David J. Brailer, M.D., Ph.D.
Office of the National Coordinator for Health Information Technology
Department of Health & Human Services
Attention: NHIN RFI Responses
Hubert H. Humphrey Building, Room 517D
200 Independence Avenue SW
Washington DC 20201

Dear Dr. Brailer:

SureScripts and RxHub are pleased to submit this collaborative response to the NHIN RFI. We are submitting a single response for the following reasons.

A collaborative response from RxHub and SureScripts affirms our strong belief that collaboration by private industry with the government will be a requirement for a successful deployment for the NHIN. RxHub and SureScripts collaborate effectively on many levels. We are currently working collaboratively on projects with health systems, health plans, physician organizations, community-wide information technology initiatives and physician technology vendors.

This RFI affords us the opportunity to share our unique and extensive experiences over the last three years in creating national healthcare networks on behalf of our parent organizations and in working with a wide range of healthcare stakeholders. We would like to use this collaborative response to look forward together and apply our learnings to recommend solutions to the problems and opportunities facing the US healthcare system.

Together we have unique and complementary capabilities that can provide the foundation of the NHIN in an efficient and cost effective manner. Both companies operate with a unique non-profit type model.

- ***SureScripts'*** primary services include enabling two-way electronic communications between physician practices and pharmacies supporting automation of the entire prescribing process -- both new prescriptions and renewals. SureScripts was founded by the two trade associations that represent pharmacy, the National Community Pharmacists Association and the National Association of Chain Drug Stores.
- ***RxHub's*** primary services include patient identification and providing front end decision support information to clinicians at the point of care (eligibility, formulary and medication history). RxHub's directory service contains drug benefit and eligibility status of over 150 million covered lives, and is unprecedented in size or scope in the health care industry. RxHub was founded by the three leading pharmacy benefit managers (PBMs) in the United States – AdvancePCS, acquired by Caremark, Express Scripts Inc., and Medco Health Solutions, Inc.

Our companies have been organized and invested in by industry stakeholders in service of the healthcare industry, proving that competitors can work together to improve the quality and efficiency of healthcare for all stakeholders. Both companies have the goal of creating efficiencies in the delivery of care and reducing the number of medication errors and adverse drug events that threaten the safety of the American people. Both companies operate with a nonprofit orientation and have not sought outside venture capital. A major objective of RxHub and SureScripts is to drive transaction costs down over time on behalf of the industry and our founders. We describe in our response how what we have created is actively being used in the US healthcare market on a daily basis and can provide the core of the national health information network.

Our response is complementary to responses being developed by other collaborative industry groups in which we've been active participants. We see RxHub and SureScripts as important resources in establishing national policies and standards for participants using the NHIN. We look forward to working with you to achieve the goals outlined in this response.

Sincerely,

David McLean
David McLean, Ph.D
CEO, RxHub

Kevin Hutchinson
Kevin Hutchinson
President & CEO, SureScripts

RxHub and SureScripts
Response to Department of Health & Human Services
Office of the National Coordinator for Health Information Technology
Development of a National Health Information Network (NHIN)

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GENERAL QUESTIONS:

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.

There is a need on a national basis to catalyze specific actions leading to an interconnected, electronic health information infrastructure allowing:

- Physicians/clinical caregivers to access, review, and share health information, across all care settings and all care providers in order to make more informed care decisions and provide better health outcomes (the NHIN does not contain clinical information in a central data warehouse—clinical information is stored electronically in the individual provider organization);
- Access to information allows for fact-based decision support to reduce medical errors and redundant or unnecessary tests and procedures;
- Consumers/Patients to access, review and update their health status electronically;
- Suppliers to receive information regarding patient and provider needs and to deliver "just in time" inventory;
- Public Health providers—the ability to improve public health through enhanced surveillance and information capture as well as the ability to improve health status through streamlining research and results reporting.

The NHIN connects care providers in all clinical settings through interoperable healthcare systems and services, such as those serving physician practices, hospitals and long term care facilities with healthcare stakeholders including pharmacies, pharmacy benefit managers, health plans, hospitals, clinical laboratories and other entities that support the care delivery and management process. The NHIN is transaction oriented, and at a minimum, supports the workflows of today's healthcare providers including prescription routing, patient eligibility and health benefit information, clinical laboratory orders and results, and provider to provider referrals and consultations.

For example, if a provider wants to send a prescription to a community pharmacy, or check a patient's eligibility for a prescription benefit, or see a cross-provider history of medications, or get a lab result, or get the current problem list from another provider's office system, a NHIN would provide such services to the provider, most often through connections to their core clinical information system. Information of most significance includes current problem list, current diagnosis, allergies, current lab results, current medication list, immunizations, health and medication insurance benefits, visit history and summary.

