditions as authorized by the patient - Leverage as a way to regulate and manage the clinical trial processes - Create business opportunities to track and communicate evidence-based medicine - Codify patient identities to track population-based studies and findings – savings from other census and statistical work performed by the public sector - Enable "post-marketing surveillance" of FDA approved drugs and devices for	- Pharmaceutical companies are in competition with each other - Information can be used for malpractice law suits - Potential privacy and security concerns - Businesses may begin to rate medical practices (such as consumer rating type services) that will hurt providers who are not ranked favorably - Most providers may not have the time, interest or resources to leverage information shared by others, therefore will not be able to see the value of their providing their patient's information - Consumers may not like to share information in fear of "Big Brother" is watching – loss of privacy - Potential financial burdens

NHIN Attributes	Enablers	Barriers
	performance evaluation - Provide new business opportunities (such as Akamai - a service to gather relevant information through the web to meet special information needs – reduce technology requirements and improve response time) to manage information portals - Partnership with software development companies to create value adding tools such as medical records management with direct interface to NHIN	
Easy to use	- Leverage model built by successful examples such as BCBSA Blue card model - Prevalent use of Internet technology - Partnership with major technology developers such as Microsoft, Apple, IBM to come up with "plug and play" technology - Partnership with major electronic medical record and practice management software developers - Partnership with the Federal and State educational and library systems to support usage issues	- Not all providers and consumers have the needed technology savvy to take advantage of the NHIN - Fear of out-sourcing to foreign countries
Leverage existing interoperable technologies	- Increasing use of technology by providers including use of electronic prescribing tools - Internet, Telehealth - Data availability, e.g. mandatory disease reporting, state institutions, and state program - Leverage existing technologies and available information. - Enable local autonomy to choose technologies or vendors	- Hardware and software incompatibilities - Costs associated with compliance and technology upkeep - Ownership of infrastructure (and associated costs) that are not individually owned
Use existing data and technology standards	- Ability to build upon HIPAA EDI - Financial incentives such as tax credits or breaks for efforts to move to standards prescribed by the NHIN - Leverage insurance companies, financial, automotive, and retail industries experience and infrastructures - Use extensive health care industry EMR, medical claims information and support interoperability with federal funding and other financial incentives	- Ability to link (or correlate) medical information when they are practiced in silos - Ability to standardize terminologies including measurements used - Ability to standardize codes and transition to standard code use (DRG vs. APR DRG, ICD 9 vs. ICD10, Snomed, etc.)
Leverage the use of existing	- Enable regional autonomy - Enable provider and payer EMR autonomy	- Decentralized model requires extensive network capabilities; administrative

NHIN Attributes	Enablers	Barriers
interoperability models	- Leverage existing information and technology used - Models can be of one or combinations of the following options: - National level indexing or summary information (such as Google search) with detailed medical records maintained at the point-of-care provider level - Regionalization – (a clearinghouse model) with indexing information at the national and regional level for dynamic data linkage · requestors send requests to holder of information · holder of information authenticate and approve information request · No centralized data repositories except for common indexing or identifier keys for interoperability	overhead by detailed information holder - Centralized model will be too huge and become unmanageable
Flexible	- Enable appropriate access to medical records. For example, accessibility of an individual's medical information for providing remote medical care - Enable the size of the NHIN to be relatively smaller	- Data security during transmission - Network requirements
Patient centric timely (up-to-date), complete and accurate information to support an individual's medical treatment	- Decentralized data storage with national level indexing will facilitate more timely updates. For example, like banking system where persons may physically store money in a bank's vault and access information about the money as well as the money through the Internet, ATM network, etc. - Existing electronic health record systems (even if they are in different formats)	- Ability to capture adequate historic information for NHIN to be useful within a short period of time - If patients or providers can opt out, then information will not be complete, such as medical history and medication usage - HIPAA Privacy and Security regulation require minimum necessary rules be applied – covered entities may only use information for the intended purposes - Extensive data available at a national level may not create adequate values to justify the associated costs
Useful information – standardized	- Accessibility of data to reduce administrative burden of manual reporting for state and federal mandatory disease registries and other federal and state reporting requirements - Providers' patient EMRs	- Differences in state laws - Lack of nationally recognized standards of care - Lack of ability to enforce total disclosure of information - Lack of ability to enforce disclosure of privately held notes - Ability to standardize terminologies and measurements used
Low costs – less than current costs	- Incentives to support the NHIN concept, e.g. free or low costs (subsidized) productivity software for medical record	- Costly setup and conversion - High on-going administrative costs

