

**CENTER FOR COMMUNITY-BASED HEALTH INFORMATICS
Primary Care Coalition of Montgomery County, MD, Inc**

RESPONSE TO:

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 :

Responder

The Center for Community-Based Health Informatics (CCBHI) is a team of experts within Primary Care Coalition of Montgomery County, MD, Inc (PCC), a non-profit organization focused on assuring access to health care for Montgomery County's 80,000 uninsured, low income residents. CCBHI approaches the need for improved quality of care in the safety net world by *providing an informatics infrastructure* for the county's independent, non-profit safety net clinics which:

- 1) *increases clinician access* to patient and other medical information,
- 2) *links the multiple safety net clinics together* into a more seamless system of care, and
- 3) *plans for the electronic linkage of the safety net system with mainstream healthcare*, including area hospitals, labs and specialty providers.

CCBHI has made progress on these three fronts with the help of grants from HRSA (a single, shared Electronic Health Record system has been developed and implemented in 22 locations with additional clinic implementations funded by the county), NLM (a clinical desktop, with Internet access to medical sites, is being deployed), and AHRQ (CCBHI has an AHRQ planning grant to plan the linkage of metropolitan DC safety net clinics with area hospitals, labs and specialty providers). With this background, CCBHI offers the following response to this Request for Information and offers to provide further support as deemed appropriate by ONCHIT for this critically important endeavor.

General

1. **The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned,**

and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this RFI regarding interoperability.

Response: The NHIN is both the technology and governance infrastructure that enables three objectives: 1) *real-time point of care access* to patient health information from all healthcare providers participating in Regional Health Information Organizations (participating providers), 2) *patient-centric aggregation* of health information from all participating providers into a patient-owned model (e.g. patient smart card) and 3) *de-identified aggregation for public health* for improvement of public health, including bio-terrorism surveillance. The governance and technology models for these three objectives have different requirements:

- *Real-time point of care access* supposes a model that is fully federalized, where providers who originate protected health information (PHI) are the only ones who own and hold that PHI (the PHI is not centrally owned by a RHIO or the NHIN). This PHI is accessible on a real time basis by another, unaffiliated provider (a requesting provider) assuming that both are affiliated with RHIO's (although not necessarily the same one). Originating providers for matters of convenience may choose to maintain PHI in shared databases, such as a database managed by the provider's RHIO, or an exchange within their RHIO, however the PHI remains nevertheless the responsibility of and controlled by (through database administration and governance regulations) the originating provider, not by the RHIO or NHIN. In this respect the originating provider maintains responsibility for the PHI, including under what circumstances the PHI may be shared with a requesting provider. The originating provider thus is the responsible link between the patient (who authorizes the originating provider to share the PHI) and the requesting provider.

An assumption is that personal verification between requesting and originating providers may not be practical because of the real time nature of the process. This necessitates a governance model addressing **sharing of trust** between a requesting provider and originating provider, specifically authenticating the identities of the requesting and originating providers, the veracity and authenticity of the PHI and the method for correct patient identification. The governance model must also address **medical malpractice liabilities** associated with the requesting provider's use of external data (data collected and categorized by others with whom the requesting provider has no legal relationship).

The technology model must address issues of **data format standards** to ensure proper interpretation of external data by the requesting Electronic Health Record (EHR). Note the assumption that the external data is brought into the requesting EHR system, not simply displayed separately to the requesting provider. This process requires significant changes in EHR's such that external data can be tagged as external and displayed despite data format differences. The NHIN must establish a complete set of data standards (what the data is and how it is formatted) to facilitate this, but differences will exist wherever the data standards permit choices. For example, if an originating EHR collects body temperature in degrees Fahrenheit, while the requesting EHR only handles temperature in degrees Celsius, then the requesting EHR must be changed to either convert the external

data or convert the internal data, such that the EHR displays data consistently to the provider, uses consistent data in alerts and other decision support algorithms, etc.

