Please Note: MedCommons Response in Arial indented. RFI Questions are reproduced for clarity.

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.

The proposed NHIN is a vendor and enterprise-neutral registry and archive of private, patient-specific information. The information within the NHIN is virtually indistinguishable from the patient-themselves; it is the agent or avatar for the patient; it is a digital representation of the patient. This digital representation of the patient can be accessed for use by health care providers and anyone else that the patient chooses. The NHIN is the patient's information highway.

Electronic health records (EHR) are related to the NHIN as providers are related to patients. Providers accept for review and may collect information about a patient into an EHR based on information presented by the patient (or on the patient's behalf) via the NHIN.

The key barrier to a NHIN is the tendency for vendors to commingle patient management tools with private health information. Patient management tools are the domain of intellectual property, branded by the software vendor or content author. Private health information represents the patient themselves and is not subject to branding or authorship. Unless this distinction is made and enforced as national policy, interoperability will always be held hostage to the natural tendency of vendors and enterprises to seek to lock in their customers with proprietary features and barriers to portability. When a patient walks out the door, all of their PHI should be able to go with them and it should be in a form that is as fungible and accessible to the next health care provider as money in your bank account is fungible between merchants.

The key enablers of a NHIN is effective, patient-centric interpretation of privacy and portability laws such as HIPAA in combination with additional, separate support for registration and archiving of a patient's private health information when that information is banked separately from any health-care provider's information management system.

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.

The model we propose is a collection of standards-based registries + repositories (e.g.: IHE-XDS as currently prototyped by NIST) that operate and are regulated in the manner analogous to banks. These banks would register and store PHI documents on the patient's behalf and could provide simple patient and physician viewers for documents that are stored in a standards-based format (e.g.: ASTM-CCR and ACR/NEMA DICOM). For the rest of this document we will refer to these as Patient Health Information Banks (PHIBs, which are not to be confused with PHBs).

PHIBs would be regulated per guidelines established by an organization such as the Certification Commission for Health Information Technology (CCHIT) to ensure a baseline of accountability, open access, privacy protection, standards-compliance and account portability.

PHIB accounts would, as with any bank, be under control of the individual but subject to mandated disclosure for public health or national security reasons.

PHIB accounts would be paid for by the patient or sponsored on the patient's behalf. The bundling of PHIB accounts with accounts at any particular health care provider or payor would be discouraged by law and/or by reimbursement practice. For example, subsidies might be made available only to PHIBs that are operated separately from a health care provider enterprise and are equally accessible to all patients and physicians in a community.

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.)

Routing information, patient access controls as well as document content and communication standards should be national in scope to ensure that all health care providers have access to PHI in a convenient and non-discriminatory fashion. An entity such as CCHIT could play a role in certification to these national standards.

Regional scope might be most appropriate for sponsorship and community-oriented programs aimed at affinity groups such as the customers of a bank as long as this group was not associated with a particular health care provider, pharmaceutical or device vendor or a health insurance company.

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?

The NHIN could be developed through a combination of standards, certifying organizations and investment in PHIBs that seek certification by implementing these standards.

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

To enable private investment, PHIBs would have to be protected from shifting of resources by incumbent patient management systems vendors and health care provider enterprises. Standard interfaces and ontologies must be established that isolate PHI from information management systems and provide all certified patient information banks an non-discriminatory access into and out of a provider's information management system.

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

Adoption and acceleration of NHIN would be accelerated by providing separate payment (reimbursement) for the patient information registration and archive portion of a health care encounter.

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

The NHIN would be the inevitable result of the operation of certified PHIBs. PHIBs could be operated by a range of public and private enterprises including banks, community-based organizations and new businesses designed to serve the information management needs of individuals.

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.

Voluntary industry funding for participation in standards and certification organization is expected to continue since both information systems vendors and their health care provider customers will benefit from effective standards for import and export of PHI.

Private corporations such as MedCommons are already investing in the development of software and systems to support the operation of PHIBs. The cost of private capital should decrease as the perceived risk due to indefinite government initiatives such as this RFI resolve to specific policies.

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

The fair value of information management must be accessible to independent PHIB operators. Transport of information to and from a health care provider is no different from transportation of the patient herself. We would look with suspicion at a hospital that was offering “free” taxi service to their emergency room or joint replacement clinic. The support of independent patient control over their own PHI will sustain a functioning NHIN.

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?