NHIN Attributes	Enablers	Barriers
	management; discount in Internet connectivity (volume contract); free or low cost consultation; E&O insurance discount (charge more from non-participants to pay for discounts to participants) - Financial incentives such as tax breaks	
Protection against unnecessary litigation	- Potential legislative controls - Masked provider and patient identity – detailed records to be requested via individual authentication - Mandatory reporting of malpractice settlements that do not get recorded in court	- Providers' oppositions to disclose information that may result in errors and malpractice suits - Differences in state laws - Federal laws and agency regulations; multi-jurisdiction - Require federal and state level tort actions or reforms
Ability to ensure privacy and security	- Classify information into various levels to implement appropriate privacy and security controls – not all health data elements have the same degree of sensitivity and therefore; should not carry the same investment in controls. - Security tools to ease the administrative burden of identity management at NHIN - Store detailed medical records at the sites controlled by the provider or data initiating entity. - Information should be requested (versus directly accessed) with appropriate authentication and authorization tools in place. Providers (stewards) and patients (owners) must have the ability to authorize access. - Sanctions and enforcement for offenders must be in place – threat of sanctions is not good enough - Ability to log and maintain audit trails of who accessed what information	- Fear of identity theft, invasion of privacy, solicitation, adverse employment decisions, lost of market share, etc. - Patients may want to withhold past (potentially embarrassing medical history) - Fear of export of information to foreign countries - Linking to international databases

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.

We agree with the Office of the National Coordinator Health Information Technology in their assessment of the U.S. not having meaningful health information interoperability examples, except for a few isolated regional projects. The Care Data Exchange model seems good but there is no track record. The Indiana model, which appeared promising, cost more than $60M to implement and now appears to be unable to secure sustainable funding without reliance on grants or federal funding. There isn't enough evidence to suggest that there is a good working model within healthcare.

It seems that a viable NHIN/RHIO model can be developed after first having IDNs and EMRs in place. It seems to make sense to first allow that to occur at local levels, before addressing national interoperability solutions. It also seems to makes sense to let communities continue to explore options with AHRQ so they can set their own pace and priorities. However, there seems to be some success of U.S. interoperable models in other industries. These examples include:

- ATM network
- Credit card network
- Credit bureau services
- Search engines, like Google

Viable models appear to be generic (scalable and open source versus proprietary) architectures that can accommodate scalable access so that both large institutions and single physician offices can access records of care that are comprehensive, communicable, complete, secure, portable over systems, and will retain their integrity over time. The initiating source (steward) of the data needs to be able to retain control over access to the data, (or contractually retain the services of some other entity) to provide appropriate health data retention and access to the data. The models described below can be used as either independent models, or jointly as the hierarchical components of a single model.

Model Options	How	Benefits
1. Repository at a national level to house names and contact information of individuals and providers to identify information availability	- Central repository of indices managed by government or within state RHIOs. - Fund by subscription to services of information – e.g. credit bureau services - Incorporate as part of industry best practice – such as NCQA accreditation	- Enable providers to check with each other even if it is only telephonically - Provide links or access path to the next level of information
2. Network-based many-to-many connections through the NHIN	- Network services would need to be defined to manage the query and response. · A query could be sent to a central query/response engine, which would then redistribute the query to all RHIOs · Positive and negative responses from each RHIO can be then combined into a single query	

	response and sent to the requestor. - The 'hub' of this network could be a private vendor, similar to existing EDI clearing houses. - A network of regional 'hubs' could be combined to create a national network.	
3. Decentralize data elements except for minimum data elements required for interoperability (I.e., minimum data and identifier indi1ces)	- Centralize data indexing (with appropriate de-identification or aggregation) through a "master identifier engine" that would ensure that the data is correctly indexed. - Keep details decentralized at providers and payers - Not all medical record information will provide value at a national level - Enable security and privacy controls. Patients and health care organizations will not participate if appropriate controls are not in place. - Keep initial NHIN smaller in size and limited in scope to improve initial manageability and success - Feed summarized information to national level, e.g. health trend, usage, etc.	- Ability to differentiate what should be at a national level and what should be at a regional level - Regional level requirements may vary greatly

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

- Given that the majority of an individual's health care is provided near the individual's residence, most of an individual's medical information should be shared/managed locally or regionally and only shared nationally on a need to transfer basis. For example, for an individual who requires medical treatment away from their local area of residence, or for addressing national bio-terrorism or disease emergencies. A "virtual national data warehouse" is more feasible than a physical data warehouse.