The technology model must also address issues of **data exchange standards**, such that an EHR that is able to exchange data within its RHIO can also exchange data with any other EHR in any other RHIO. If all RHIO's adopt the same EHR data exchange model then the NHIN could use an exchange model that facilitates direct EHR to EHR exchange without requiring an intermediary NHIN application for data switching/interpretation. This would be a far preferable model, similar to the model of the Internet, where a browser speaks directly to a web server, with "the Internet" providing the single model for the lower layers of infrastructure (data exchange protocols, security protocols, naming and location protocols, etc.), obviating the need for a centralized application to perform data switching/interpretation between the browser and web server. However if RHIO's adopt varying models for data exchange, then the NHIN would likely be required to have the much more complex technology model of a centralized application (many of them actually, to handle the volume of exchange) that would handle the differences between the data exchange standards of the originating and requesting EHR's. To understand the differences in degree of difficulty and ultimate effectiveness of these two approaches, one needs only consider where online activities such as banking, buying, information searching, etc. would be if the Internet model for data exchange had instead been one where a centralized application was required to handle the differences between varying browsers and varying servers instead of establishing a single exchange protocol to which the browsers and servers conform. A major hurdle to proceeding with the dramatically simpler model for the NHIN is the establishment of a common standard of data exchange for all RHIO's to adopt. This is likely to happen only if ONCHIT or another arm of the federal government establishes that standard and ensures adoption by RHIO's.

The NHIN model recommended is one where

- *RHIO's are certified as abiding by interoperability standards, policies and operational guidelines promulgated by the federal government and chartered standards groups.*
- *EHR's within federally certified RHIO's directly exchange with other such EHR's without a NHIN application in the middle – the Internet model of direct server-to-server exchange.*
- *The NHIN operates authentication services (for providers and provider organizations) and naming/uniqueness services (identification for RHIO's, provider organizations, and providers) to support RHIO-to-RHIO interoperability.*

The technology model must also address the issue of **patient identification**, such that a requesting provider will be able to determine with near 100% assurance that the data presented by an originating EHR does in fact belong to the patient at hand. The assumption here is that in many practical examples, such as a patient admitted to an hospital's emergency department, there will be no prior linkage of patient identity between the requesting EHR and external EHR and therefore the patient identification

must be made on a real time basis, without necessarily the benefit of discussion between the requesting and originating provider. This places the burden of patient identification on the requesting provider, the patient and the technology of the NHIN/RHIO patient identification model. RHIO's may evolve various patient identification models; it is critical that the NHIN institute interoperability standards between such models so that a requesting provider, using their RHIO, will be able to initiate a check against other RHIO's Master Patient Index's (MPI) without requiring an intermediary NHIN MPI translation application.

There are additional capabilities that may be required for real time point of care access of PHI that may require capabilities within the NHIN, for instance there may be a requirement for secure messaging between requesting and originating provider.

- ***Patient centric aggregation*** supposes a model where a patient can aggregate most (certain data will be excluded) of their PHI locally and permanently for their use. CCBHI assumes that much responsibility will rest with the patient: the patient will initiate aggregation and will be required to request PHI from specific providers rather than requesting data from all possible sources. While there are several governance and technical models that could be deployed for this, there is little precedence. CCBHI therefore describes a model that would place limited responsibility (and therefore limited functionality) with the NHIN and instead rely on more sophisticated patient centric aggregation applications.

The governance model for patient centric aggregation might consist of a simple User Agreement for both the patient and originating provider, where the patient agrees to be responsible for identifying himself/herself to the provider in a means the provider can accept (face-to-face, secure email address, federally sanctioned digital certificate, etc.), and agrees to be responsible for proper aggregation. Proper aggregation by the patient's Personal Health Record application includes the ability to overlay prior data and recognize new data, as well as convert data into the PHR preferred method. (For example, the PHR would convert Celsius into Fahrenheit so that longitudinal decision support functions use consistent data).

The technology model for patient centric aggregation should leverage directly on the real-time point of care access model, described above. This should be possible given the federated, Internet model described above.

- ***De-identified aggregation for public health*** requires a model that centralizes selected data on a regular basis, rather than the model of requesting PHI for specific patients on a real-time basis as described above. The NHIN network for de-identified aggregation will need to address additional difficult technical issues as well as new governance issues.