The HIPAA Act is compatible with and an enabling legislation for an NHIN based on PHIBs. Vendors such as MedCommons supply systems that secure and log access to PHI and provide an FDA-cleared viewer for standards-based documents independent of the context of a health care provider or payor. PHIBs can adopt MedCommons and similar systems to effectively meet HIPAA mandates. Health care providers can adopt MedCommons and similar systems to add Portability, as intended by the P in HIPAA, to their legacy information management systems.

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

By rapidly providing open and non-discriminatory certification criteria, the framework for a NHIN will support open-source software systems that benefit from peer-review by security and medical

research experts and promote the rapid development of effective standards for information exchange.

Management and Operational Considerations

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

Private sector competition would be encouraged by a rapid conclusion of this NHS initiative and by the adoption of strong and clear privacy rules that reinforce the patient's sovereignty over their most private and sensitive details.

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

a. evolves appropriately from private investment;

Make the rules clear ASAP and prevent cost shifting by incumbents that benefit from lock-in of customers into existing proprietary systems.

b. is non-proprietary and available in the public domain;

Enable competition by open source software projects by mandating open Internet-style standards such as the W3C and avoiding high certification and patent prosecution costs. For example, purchasing a national license to SNOMED was a truly commendable act.

Publicly funded projects such as VISTA should be required to go beyond the mere placement of source code into the public domain. They should be mandated to adopt standard and clear open source licenses (e.g. as certified by the Open Source Initiative – OSI) that would make these projects active participants of the commercial and voluntary developer community.

c. achieves country-wide interoperability; and

Adopt practices that support interstate commerce (e.g.: similar to the Internet) and avoid regulations derived from state-oriented medical licensure.

d. fosters market innovation.

Provide separate reimbursement for transport and control of patient-specific medical information so that patients can visit with and seek opinions from the broadest range of providers.

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?

The availability of open source software for transport and physician review of patient information will make the NHIN accessible to all by enabling competitive technical support by the providers and community organizations even when they could not otherwise afford more complex "integrated" information management systems. MedCommons believes it is the first vendor to have received FDA approval for a user-supported open source medical image viewer.

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?

Community and regional information exchange projects would be strengthened by the implementation of a NHIN based on PHIBs.

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

The broad adoption of a NHIN could reinvigorate medical science by eliminating artificial institutional barriers to outcomes analysis and allowing both physicians and patients to make evidence-based comparisons between treatment approaches.

Broad adoption of a NHIN would reduce costs and improve quality of life by reducing the tendency for unwarranted therapy as described by the Dartmouth Atlas project. The ability for patients to choose therapy independent of diagnosis on the basis of an objective review of their actual PHI is a pre-requisite for capturing patient preferences and will go a long way to convince patients to accept high co-pay insurance and health savings accounts.

The major benefits of true portability will accrue to the patients and employers. Health care providers will benefit to some extent by reduced lock-in into the systems of a dominant vendor and by an increased ability to respond to marked demands by adopting new information technology or collaborating with unaffiliated institutions.

Lack of portability is a cost to patients and employers. Unfortunately, these groups are not the customers of medical information technology vendors. By mandating separate payment for PHIBs, policy makers can create a market for portability and interoperability that will serve the interests of health care consumers and make them more willing to accept responsibility for their lifestyle and therapeutic choices.

High switching costs have a direct impact on health care providers. By facilitating the separation of PHI from clinical management tools, the marketplace will be given valuable leverage to act. NHIN policy will strengthen the market for medical information technology by reversing the current trend toward single-vendor information systems.

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?

Interoperability standards and policies are adequately managed by today's organizations. A healthy competition is evident between vendor-supported organizations such as HL7 and physician led initiatives such as CCR. Vendor and physician involvement in the standards process are both necessary. Participation in somewhat separate standards organizations by the two interest groups may be suboptimal but it can still lead to harmonized and effective standards if the overall incentives of the marketplace are aligned.

What is missing today is oversight and certification of information systems hygiene. Most health care providers are not well-equipped to judge standards-compliance or use the power of the marketplace to keep vendor greed at bay. The accelerating trend toward highly integrated, proprietary single-vendor information systems works to reduce a health-care provider's leverage over their vendor and has spawned a wasteful and mostly futile industry of consultants and lawyers focused on the mechanics of vendor selection and procurement. Once the contract is signed, the vendor moves on to a fresh prospect and high switching costs keep the provider from

innovating. As with banking and securities regulation in the last century, clear oversight and national policy can go a long way to instill confidence and drive rapid progress.