- Data movement should be request oriented, meaning initiated/pulled by the requesting party if authorized, versus being pushed by the supplying party. Regional groups may be willing to trust a third party with managing data movement on a regional basis; however, we do not support a national third party being entrusted with managing the movement of medical data on a national basis.

<u>National Level Scope</u>
- Unique Patient Identifier defined at the national level.
- There should be a minimal set of nationally defined Data Elements. This cannot be done locally.
- There should be no national database or central repository. All data should remain decentralized, residing at the entity level (not RHIO).
- Patient data requests occur real-time across the NHIN using pull technology through the RHIO.

<u>Regional level</u>
- Should be used to resolve and process transactions in the region. Requests outside the region are handed to the NHIN.
- There should be no regional database or central repository. All data should remain decentralized, residing at the entity level (not NHIN).
- Should be used to demonstrate new interoperability standards and solutions before national adoption

<u>Local level</u>
- All patient data should be maintained by the entity (provider, etc.).
- EMR and data management.

National	Local or Regional
- Establish interoperability requirements/specification - Keeper of provider, payer, and patient identifiers - Maintenance, security management, standards (e.g. encryption) - Appropriate accessibility for health care planning and other administrative health care operations - Network standards - Data and access standards - Management of conflicts between national and state requirements - Initial Funding	- Detailed information pertaining service particulars - Coordination and agreement on development of regional standards that can interoperate with federal standards; or use federal standards as baseline to add on additional requirements to regional requirements - Administer enrollment, registration, and access controls - Work with national body to ensure compliance with standards while meeting regional requirements - Ongoing funding - Endowments and grant funding through community business partners

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. The NHIN should have a federated model with centralized controls of certain components (identifiers) and distributed regional/local housing of details where most value can be realized. Communication network and overall linkage will enable real time query and accessibility of patient information and aggregated health data on an as-needed basis. NHIN should be developed by an independent organization (versus individual vendors or health care organizations). The independent organization(s) should be federally contracted and funded.

Provide federal money and guidelines (data standards) to states, while allowing them some flexibility in how they implement their actual regional networks. We all have information systems from different vendors that interconnect with data standards, and each state could interconnect with the others with national data standards.

b. Federal government and designated standards organizations to work with the technology industry, national health information system vendors on adopting baseline standards for functionality, data, and interoperability. A consortium of vendor representatives, along with HIMSS, CHIME, AMA, WEDI, AHRQ, NCVHS, NAHDO, AHA and other stakeholder organization representatives can establish NHIN standards.

c. Federal funding, definition of acceptable data, interoperability, and security standards and oversight of how access to patient information will be controlled to ensure appropriate use are required. Standards for interoperability and functionality need to also be adopted by the technology sector. Federal government must also provide tangible incentives and acceptable business case for industry to justify adoption of NHIN participation.

d. The national level should provide only standards, guidelines, and financial incentives to utilize a NHIN, and should operate the NHIN. A NHIN will operate itself (market forces) if financial incentives are properly aligned. See chart continuing on next page.

Stakeholders	Key considerations	Development / policies standards setting approach	Adoption
ONCHIT	Work with financial industry to learn from the ATM and credit bureau network	Leverage existing network and information interchange forums	Leverage lessons learned paid by other industries
CMS as a start	Establish governance framework	Involve state and medical governance bodies Allow local autonomy	Support CMS's and the RHIN missions
FDA cooperation and support	Ability to obtain revenue through its oversight process, e.g. drugs approval	Leverage existing governance with improved information	Enforce adoption by pharmaceutical related entities
Incorporate as part of national accreditation requirements	Not all entities require accreditation	Create upfront mindset change for long term synergy	Enforce adoption by hospitals or entities these agencies oversee

Stakeholders	Key considerations	Development / policies standards setting approach	Adoption
Incorporate as part of the continuing education process	Ensure understanding of the appropriate contribution and use of NHIN	Leverage existing continuing education governance and management framework	Enable mission, knowledge and appropriate use to be sustainable
Provide tax incentives for technology industry to participate in building the RHIN	Create incentives to create technological alternatives	Provide technology choices Allow technological autonomy	Improved technology and infrastructure Business incentives for adoption and support
Involve insurance companies (such as BCBSA), local health care organization, state government to lead, build and oversee ongoing operation	Existing information held by these entities These entities are potential benefactors of the NHIN Leverage existing knowledge	Leverage current policies and controls Identify gaps and conflicts Resolve gaps and conflicts rather than building from scratch	Minimize changes to existing environment

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.

Build-out of the NHIN and RHIO should be funded nationally.