The primary governance question to be addressed is whether RHIO's will be *required*, as part of the operational guidelines, to perform regional de-identified aggregation such that the federal government will work with regional data that has already been de-identified and aggregated. In this case the role of the NHIN will be one of aggregating a relatively

small number of regional databases that have been pre-processed and de-identified. Alternatively, the NHIN could avoid requiring RHIO aggregation and instead perform the collection, de-identification process and aggregation from all providers in the country – a decidedly much more difficult technical and operational task, and one which because of a “big brother” notion, may not be politically viable.

The technical issues to be addressed will depend on the above question of RHIO aggregation. If RHIO’s are not required to aggregate, then the technical issues facing the NHIN will include: 1) determining an acceptable technical and operational burden of effort on each EHR in the country requiring each to establish a process for extracting PHI data and delivering to the federal government via the NHIN. The data format and exchange standards defined for *real-time point of care access* should be acceptable. 2) Determining whether the federal government or the originating EHR will be responsible for the method to be deployed to avoid duplicate data (while this might sound trivial, it is likely to be a significant effort). 3) Determining the mechanism for linking records from disparate systems to a single patient. This correlation algorithm will likely be different from that used in the *real-time point of care access*, since 100% assurance of correct linkage is not required and provider-to-provider verification would not be practical.

It is apparent to CCBHI that *de-identified aggregation for public health* will require a different set of governance and technical solutions than those needed for either *real-time point of care access* or *Patient centric aggregation*. It will be incumbent on the architects of the NHIN to search for commonality to keep the resulting impact on providers and RHIO’s as straightforward and implementable as possible.

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

Response: As we look to *best practices* to help define a model that will in fact be adopted and result in the desired outcomes, there are successes and failures from which to learn. A most obvious success is the phenomenal use of the Internet, where key lessons include:

- 1) Establish bodies of authority to handle the expected need for standards.
- 2) Establish open (not proprietary) standards for all exchange and program interface. Http, https, html, xml, smtp, imap, etc. were set such that interoperability is readily achievable amongst proprietary as well as open source commercial applications that play a key role in the use of the Internet.
- 3) Recognize the need for uniqueness and from the beginning establish the means to ensure uniqueness. Email address uniqueness and URL uniqueness are two different models where uniqueness was a critical factor in the growth and use of the Internet.
- 4) Tackle security issues by embedding security into lower layers of the process. Here the Internet model shows an example of doing it right (HTTPS was an early, well defined,

yet flexible security protocol that kept the implementation relatively low in the protocol stack enabling commercial applications to readily use it), and an example of missing an opportunity to doing it right (email protocols came close to including requirements for secure/authenticated connections between mail servers, but did not implement this, to the delight of the spammers).

- 5) Keep the centralized infrastructure to a minimum; push as much “application work” to the edges (users and servers). The decision to have the Internet be just the connectivity, with applications “hung” on rather than embedded, has been a key reason for the rapid growth of applications by entrepreneurs. The rapid rise of Google is an excellent example of this – the Internet does have the low level IP address search capability necessary for interoperability, but does not have an (unnecessary) embedded application level search, leaving this “edge” function to be evolved (more effectively!) by others such as Google. The Internet model pushes as much to the edges as possible, while focusing its internal functions on enabling the edge players to prosper.

There are numerous examples of attempts to build proprietary, application-heavy data exchange capabilities; to the extent that they were successful (and many were) their ability to sustain themselves in the market has all too often depended on proprietary lock rather than value to the users. The lessons to be learned from these are for the most part the inverse of those above.

If we accept these notions of lessons learned, the NHIN will:

- **Establish standards committees** (or charter existing ones) to define complete (as in, nothing else is needed in order to...) standards for data format, exchange protocols, naming conventions, uniqueness protocols, de-identification processes, provider and user authentication (for within RHIO requests for PHI as well as RHIO-to-RHIO requests), and other topics as may be required.
- **Establish governance models** for NHIN behavior, including the topics of sharing of trust; managing medical liabilities; relationships between NHIN and RHIO's, and federal agencies who use (have applications “hung” on) the NHIN such as CDC.
- **Establish required activities of RHIO's**, such as aggregation of de-identified health information (should it decide on this model), acceptance of requests for PHI from providers outside of the RHIO participants.
- **Engage the private sector, NGO's and stakeholders in the federal, state and local governments in the above deliverables.** It is important in CCBHI's opinion to be certain that the stakeholders' business objectives be considered, but not viewed as primary objectives (the primary objectives are described in the July ONCHIT HIT Strategic Framework document). Had the Internet committees for example decided to consider Microsoft's and IBM's business objectives as primary, would the entrepreneurial/competitive spirit have been engendered to the extent it has? Would Google be here today? Or Internet banking linked to QuickBooks? The fine line that needs to be walked is to include the private sector, to understand the impact of NHIN directions, solicit private sector support and position the private sector to respond quickly to NHIN needs, and at the same time not to confuse private sector objectives with the objectives driven by *real-time point of care access, patient centric aggregation and de-identified aggregation for public health.*

The model for the NHIN will be a composite as necessitated by the requirements of the three above-stated objectives. CCBHI's premise is that the most effective model will have a national health information infrastructure consisting of:

- RHIO's which behave at the edges, from a governance and technical perspective, *identically to each other*, such that a great deal of learning/sharing can be done across RHIO's, facilitating availability of standardized software and governance agreements, and such that interoperability directly between RHIO's is facilitated. As RHIO's all appear the same (except for content) from the outside, the challenge of managing a centralized NHIN is dramatically reduced.
- A NHIN which enables the exchange between one RHIO's EHR and another RHIO's EHR, through:
 - **Standards, Policies and Operational Guidelines.** NHIN will manage or charter other organizations to manage data, exchange and uniqueness protocols, policies and operational guidelines as the framework for construction of certified RHIO's and the NHIN.
 - **Authentication Services.** NHIN will manage or charter other organizations to manage services to authenticate all users within the NHIN, such that a requesting provider of one RHIO will be authenticated, through these NHIN services, to the originating user (who owns the requested data) in another RHIO. Other approaches for authenticating users, which are not preferable and not recommended, include 1) RHIO-managed authentication services, which could be dissimilar, where requesting and originating users could be authenticated by their RHIO, with NHIN Authentication Services providing RHIO-to-RHIO trust sharing to enable this end-to-end authentication and 2) Provider-managed authentication services where the provider organization provides user/provider authentication, which is then shared first within the RHIO authentication services and then within NHIN services. These two alternatives will be more difficult to manage cross-RHIO interoperability due to the variation of authentication rules.
 - **Naming/Uniqueness Services.** NHIN will manage or charter other organizations to manage Naming/Uniqueness Services for RHIO servers, provider organizations, providers, MPI indexes, and other elements requiring uniqueness within the RHIO/NHIN architecture.
 - **Master Patient Index Services.** The recommended model is for the NHIN to not be required to have operational responsibility for any MPI Services, but instead to facilitate direct RHIO-to-RHIO MPI interoperability through the use of standards for MPI structure and interoperability. The alternative of having an NHIN MPI translation service for MPI transactions between RHIO's places an unnecessary coordination and operational burden on the NHIN. RHIO MPI interoperability will require that MPI exchange protocol and index structure standards be promulgated rapidly by the NHIN to prevent multiple, non-interoperable MPI models being adopted by RHIO's.
 - **Centralized Databases of De-identified Aggregated Information.** The NHIN will likely be required to be responsible for the databases of de-identified aggregated data, including the operational collection, screening for duplication, de-identification process (if not performed by the RHIO's) and other data

management activities. If the de-identification process is the responsibility of the RHIO these NHIN responsibilities will be more limited, although the value of the data may be compromised by the inability to 1) link de-identified data to a single patient across multiple RHIO's, and 2) link de-identified data from differing time periods to a single patient. An alternate approach which requires the maintenance of identifiable patient data in a central database (to permit aggregation from different time periods and different RHIO's) may however be politically unacceptable.

- **Lower level infrastructure.** The NHIN should utilize the Internet, including Internet connectivity, secure transport protocols and web services to minimize costs and complexity of implementation of the three objectives.