The NHIN must have the flexibility to accommodate the fragmented, and for the most part, regionally focused delivery system that is currently in place. A decentralized approach negates the need for storing identifiable data in a central data warehouse, yet allows information to remain at

the source and permit access to that information from that source to the point of care. A decentralized approach would meet the legal, political, and market realities of the healthcare delivery system that exists today.

With appropriate security in place, this model will allow consumers/patients to connect either directly to the NHIN or more likely through other regional/local connections in order to have access to information available from key stakeholders such as physicians, hospitals, health plans, pharmacies and labs. This partnership allows consumers to take responsibility for their own health care choices, involving them to make decisions that impact quality and cost of the care they receive.

Although momentum is building and awareness of the importance of the NHIN is evolving, there are barriers to the needed interoperability which include:

- **Immature standards for data exchange**: While NCPDP, HL7, LOINC and other standards are being recognized and sanctioned as "foundational standards", additional work is needed. For example, how clinical data is represented in different systems, particularly for drug, allergy, laboratory and problem/diagnosis data, varies widely. In addition, there is incomplete agreement on a core clinical minimum data set.
- **Provider technology adoption and utilization issues**: While the rate of adoption of technology and clinical systems is increasing, it is not clear that systems are being fully and effectively used. This can be attributed somewhat to the lack of user-friendly interface designs for clinical and other applications which require more time from the physician as compared to paper-based processes.
- **Lack of a universal patient identifier** Although RxHub has a solution to uniquely identifying individuals, some in the industry believe there is a need for a National Patient Identifier.
- **Cumbersome cross-industry workflows**: The workflow within a clinical setting is challenging. Communicating with other stakeholders requires, at best, translation between multiple standards, or, more likely, creation of new standards where none exist today.
- **Resource constraints**: Although the market is starting to provide solutions, smaller practices may have difficulties affording technology and finding support systems to help with procurement, implementation and management of that technology system. Most software and services suppliers still gravitate toward supporting larger practices and hospitals.
- **Education/Industry Knowledge**: Health plans, health systems, physician organizations and other industry stakeholders have been slow to collaborate on technology projects because of the difficulty in sorting out the myriad of options and getting to solutions. Common questions include:
    - ✓ What is the role of pharmacy and PBM networks?
    - ✓ Should we promote Electronic Health Records (EHRs) or start with electronic prescribing or lab?
    - ✓ How do we get technology connected to labs without a hub?
    - ✓ Do we select a subset of solutions or support all of them?
    - ✓ Is there really a change in safe harbor or will we be at risk?

- **Fragmentation:** A fragmented and complex healthcare delivery and financing system plus political, organizational, competitive, societal (e.g., privacy, legal) barriers to cross-organizational data sharing in general and to CDR-based (clinical data repository) strategies in particular.
- **Capital:** Lack of adequate capital for initial investment in technical infrastructure and systems to support applications and solutions.
- **Privacy/Confidentiality:** Continued public concern about privacy and security issues and who owns or has access to the data and what can be done with it must be addressed.
- **Concerns about liability:** Many physicians fear that with access to additional information they may experience increased liability if a non-compliant patient has an adverse event.

At the same time, there are a number of enablers to interoperability including the following:

- **Progress on data transaction standards:** The continued progress on, and more universal use of, standards for representing clinical data (e.g., SNOMED, LOINC, NDF-RT, RxNorm) and for clinical messaging (HL7, NCPDP).
- **Progress on business standards/policies:** Promulgation of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) requirements for permitting use of appropriate messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures. Appropriate messaging should be defined more clearly to ensure that the information systems used in the clinical process will be free from commercial messages or pop up advertisements that are not specific to the patient's safety or an improved clinical decision or are intended to change a clinical decision at the point of care. Appropriate messaging should allow information on formulary and benefit plan design so long as all medical options are available to the physician and patient. This law must be enforced as to protect physicians' choice of treatment and patients/consumers' choice of pharmacy.
- **Adoption and utilization tool sets:** Market demand will drive interoperability. Adoption and utilization by healthcare providers will drive demand. Tool sets—"how to" guides and templates are required that encourage best practices for procurement, implementation, on-going utilization and technology management processes.
- **Technology certification support:** The formation of the Certification Commission for HIT is an enabler, because solution vendors require support to build recommended functionality. They benefit from implementation guides and best practices tools.
- **Master Patient Index (MPI) strategies:** Minimizing dependence on a national patient identifier due to available technologies to uniquely identify individuals using key data elements.
- **Trusted components of the NHIN:** Trust is at the center of interoperability. The industry as a whole needs to trust the components of the NHIN as operating in the interests of the patient and the industry as a whole. It is likely that such components will need to be organized to serve industry constituencies similar to a public utility function and not be profit-oriented commercial ventures.
- **Pay-for-performance or pay-for-utilization programs:** Adoption incentives are an important enabler. Pay-for-performance or utilization programs are better suited as incentives than our industry's continued emphasis in technology giveaways.