Model	Funding	Implications
Similar to Credit Bureau for ongoing funding	- Individual business funding with regional subscription - Contributors of information – reward with discounts in information usage - Allow for profit ventures such as for marketing purposes, medical research groups, medical suppliers, insurance groups, etc. to subscribe information for a fee	- May not house adequate information to meet RHIN goals - Privacy and security issues – opt-out administration may limit information's business value
NIH and FDA	- Funding should be obtained from the NIH and the FDA for clinical trials, drug therapy trials and evidence-based medicine	- High cost burden - Require pharmaceutical companies to be covered entities - Potential modifications to FDA charter
Initiate setup by government then transfer to private ownership	- As part of malpractice tort reform, have a percentage of all attorneys' fees or interest earned to be set aside in a trust account that is transferred to the government to fund the NHIN - Take a percentage of the law suit (e.g. malpractice suits) awarded dollars to fund RHIN/NHIN - Ask for voluntary contribution in tax return, e.g. like the presidential campaign fund - Assess fees for FDA approvals, accreditations, provider licensing, etc. - Assess funds via NIH and the FDA for clinical trials, drug therapy trials and evidence-based medicine	- Opposition to assessment of fees - Since EMRs will serve as a critical part of the NHIN solution on the provider side, modernization by using IT tools for providers must be assisted via tax breaks, additional reimbursement for NHIN adoption, and/or grant money to partially fund these systems - Federal balanced budget issues need to be addressed
Non-profit private businesses to provide value added services	- Establish non-profit agencies to provide tools to gather information for a small fee, such as medical records, claims management tool - Gather information from services provided to feed RHIN - Revenue gain to fund RHIN - Provide seed money to start non-profit entities from assessments described in earlier section - Ongoing funding dollars can be obtained through subscription fees	- Leadership and initial funding to start up these non-profit agencies - Governance required to guide these agencies to be on track to achieve the NHIN objectives

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

A free market approach would be best, but this cannot be realized until the infrastructures are in place and the economic benefits are clearly demonstrated. Heavy subsidization at the national level should occur for a proving period (it might be 1 – 2 years to validate whether NHIN has long-term viability). At the completion of the subsidization period, funding should come from those who benefit the most. For example, consumers may benefit the most.

Another potential alternative is one that ties funding for NHIN participation to payment to providers, payers, patients, other participants. A privatized healthcare system must utilize a privatized funding model.

Model	Funding	Implications
Government funds initial setup – hand off to non-profit self-sustaining operations with regulatory oversight	- Provide value-added services for a fee, e.g. selling information to pharmaceutical manufacturers, medical suppliers, etc. - Selling medical record and reporting services to providers	- Privacy - Security
Free market / privatized for ongoing operation	- Provided by NHIN participants - Provided by NHIN participants who most benefit. For example, insurers, consumers, providers, and employers may most benefit through reductions in unnecessary health care services, adverse drug interactions, and medical errors.	- Privatized models can be governed by federal laws and regulations, which are necessary for a functioning NHIN - No linking to international data repositories - Free market approach cannot be realized until infrastructures are in place and economic benefits are clearly demonstrated
Lottery	- Levy dollars from state lotteries	- Inconsistent contribution - Not all states have lotteries
Governance part of HHS	- Tax dollars - Reallocation of federal budget monies	- Increasing public taxation burden or shifting tax dollars from other usages

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?

- Most of these issues are self evident. The Internet is the most practical communications backbone for an NHIN, so countermeasures must be put in place to guarantee data integrity and security. Guaranteeing privacy while easing the access to patient information is difficult to achieve. Providing clear guidance on how far each of these can be achieved will be critical. Some physicians may not want their patient information shared – clear policy must be developed to permit a patient to override this resistance if they so choose. Patients must still be given the opportunity to 'opt out'.

- Part of the certification standards for the RHIOs will be documentation and assurance that the RHIO meets all of the minimum Privacy Rule and Security Rule provisions under HIPAA, as well as state privacy law compliance. Most state and local areas have responded to HIPAA Privacy provisions, so the RHIOs would build on these efforts to review and document their own HIPAA compliance.

- There is no entity charged with setting privacy and security standards under HIPAA, unlike designation of X12N and SDOs for transaction standards, leaving the Office for Civil Rights and CMS to sort it out and create DHHS guidelines. Also, requirements between and within federal and state laws need to be consistent to assist industry to establish common standards for privacy and security.