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

Response: The following is a tabular view of the national vs. regional roles as recommended above:

| Aspect | National | Regional |
|--|-----------------|-----------------|
| Establish required activities, operational guidelines for RHIO's | X | |
| Establish interoperability standards for RHIO's | X | |
| Perform Authentication, Naming/Uniqueness Services | X | |
| Perform MPI interoperability | | X |
| Perform Health Information Exchange | | X |
| Perform Patient Singularity (link disparate records) | | X |
| Perform De-identification process | ? | X |
| Maintain De-identified databases | X | X |

Organizational and Business Framework

4. What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Please describe the kinds of entities and stakeholders that could compose the framework and address the following components:

- a. **How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?**

Response: To develop the model for a NHIN, both NHIN and RHIO models should be developed in concert, so that the role of the RHIO's is to perform health information exchange through standards interoperability, while the role of the NHIN can be positioned as the lower level facilitating infrastructure (authentication services, uniqueness services, etc.) much as the Internet is to e-Commerce. To achieve this,

stakeholders for both RHIO's and a NHIN must be included in the model development. A single location in the federal government (ONCHIT, presumably?) could have the responsibility/accountability for establishing these models and could do so through working groups comprised of representatives from a) RHIO-like pilots/projects such as MASHARE, the Regenstrief project and OpenHRE, b) the spectrum of healthcare providers (hospitals, HMO's, Specialty clinics, Safety Net clinics, lab services, pharmacies) c) public health agencies (CDC, FDA, AHRQ, NIH etc.), d) appropriate current standards committees (ANSI, ASTM, W3C, etc.), e) other parties, such as Markle, which have interests in/knowledge of healthcare interoperability processes.

Accomplishing the construction of the NHIN will depend on the degree of success in establishing an interoperable model for RHIO's. If the models (NHIN and RHIO) are developed as recommended, then the construction of the NHIN should be considerably more straightforward than if the interoperability of RHIO's is less successful. Current vendors in the healthcare field, such as those providing EHR systems and insurance data exchange, should be consulted, but care should be taken not to consider their business objectives to the detriment of the three primary objectives of the NHIN articulated above. Rather, include their inputs as they relate to determining costs, degree of difficulty, and likelihood of success of implementing aspects of the models that impact their businesses. Include vendors to other markets as well, for example vendors providing authentication services to the banking industry, in order to gauge feasibility of construction of new elements of the NHIN. A Reference Implementation of both the NHIN and RHIO, deployed to verify completeness and correctness of the model, protocols, etc. will be an invaluable step in assuring success of the models, and will be an invaluable tool in qualifying software systems as interoperable.

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

Response: Policies, standards and operational guidelines (for development, use and operation) could be set by working groups responsible for both the NHIN and RHIO (combining the promulgation of both NHIN and RHIO policies and standards will maximize interoperability between RHIO's, as described earlier). Working groups could be established either within the domain of the federal government, or externally in existing standards groups if chartered by the federal government, where their charters will be to develop and maintain policies and standards for all aspects of NHIN including trust sharing, liability management, authentication services operation, data standards, etc.

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

Response: The best approach for accelerating the adoption of use of the NHIN, in CCBHI's opinion, is to *provide motivation to the users* and at the same time *simplify the effort required to use the NHIN and promote formation of RHIO's*.

- To *motivate users*, an education effort could be effective in encouraging provider organizations to join their RHIO. Financial encouragement by the

federal government where it is the health care payor (CMS and federal employee plans) could encourage provider organizations to join their RHIO.

- Implementing the recommended model should *simplify the effort required to use the NHIN*. The high degree of structure in the model for RHIO's to facilitate direct RHIO-to-RHIO interoperability should minimize or eliminate the amount of effort by RHIO's (and their users/providers) to extend their use of RHIO-based health information exchange across the NHIN. In this model, RHIO implementation de facto adds to the national deployment of the NHIN.
- The above-described model, which envisions a RHIO model with defined interoperability requirements, defined activities and a reference implementation against which to test RHIO piloting, will also *promote formation of RHIO's* by reducing risks, providing lessons learned, and enabling software and systems suppliers to develop standard, cost-effective offerings for the RHIO marketplace.