- **Data exchange standards:** Emergence of the continuity of care record (CCR) as both a definition of a core clinical data set and a vehicle for transporting that data across systems/care delivery settings.
- **Regional health information organizations:** Efforts that emphasize real-time clinical data acquisition from source systems can avoid many of the political, organizational, and societal barriers inherent in clinical data repository (CDR)-based approaches (e.g., delivering prescription claims history directly from the source PBM to a requesting provider, via and "exchange", without having the data stored in a regional CDR).
- **Widely available broad-band access:** Broader availability of low cost Internet and/or other high speed connectivity alternatives
- **Mechanisms for protecting privacy, security and integrity:** Industry agreement on the mechanisms to ensure.

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 envision the NHIN as collaboration between private and public sectors. Initially we see a Core Framework comprised of a relatively small number of private, nonprofit oriented companies, such as SureScripts and RxHub, whose mission is to serve a major healthcare business segment, representing key stakeholders in community pharmacies, pharmacy benefit managers and health plans. We are hopeful that a similar type of company could be formed by the clinical laboratory segment and could ultimately become part of the Core Framework. Other nonprofit type structures and organizations may also be in the Core to help manage provider referrals and patient clinical summaries and broker patient information requests in support of a personal health record. The entity will develop incrementally, and its structure must be flexible in order to modify its governance and operating structures over time as adoption increases and the industry evolves and should consist of broad stakeholder representation.

Collaborating with the Core Framework is the ONCHIT and other appropriate federal agencies and departments as well as Standards Development Organizations (i.e. HL7, NCPDP, LOINC) and certification organizations such as the Certification Commission for HIT. These organizations would provide important resources for the NHIN and become an important advisor for industry standards and adoption support.

Other private healthcare networks and clearinghouses will be linked to the Core Framework through a set of standards and implementation guides that are created collaboratively through industry workgroups attended by all interested stakeholders. Also connected to the NHIN would be healthcare information technology solutions that serve physician practices, hospitals, long term care facilities, community pharmacies, pharmacy benefit managers, health plans, clinical laboratories and other healthcare stakeholders.

Currently several dozen healthcare technology solution providers are certified by both SureScripts and RxHub—representing approximately 150,000 US physicians, 46,700 community pharmacies, and PBMs representing hundreds of health plans serving 150,000,000 Americans. Additional vendors are in discussions, with agreements targeted over the next several quarters. The list of certified technology solution providers is expected to grow significantly throughout 2005 (see attachment 1 for a list of certified and contracted physician technology partners and pharmacies).

The NHIN also has a key role in supporting this national network of solution providers particularly in the area of encouraging utilization. Too often the commercial interests of solution vendors and their respective business models make it difficult for them to ensure that the benefits of the technologies are being achieved and that they are used effectively throughout their customers' enterprises. It has been acknowledged that even when new technologies are implemented in physician practices, there can be significant challenges to get the entire practice to optimally utilize these technologies and achieve their benefits. The NHIN needs to play an important leadership role in creating templates for evaluation, education, training, workflow integration, and best practices, to ensure the most effective utilization and outcomes.

Widely available access

In preparing this response we considered two broad models – one that relies on a clinical data repository ("CDR model") and one that doesn't ("transaction-only model") – each with its own pros and cons. While the CDR model has advantages in areas such as performance, centralized data standardization, and cross-organization reporting, it is likely less acceptable from an organizational and political perspective to local and regional stakeholders in most markets in the US today. Indeed the CDR model is the vision in some communities. In the transaction-only model, information is stored where it is produced including information related to: medication history, prescription claims data, laboratory data, ambulatory EMR data and referral data. These "source" entities would all subscribe to and regularly update a common master patient index (MPI).

In this model, only 5 key data elements, first and last name, date of birth, gender and zip code as well as pointers to the location(s) of source data would be stored centrally in the MPI. A requesting clinical entity would send an agreed upon set of patient demographics (used in combination in lieu of a universal patient identifier). Upon a successful match, the pointers to source data locations stored in the MPI would then be used to fetch, in real-time, the source data and send it to the requesting entity. This model has withstood large-scale production testing over the past three years with prescription-related data at RxHub, and could be expanded to include other types of clinical data (e.g., lab, radiology, and pathology dates and results; procedure and diagnostic claims; actual EMR / EHR records).

Taken together, these data sources can provide a relatively complete picture of a patient's clinical history and can be used to create a patient's EHR "on the fly". Under the transaction-only model, the health information exchange does not store the clinical data retrieved – it just passes it on – and thus avoids having to solve technical, political issues, as well as potential privacy and confidentiality issues associated with the CDR model.