Laws/Rules	Considerations	How to address
HIPAA Privacy and Security regulations	Include other entities who may have use of the information made available via the NHIN to be covered under HIPAA, e.g. workers comp, life insurance companies, etc.	Expand HIPAA Privacy and Security regulations to all NHIN users
GLBA	Consumers are allowed to opt out of disclosures to non-affiliated third parties Modify this law for medical services at least for a period of time to enable RHIN to establish its foothold	For insurers, states were allowed to pass enabling laws; all state laws may not be the same
Mental Health Federal Laws	- Currently require patient authorizations for disclosure of medical information - The laws requiring patient authorization for disclosure must be updated to enable interoperability. - Patients may not authorize disclosure, creating potential gaps in medical information accessible via the NHIN that could hinder patient care	- Amend laws to make it consistent with the objectives of NHIN - Level set expectations that accessibility to information does not replace human elements such as patient input and professional judgment
Laws related to minors	These laws vary from state to state	Obtain state operation to collate laws or issue federal preemptive laws to override variations
AIDs and HIV related laws	These vary from state to state	Either the federal government must pass preemptive laws or the laws of each state must be collated.
Privacy considerations	While most of the envisioned users of a health information network will probably be covered entities that are legally	- There needs to be a way to control the use of information only for the purposes stated when the information was collected or given.

Laws/Rules	Considerations	How to address
	obligated to comply with HIPAA, there will be non covered entities that may have access to the network that are not obligated to comply with HIPAA. Examples include workers comp, auto/life insurance companies, etc.	Information could potentially be used for purposes outside of the authorized purposes - Access control requirements; searches for individuals by last name and first initial, for example, cannot be allowed - The Privacy Rule requires an accounting of disclosure of information for certain purposes including law enforcement, public health activities and health oversight. Access and disclosure will need to be logged and reported - Infrastructure will need to be set up so that it can respond to individuals' rights to access, restrict access, and amend their information - Confidential communications – individuals whose lives are endangered have their information protected. The infrastructure will have to be able to protect the information to the same degree
Security	- Decentralize access control to regional accountable entities with accountability to a central national entity - Work with stakeholders and others to align authentication of individuals (for example Smart ID cards) - Classify information into various levels for appropriate privacy and security controls - Manage indexing or identification keys to authenticate NHIN users and data indices at a national level - Promulgate standards for data security and technology at a national level - Decentralize authorization to access medical data at point-of-care EMR via explicit provider and patient approval	- Potential identity theft and health care fraud - Costs and administrative burden - Potential liabilities of information providers

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

A successful NHIN framework will have to address concerns surrounding legal liability in order to achieve HHS' objectives. The technical aspects of a framework will be fairly easy given the current state of technology; however, the procedural and legal policy issues are complex. NHIN objectives will be achieved if health care stakeholders are rewarded with adequate incentives. Federal policy to encourage broad participation and implementation of non proprietary infrastructure should come via agreed upon technology, data, and interoperable standards including:

National standards for transactions and formats including:
- Definitions for acceptable and practical solutions / standards for security, privacy and maintenance of those definitions.
- Enable the use of the Internet for secure and private data interchanges.

Carrots	Sticks
- Financial incentives such as tax credits, insurance discounts, designated vendor solutions of choice - accredited, group purchasing options, and reimbursement uplifts - Operational efficiency gain through value added services; e.g. medical record management to claims management - Accreditation advantages - Consumer (educate consumer) demands for integrated care	- Government mandate - Tax levy on non-participating entities - Accreditation discounts - Authority (Medicare or insurance carrier) to withhold payment for redundant services (such as lab tests) if medical information can be obtained via the NHIN

Management and Operational Considerations

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

- Incentives and/or clear business case for developing and participating in NHIN must be made in the private sector. The federal government can facilitate this through tax incentives, accrediting/certifying NHIN vendors, etc.
- Provide for EMR certification that vendors can apply for and demonstrate ability to meet minimal NHIN integration/interoperability standards. Vendors will move to standards to ensure retention of market position.

Potential private sector competition	Encourage private sector involvement
- Leverage sector participation via tax incentives For example, private sector in Hawaii could be addressed by tax relief for companies developing software (Act 221) to achieve NHIN / RHIO interoperability - Incorporate existing services into NHIN model - Allow time for private businesses to reshape their business based on potential changes brought on by NHIN - Leverage health insurance companies (with incentives or compensations - where most health care dollars go) to help influence private sector competition	- Tax credits or seed money to help shape private business development - Allow adequate regional autonomy – provide business opportunities for vendors to build specialized solutions to meet regional needs while meeting the minimum necessary requirements to interoperate with the NHIN

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

There is no clear business case for providers. Most providers are still struggling with integrating silo'd systems and installing EMRs, and refining their revenue cycle systems to help offset the effects of declining reimbursements. If a business case cannot be made to key funding groups (providers, payers, employers) so that they pick up the cost, private investment will not be possible.