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

Response: The recommended NHIN model requires only a modest amount of "operation" by the NHIN, for activities such as authentication and naming services. These could be performed by private industry at the direction of the federal government or at the direction of the chartered working groups. Public health applications that utilize de-identified aggregated data will likely be owned and managed by the responsible federal, state or local governments.

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

Response to #5 and #6: Several financial models are possible including funding from: 1) federal sources for the NHIN and regional sources (from provider organizations, insurance carriers, state governments, etc.) for the RHIO's, 2) regional sources for both the NHIN and RHIO's where the participants in RHIO's are required to fund the NHIN as well as their RHIO, and 3) funds derived from provider organizations regardless of their participation in their RHIO (a tax on provider revenue, for example). In CCBHI's opinion, it is critically important to minimize the operations duties of the NHIN by establishing consistency of operations/interoperability across RHIO's, so that the NHIN funding models do not become drivers in NHIN architectural 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 considerations will be of paramount concern for the working groups chartered with developing the interoperability standards for RHIO's and the NHIN. These working groups should develop, in addition to the standards, a set of privacy and security *operational guidelines* for both the RHIO and NHIN models, where the operational guidelines have the federal government (ONCHIT?) sanction as meeting the requirements of federal regulations (HIPAA, and other pertinent regulations). Providing such sanctioned operational guidelines will provide a major benefit to RHIO's and all participating health care providers by reducing the variability and guesswork (and legal expense and delay) that is currently an unnecessary part of compliance to HIPAA regulations. RHIO's must also deal with State privacy and security regulations.

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

The above noted working groups must insist on having all elements of *interoperability* (data and protocol standards, as well as uniqueness models, authentication services, etc.) be deployed using public standards. The working groups should have broad representation and a clear mandate from the federal government (ONCHIT?) to meet the objectives of responsiveness, cost effectiveness, decentralization, etc.

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 NHIN opportunity for the private sector is significant and can be encouraged by 1) including representation from the private sector in the working groups, 2) developing the model for the NHIN and for RHIO's whereby existing private sector activities are incorporated (with the public standards requirement as stated above), such as use of commercially available digital certificates and authentication servers, and 3) establishing clear data/protocol/operating standards for commercial suppliers of EHR and other participating IT systems so that these suppliers will be able to develop profitable, replicable, supportable 'edge' applications that connect into the RHIO/NHIN infrastructure.

10. How could the NHIN be established to maintain a health information infrastructure that:

- a. evolves appropriately from private investment;**
- b. is non-proprietary and available in the public domain;**
- c. achieves country-wide interoperability; and**
- d. fosters market innovation**

Response: The majority of expense in the model described above will be in the modification of existing, commercial EHR/IT systems to handle the data exchange and other interoperability requirements of the NHIN/RHIO model. The investment needed for this "edge technology" is best to come for private industry; the model, along with the standards working groups must be focused on private industries needs (clear definitions of

interoperability, public Reference Implementations/test beds, etc.) to ensure that this area of major investment is viewed by private industry as having no more than an acceptable level of business risk. While any individual enterprise in private industry may want their proprietary 'lock' on the market, taken collectively private industry should embrace the model of open standards, particularly if viewed as the mechanism to accelerate acceptance and increase the market opportunity for all players. Market innovation can be fostered by pushing as much as possible out of the realm of the NHIN and into the realm of the edge applications, such as EHR/IT systems. Innovation in longitudinal, decision supported disease management will take place in these edge applications, leveraging the data acquired through data exchange across the NHIN/RHIO infrastructure. Country-wide interoperability will be achieved as a result of the model which enforces rules of operation and interoperability at the RHIO level so that any RHIO, regardless of where it is, will have interoperability across all other RHIO's.

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

Response: An assumption from the recommended model is that healthcare providers use their RHIO to access PHI from other providers. Therefore, in order for the NHIN to achieve national coverage and sufficiently serve the lower income areas and patients, including those who have no health insurance and rely on community safety net clinics, the NHIN should focus on 1) promoting widespread adoption of RHIO's, including establishing the RHIO framework of interoperability described above, 2) assuring that the RHIO "coverage map" of the country does not exclude rural areas, and 3) assuring that the requirements of the safety net environment are included in the detailed development of the NHIN architecture, standards and operational guidelines.