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.

The separation of PHIBs from both providers and insurers is a market oriented approach to interoperability, standards and privacy. This market oriented approach is a direct result of the fact that a PHIB, like any bank, derives the vast majority of its revenue from customers that value its trustworthiness and policies. Unlike a provider or an insurer that sells other essential services on the basis of other relationships, the PHIB competes, lives and dies on the basis of their interoperability and security. HIPAA is already well-suited to support this approach.

PHIBs will compete to provide secure connectivity, mobile authentication, patient identification management and information exchange to meet patient and health care provider needs.

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?

The current efforts of IHE-XDS to promote effective cross enterprise data sharing practices and to demonstrate these practices through public connectathons are both practical and broadly applicable. These processes would be further strengthened by the evolution of certifying organizations such as CCHIT.

The current effort of ASTM-CCR is also well positioned to provide a clinically effective yet universally accessible standard for PHI transfer between unaffiliated providers. Both IHE-XDS and ASTM-CCR will benefit greatly from adoption of a security infrastructure accessible to both physicians and patients.

As has been shown by the widespread impact of open source on Internet standards, active open source communities can drive the effective development of standards and minimize the tendency for vendors to subvert the standard through unwarranted extensions. As with the Internet, open source software in health care can be supported by ensuring that public funds (e.g.: such as

support for VISTA) is spent on standards-compliant open source implementations that are licensed under commercial-grade OSI-approved open source licenses.

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?

The most critical management and business rule would be to require separation of PHI from other healthcare information management systems. Either by mandate or by reimbursement practice, management should be required to employ separate vendors for PHI vs. other clinical operations management.

Just as bank business rules require them to settle customer accounts every night, NHIN business rules might require that health care synchronize and refresh their internal cache of PHI (e.g.: the EHR) against the patient's account at a PHIB every night. Oversight of this synchronization is already significantly within the intent and processes of HIPAA. True portability and patient control would be the result.

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 continue and expand safe harbors for universally accessible PHIB systems and provide clear guidance of their responsibilities under HIPAA.

The federal government should make sure that state medical licensure laws are not used to restrain interstate competition for health care any more than state telephone regulation is allowed to restrain Internet commerce.

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?

The most effective financial incentive would be separate reimbursement for registration, archiving and transport of PHI. Bundling of PHI management into enterprise information management

systems should never be rewarded. The public interest is best served by effective portability protected by strong privacy under the HIPAA guidelines.

By supporting only the patient-controlled PHI component of health care information systems the public interest would be advanced for the least investment as health care providers would then gain the requisite leverage to insist on true PHI portability from all of their information systems vendors.

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?

Separate reimbursement for PHI management by certified organizations and partial deferral of the costs of security and privacy for organizations that use PHIBs instead of trying to keep PHIs in-house as part of their proprietary information management system.

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?

We're not aware of any regulatory prohibitions or barriers.

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

An independent PHIB is non-discriminatory and does not bundle its services with any health care service. This should go a long way to avoid manipulation of our already stressed systems of incentives and avoid conflict-of-interest.

Other

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

Private businesses and public organizations would license software and/or services to operate regional or national PHIBs from a vendor such as MedCommons. To make it's service universally accessible and easy to integrate, MedCommons provides a free, standards based open source PHI "Gateway" to health care providers and even EHR software vendors under an OSI-compliant open source license.

This open source software business model is:

- free and non-discriminatory to both health care providers and incumbent software vendors,
- promotes rapid adoption of standards for PHI interfaces by delivering a free package that is already demonstrated to be capable of FDA clearance
- is readily peer-reviewed to enable enterprises to examine for potential security and privacy problems that they might be held liable for
- is compatible with embedding in a wide range of imaging modalities, physician workstations and other clinical systems
- is free (as any OSI software would be) to physicians, health care enterprises and even software vendors who choose to use it to access their patient's PHI.

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

Success can be measured as the fraction of patients that maintain control of their PHI in PHIB accounts and the fraction of health care providers that synchronize all PHI for patients with PHIB accounts on at least a weekly basis. As these two fractions increase, the public will gain an increasing sense that their health care is under their control and their choices are made freely in a competitive and market-driven environment. For their part, physicians will increasingly feel that they are truly in control of their information management tools and that they can freely refer their patients to the most appropriate treatment without technical portability barriers.

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