- Keep the patient data decentralized.
- The federal government should dictate the minimal data standards.
- Create an EHR certification to encourage vendor compliance and have them build in the integration into their products to guarantee the data exchange capability.
- Drive the standards at the national level and drive vendors to adopt these standards and interoperability. Allow for "best of breed" solutions within established NHIN standards to develop over time at the regional level – bottom-up approach.
- The improved accessibility of data to the patient could help drive effective online services custom-tailored to the patient.

Evolve from private investment	Available in public domain	Country-wide interoperability	Foster market innovation
- Start from basic administrative business such as medical record management. - This is where the formalized medical records begin and issues that providers find most burdensome	Web-based services with standard electronic data interchange requirements	Involve nationwide players such as Blue Cross Blue Shield Association, Kaiser Permanente, pharmaceutical companies, Medicare, etc.	- Enable document management, practice management, and EMR technologies to be more affordable for increased adoption - Create business incentives - Create standards adoption incentives
- Leverage federal government health plan information	Make it easier to share information without privacy and anti-trust burdens	Leverage existing working relationship between government agencies	Streamline governmental information requirements
- Leverage existing technology	Partnership with companies like Google, Microsoft, etc. It makes sense to learn from others who have already paid	- Leverage national based technology talents - Leverage the Internet	Provide employment opportunities

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?

- Access to information needs to be secure, scalable, with little to no cost. Most private physician practices cannot afford the cost of EMR systems.
- NHIN should not repeat the mistakes of credit reporting system and report development. These include consumer (patient) information that is not easily accessed by the individual, and personal information that may be shared between other business organizations, without the individual's knowledge and express authorization.

Establish	Delivery	Use
Central NHIN	- Establish centralized switching station for all requests between RHIOs - No central repositories, except for minimum data elements to enable indexing and interoperability	Internet
Central RHIOs	- Establish centralized switching for requests within the region and to the NHIN - RHIO either routes the requests directly to the entities within the region or to NHIN	Internet
Provide tools to standardize medical record capture and management Provide network for communication	Public network such as Internet via regional portals	- Training - Initial Support - Incorporate into formal medical care related training

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?

NHIN impact to info exchange	Issues	Potential resolutions
Higher adoption of standard health information technologies to drive better quality of patient health care through increased accessibility to medical information, reduction of avoidable medical errors, and access to current medical treatment advances	- Refinement of security, technology and privacy standards for interoperability - Industry investment in and transformation in use of technology, especially in primary care and rural settings	
Different philosophy, design, technology used by NHIN	- Additional burden to community and regional health information exchange projects	- Aids - Funding - Allow transition period
Additional re-engineering work	- Resources - Market share protection and competition	- Ease current administrative burden by providing tools, training and other resources - Required federal participation through incentives

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?

Effect	Market opportunities	Benefits	Implications
Standards of care	Development and maintenance of such standards	Leverage learning from others Providing the clinician and patient with better information relating to treatment of the patient	Inability to provide business value by differentiating care levels Improved patient care Reduced health care costs
Technology	Greater opportunities for the technology industry – allow vendors to compete on functionality and standards, across larger markets	Additional demands for technology	Shifting health care dollars to technology May narrow the major technology players May increase niche technology companies
Employment	Business opportunities for technological development Challenges faced by health care providers in administrative costs	Job opportunities for both hardware and software Ease administrative burden	Further eliminate low level jobs such as medical record filing Eliminate needs for unskilled labors in administrative areas
Health care provider	Provide information to support treatment of patients in remote locations	Ability to access basic patient information that may not be accessible today to support treatment	Challenge individual practitioners who may not have the needed technology resources
Insurers and Employers	Savings can be re-directed to further improve health care inefficiencies	- Savings in redundant work ordered by different providers - Savings in reduction of medical errors	Medical dollars maybe redistributed cross regional boundaries based on performance metrics

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?

- Use existing standards and established standard setting groups – WEDI, X12, ANSI, HL7, AHRQ, CDC, NCVHS, etc. HIPAA demonstrated that this can be accomplished – do not add additional standards setting entities. The SDOs (Standards Development Organizations) will continue to develop standards, as defined under HIPAA.
- The NHIN would recognize the standards promulgated by the SDOs and establish the minimum standard thresholds that a RHIO must adopt in order to be a RHIO.
- RHIOs would participate with the SDOs to assure information and technology standards at the local / regional level are translated into national standards and to avoid localized and non-uniform approaches.
- Interoperability needs to be developed around the Internet.