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

Response: RHIO exchange projects will, if the model described here is followed, be required to follow a considerable degree of standardization of operation in order that RHIO-to-RHIO interoperability is obtained. An assumption in the model is that only RHIO's which abide by these interoperability standards will participate in the NHIN; health information exchange projects (other than RHIO's) must therefore join their RHIO in order to participate in the NHIN. As a unit within a RHIO, these projects will have to abide by most of the same interoperability standards – this may require some re-engineering on the part of existing projects. It is critically important that the NHIN establish the RHIO interoperability standards as quickly as possible to minimize the deployment of exchange projects prior to promulgation of these standards to minimize re-engineering requirements. An example of the kind of re-engineering that might be required follows:

It is possible that interoperability standards might require that each RHIO's MPI contain references to other RHIO's patient indexes – in essence forming a federated MPI for the

entire country. This will require each RHIO's MPI to include fields for all other RHIO patient indexes – cross indexing between RHIO's -- to permit RHIO-to-RHIO search and exchange. This will likely require MPI's of existing exchange projects to re-engineer.

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

Response: Adoption of an NHIN that focuses on direct RHIO-to-RHIO interoperability and the required enabling standards, would have a positive effect on the health information technology market by 1) establishing an open standards approach for all of the edge technology players (EHR systems, Hospital IT systems, etc.) where suppliers compete on value provided within their applications rather than on proprietary interfaces, 2) the significant IT human resources required to implement US-wide RHIO deployment will benefit from having increased consistency of skills needed and 3) increased ability of IT vendors to sell into multiple markets, driving benefits for both the suppliers of IT systems (larger, more structured and predictable markets for software and services) and the provider organizations (more competition in those larger markets). The majority of the market will be for the edge products; the actual costs of establishing and perpetuating the NHIN should be minimized with the model described above, leveraging on the existing deployment of the Internet.

Standards and Policies to Achieve Interoperability

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

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

Response: The most important entity is a designated agency/office (ONCHIT?) within the federal government which will be responsible for:

- **chartering existing or new working groups** to develop NHIN and RHIO interoperability standards, define governance solutions (shared trust models, solutions to liability issues, etc.) and operate NHIN activities (authentication services, for example)
- **approving the resulting standards, policies and operational guidelines of the working group** to promote clear rules for deploying RHIO's and interoperability between RHIO's
- **certifying RHIO's** without which exchange of PHI between RHIO's can not take place
- **assessing needs within the broad healthcare IT environment** so that federal resources can be marshaled effectively.

Many other entities exist today that could participate in the development and diffusion of these standards and policies, including industry data standards committees such as ANSI and ASTM and organizations focused on healthcare IT. These entities should share the goal of open standards; private industry representatives should be encouraged, provided there is agreement to the open standards model. Standards that are not in the public domain should not be used, unless absolutely necessary; the use of CPT codes for instance is a necessity, although these are not in the public domain.

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

Response: There will be several working groups and standards committees required to develop the interoperability standards, policies and operational guidelines; each must be given a charter and direction from the federal government, and the federal government must be the final approving authority, so that objectives, such as in the question above (to protect against proprietary bias), can be met. A clear chain of accountability for these standards, policies and operational guidelines must be in place, with the federal government the final authority.

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

Response: The federal government, as the chartering and final authority on the standards, policies and operational guidelines, should charter existing SDO's wherever appropriate to perform the functions of the working groups.

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

Response: The federal government (ONCHIT or its designee) should certify each RHIO as meeting the standards, policies and operational guidelines; a RHIO reference implementation could be an effective mechanism against which to test compliance. Organizations that do not gain this certification should not be permitted to participate in the NHIN, should not be permitted to exchange PHI with certified RHIO's. Periodic re-certification should be built into the process.

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

Response: Recommended roles and relationships regarding standards, policies *and operational guidelines* are described 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?**

Response: Incentives may be needed for two organizations: health care providers and RHIO's. Health care providers may need incentives to help build the business case for joining their RHIO and funding the IT and other changes needed for health information exchange. The federal government, as the largest single payor for health care, could initiate an incentive by instituting a two tiered reimbursement fee structure for Medicare, Medicaid and federal employee health care, with a higher reimbursement for providers who participate in certified RHIO's. This could be considered a form of a "pay for performance" fee structure, since higher quality healthcare will be a result of health information exchange. RHIO's would be the beneficiaries of this two tiered reimbursement; providers will be more willing to fund the sustainability of their RHIO knowing that the RHIO is needed to gain the benefit of the higher reimbursement. Other means of incentives should be explored to promote provider organizations joining RHIO's and for the formation and sustainability of RHIO's.

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

Response: See #19.

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

Response: Unfortunately, government regulations, particularly HIPAA security and privacy, are *perceived* as barriers, in large part due to the lack of federally approved operational guidelines. Currently each provider organization must develop its guidelines and gain agreement from their legal counsel and corporate leadership. This process is particularly difficult because of the new nature of the regulations and the risks associated with failure to meet their intent. If the federal government were to issue guidelines on how provider organizations could meet the intent of these regulations when participating in a certified RHIO, this perceived barrier would be dramatically reduced resulting in the more rapid adoption of use of the RHIO/NHIN model.

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

Response: RHIO's could shoulder the bulk of new governance approaches needed to address these issues by establishing legal agreements between provider organizations (information sharing agreements, trust sharing agreements, etc.) and by meeting the operational guidelines set forth by the chartered working groups.

Other

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

Response: The design principles were described in #1 above and are repeated here:

The NHIN model recommended is one where:

- RHIO's are certified as abiding by interoperability standards, policies and operational guidelines promulgated by the federal government and chartered standards groups.
- EHR's within certified RHIO's directly exchanging with other such EHR's without a NHIN application in the middle – the Internet model of direct server-to-server exchange.
- The NHIN operates authentication services (for providers and provider organizations) and naming/uniqueness services (identification for RHIO's, provider organizations, and providers) to support RHIO-to-RHIO interoperability.

The technical architecture for the recommended NHIN / RHIO is comprised of :

- RHIO's which, except for content, appear identically to each other in their health information exchange characteristics, include:
 - A **Master Patient Index** which holds index linkages for any/all patients who have at least one record in a participating healthcare organization's EHR or other IT system. The MPI index for this patient will contain:
 - demographic and other data (as defined in working groups) necessary for determining patient record singularity (determining that multiple records from disparate systems belong to the same patient),
 - indexing to all EHR's of participating healthcare organizations within the RHIO which contain records for the patient, and
 - indexing to all other certified RHIO's MPI's where patient singularity has been determined between the RHIO's.

The RHIO MPI will build the database of indexes as requests for health information exchange are made (pre-population of indexes is not deemed practical)

- A **Health Record Exchange** capability which accepts authenticated requestors, determines requestor authority, determines which participating provider organizations or other certified RHIO's have records for the requested patient, authenticates itself to those organizations, places a real-time request for the records, and delivers the records to the requestor. Data on the transaction will be tracked and recorded.
- A **De-Identification** capability which can de-identify PHI for aggregation at the RHIO level for public health purposes. The assumption here is that this capability will be able to request certain data from all participating healthcare organizations, de-identify and aggregate for use within the RHIO as well as forwarding to the NHIN for national aggregation.
- **Aggregated Data Exchange** capability to forward de-identified, aggregated data to the NHIN.
- NHIN consisting of:
 - **Authentication Services** which provide authentication for all users of all certified RHIO's. This could be real-time services, which are accessed for each RHIO activity as it requires user authentication, or off-line services, such as issuance and management of end user digital certificates.
 - **Naming Services** which provide name spaces for all certified RHIO's, to include uniqueness for MPI index numbers, provider names (although not for Patients, since Unique Patient Identifiers are not part of the model), RHIO MPI and HRE server identifiers, etc.
 - **Reference Implementation of RHIO interface** against which to certify RHIO's.

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

Response: NHIN System Readiness success could be measured by 1) number/percent coverage of healthcare providers participating in certified RHIO's and 2) percentage of population covered by certified RHIO's. NHIN utilization could be measured by 1) number of patients included in RHIO MPI's (assuming patients are added to MPI's as requests for health information exchange are initiated) and 2) number of requests made for health record exchanges.

Signed January 18, 2005

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