Type of entities	Characteristic	Existence
Coding standards such as ICD, CPT, etc.	- Independent	- ANSI - AHIMA - NCVHS - NAHDO
Standards of care	- Independent - Supervisory - Industry respected	- JCAHO - AHRQ - AMA - AHA
Network standards	- Independent - Represented by key players in the industry	- IEEE
Efficiency standards	- Independent - Industry respected	- ISO - NCQA - URAC - JCAHO - AHA
Operating standards (e.g. Service level agreements)	- Mandatory	- JCAHO - NCQA - URAC - AMA - AHA

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.

- Drive NHIN national standards through HL7 down to the data element and create an EHR certification process for vendors. The certification should include requirements for an external interface to support the RHIO/NHIN queries.

- Each RHIO should have a mechanism for resolving MPI issues with minimal overhead at minimal cost and bureaucracy.
- Standardize the SSL/TSL methodologies and certificates to make secure transmission easy between entities.

Establish and manage by	Ensure un-bias and free of undue influence
- Governance body comprised with representation from involving industry such as technology, health care, government, legal, consumers - Representation to be elected by industry groups or public non-partisan forums - Public input	- Voting rights by non-partisan representatives only

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?

Carrots	Sticks
- Preferential treatment to do business with government	- As a requirement to do business with government
- Tax breaks	- Tax levy
- Accreditation	- Potential public scrutiny
- Public demands (campaign to educate public that it is a good thing if their health care providers participate and supports the NHIN	- Potential public discriminations
- Ability to work with (input to) industry standard groups to maximize coordination and participation	- Mandatory compliance with standards established - Potential sanctions for non-compliance

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?

- Do not reinvent the wheel – use existing standards and established standard setting groups – WEDI, X12, ANSI, HL7, AHRQ, CDC, NCVHS, etc. HIPAA demonstrated that this can be accomplished.
- Licensing requirements
- Accreditation / certification requirements
- Revise Stark Laws to facilitate greater information flow integration in health care
- Rules for patient identification algorithm
- HIPAA EDI continuation
- Further refine/clarify HIPAA for use of medical information for treatment, payment, operations, and research
- Leverage insurance companies to incorporate requirements for claims

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?

The federal government should be the primary facilitator of NHIN/RHIO standards adoption through use of incentives - monetary, cost reduction, and certification to make NHIN interoperability adoption advantageous versus mandating the development/use of NHIN.

Roles to take	Roles to refrain from
- Provide incentives - Provide enforcement and support to ensure people play fair - Provide oversight to ensure that NHIN is used appropriately and not abused - Ensure undue burdens / incentives are not created for individual segments of the health care continuum - Accountable for overall ROI and performance - Oversee financial soundness to ensure NHIN sustainability - Participate as a RHIO and participate with other RHIOs to establish and maintain NHIN	- Interfere with how care should be delivered - Use information provided against information provider - Share information with other agencies who may use information against participants

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?

Yes, financial incentives are essential for NHIN adoption within the next 10 years. Health care providers and payers have not realized the monetary benefits estimated by HHS to implement HIPAA, and continue to struggle with negative to no margins to meet increasing financial demands to survive in a highly regulated and costly industry. Even for non-profit health care organizations, finance is a key driving force for survival. Patients and providers (physicians, etc) are the key NHIN stakeholders who will drive NHIN adoption.

Consider aiming financial incentives primarily at providers of health information to create a natural demand that will drive relevant private information technology vendors to participate in an available, open, and interoperable NHIN. Financial incentives do not have to be solely from additional gains, it can be from reduction of existing costs.

Types of incentives	Who/What	Restrictions/limitations
- Tax incentives – for using standard health IT solutions - Cash discounts – for health services, drugs, etc. through NHIN - Vendor EHR certification – no provider will invest in a system that is not on track to the have this certification and baseline NHIN standards	To insurance carriers To employers To providers To patients To vendors	Potential discrimination suits Potential Administrative burdens
Seed money	- To fuel participation with NHIN / RHIN as a requirement of doing business - quality of care improvements - To drive standardization of medication records and appropriate medical information sharing	Administration of seed money in a fair and consistent manner
Enhanced Medicare and Medicaid reimbursement	To providers	Potential Administrative burdens
Ease of administrative burden	Minimize existing health care organizations' regulatory reporting	NHIN to provide automated means to extract needed medical information to reduce the costs associated with regulatory reporting and gathering of medical data needed for patient payment/treatment purposes.

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?

- Lifting regulatory or regional reporting requirements – Let NHIN extrapolate information from shared information
- Direct federal funding to states supporting NHIN initiatives
- Increased reimbursements rates
- Provide "standard" NHIN technology and implementation support at minimal cost through federal programs/subsidies and federal cooperative vendor arrangements

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?

Yes. Some HIPAA and statutory requirements seem to be at odds with the goals of a NHIN; especially the far-reaching privacy regulations.

The federal government should work with states and accrediting agencies, like JCAHO, NCQA for example, to make NHIN objectives consistent and a priority for accreditation for doing business as a U.S. health care organization. Federal leadership to resolve consistency issues between privacy laws and therefore the liability for health care organizations to disclose patient data for appropriate patient care and payment for health care services while protecting patient data. There are currently too many risk liabilities and nearly impossible technology challenges for a viable NHIN under existing state and federal privacy laws.

Regulations	Barriers	Supports
HIPAA Privacy and Security regulations	Fear of adverse employment decisions Lack of security standards for technology sector's "appropriate" NHIN infrastructure	- Allow health plans (which can include self-funded plans set up by employers) to receive detailed claims information if such information is placed into a regional or national repository, it should be clear that information from periods before and after current employment may not be accessed - Consistent implementation of standard technologies and security measures to drive community confidence in and therefore use of NHIN
GLBA	Consumers are allowed to opt out of disclosures to non-affiliated third parties	If we want a national database this will have to be modified. For insurers, states were allowed to pass enabling laws; all state laws may not be the same
Mental health federal laws	Currently require patient authorizations	Authorization requirements in the laws may need to be updated or changed as patients may not authorize disclosure; creating incomplete treatment information.
Laws related to minors	These vary from state to state	Either the federal government must pass preemptive laws or the laws of each state must be collated
AIDs and HIV related laws	These vary from state to state	Either the federal government must pass preemptive laws or the laws of each state must be collated

Alcohol and substance abuse laws	These vary from state to state	Either the federal government must pass preemptive laws or the laws of each state must be collated
Privacy	Not all potential NHIN users are subject to Privacy laws e.g. pharmaceutical companies and non-covered health care organizations. These vary from state to state	- Review federal criminal statutes to strengthen violations of privacy and security that might occur on NHIN. - Provide national assistance to individuals who might suffer from a violation of privacy or security that might occur on the network – e.g. identity theft across state lines
Antitrust and Stark laws	- If information is improperly used. Risk of increased antitrust sanctions and/or legal fees for participants - associated with a widespread and interoperable NHIN model - Inhibits providing bundled EMR/Billing software to private practitioners at free or at heavily discounted costs to private practitioners.	- Enable community private practices, employers, laboratories, hospitals, and payers to leverage EMR/Billing technology infrastructures for secure NHIN/RHIO communications.

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

See discussion in #21 above

Other

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

Non-proprietary	- Open architecture to keep implementation costs low
Broad user availability	- Investment to participate must be minimum or at no cost - Technology must be easy to use and to install – scalable
Decentralized network	- With local hubs to facilitate within region traffic - With local administration to administer backup and maintence
Centralized indexing – for example MPI at the RHIO and HNIN levels	- To facilitate linkage of information across regional boundaries
Centralized technology standard administration – NHIN and RHIOs act as the query clearinghouses	- Oversee technology interoperability - Allow open technology choice – encourage building of bridging technology - Require a standard query that allows qualified healthcare organizations to securely access other participants' EMR
Decentralized data storage (at entity level)	- To facilitate ease of retrieval - To accommodate regional data requirements including state requirements

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?

Measurement	Based on
Usage	- Participation - Timeliness of information
Linkage	- Hits - Successful hits - Available medical information from more than one source (why NHIN is needed)
Administrative savings by participants	- Surveys - Tax Returns - Establish best guess metrics. Example metrics could include organizational, personal, and national ROI savings-per-transaction. To clarify, if each NHIN query saves $1.60 (based on reduced time to track down information requested, reduction of medical error costs, unnecessary laboratory work and other procedures, etc.), estimate the annual cost savings and compare to the investment made to participate in NHIN.
Quality of Care	- Quality of Care programs by insurance carriers, federal agencies (AHRQ) - Comparison of key indicators for increases/decreases in health conditions, by geographic area - Reduction in rate of medical errors - Improvement in patient satisfaction metrics - Reduction in rate of unnecessary procedures - Reduction in numbers of underserved areas
Impact on health care costs	- Reduction in overall cost in providing health care nationally, by region, by service areas for examples - Reduction in health care related insurance premium rates with static or better coverage