Interoperability and clinical health information exchange

The transaction-only model described above has been deployed quite successfully (so far, with only prescription-related data) across dozens of HIT solutions with remarkable speed. In this model, the HIT solution vendor or clinical organization (e.g., Barnes Jewish Hospital, MedsinfoED) is responsible for engineering to straightforward transaction specifications and managing received data appropriately. The health information exchange primarily needs to manage its MPI and connectivity with its sources of clinical data. The MPI (and associated patient matching algorithms) is what enables interoperability / clinical data exchange without needing a national patient identifier.

Protection of patient information

Protecting individually identifiable health information is potentially problematic for CDR-based health information exchanges. Under the transaction model, on the other hand, there is no centralized clinical data storage and thus this is less of an issue. Of necessity, the transaction model health information exchange is highly dependent on point-of-care technology partners and transaction-requesting provider organizations to manage confidentiality and security, including user authentication, acquiring and documenting any needed patient consent, and ensuring that patient data requests are appropriate. This solution does not require the use of a unique health identifier and is based on the model of patient authorization and patient control. This is most manageable when transaction requests are triggered by, or otherwise tied to, a registration event or a patient census or schedule (these are typically machine-to-machine transactions).

An alternative approach to trigger a data-requesting transaction is to have a web form where a user can simply enter by keyboard the demographic information needed for a MPI lookup (in the case of RxHub's patient matching algorithm, there are only 5 data elements including: last name, first name, DOB, zip code and gender). This approach is quite attractive for many clinical settings (e.g., a small physician practice or a small hospital emergency room) since it is "low-tech" and doesn't require any machine-to-machine transaction engineering.

However, this approach can invite abuse, since inappropriate lookups by otherwise authorized users may be too appealing for some users to resist and are extremely difficult to guard against (or to detect by audit). These web portal / manual lookups pose a significant threat to patient confidentiality for both the CDR and transaction-only models. This issue will need to be addressed by the Core Framework in developing business policies around providing care through use of health information technology.

Healthcare vendor support

As noted above, several dozen healthcare technology solution providers are either certified by SureScripts and RxHub or are in process, with most being certified by both. Standard certification guides have been developed and are being used today by both companies when connecting (implementing) participants to the existing infrastructure.

With the passing of MMA, prescription and related information is required to be provided to the health care professional and dispensing pharmacy or pharmacist including eligibility, benefits information such as formulary and tiered formulary and requirements for prior authorization as well as information on the availability of lower cost, therapeutically appropriate alternatives (if

any). Both companies have agreed to assert policies that allow the physician to decide without undue influence or attempt to influence, the choice of treatment and the patient to select the pharmacy of their choice.

The NHIN has an important role to play in ensuring neutrality and prohibiting activities at the point of care in e-health platforms that are illegal, unethical or otherwise compromise the viability of the NHIN. Healthcare providers have an expectation that the information systems they use in the clinical process will be free from commercial messages including pop up advertisements that are not specific to the patient's safety or an improved clinical decision and are intended to change a clinical decision at the point of care. To clarify, the point of care begins when the physician or provider initiates the process of reviewing a patient's record and documenting clinical decisions made during the patient's medical exam and ends when the patient's chart is closed or in the case of electronic prescribing when a prescription is printed or sent electronically to the pharmacy. If this type of commercial messaging is prohibited, providers can be assured that pharmacies, manufacturers, labs, payers, etc., are prevented from paying software vendors to highlight products or services and attempt to persuade clinicians to change their decisions. Most pharmacies, dozens of physician and pharmacy technology suppliers and the largest drug manufacturers have agreed not to use commercial messaging at the point of care, leaving the choice of medication with the prescriber and the choice of pharmacy with the patient.

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.)

While the NHIN is national in scope as discussed above, much of the work around interoperable technology adoption and utilization takes place regionally and locally. We envision regional and local collaborations of hospitals, health systems, health plans, physician organizations, pharmacy organizations, quality improvement organizations, public health and research organizations and others, all cooperatively involved in health information exchange initiatives, community adoption and utilization programs and the supportive governance structures that enable them.

The role of the NHIN in these regional efforts might be focused on initial organization, the definition of policies and standards necessary for interoperability, providing a starter kit of foundational transactions and providing best practices support.

Helping to develop a viable organization for a sustainable regional collaborative may be important to encourage adoption and to optimize utilization. It's our view that physicians and others are more likely to adopt and use interoperable EHRs and other technologies if part of a collaborative, local, community-driven adoption effort rather than rely solely on the standard purchasing processes between technology vendors and healthcare buyers.

These regional health information organizations (RHIOs), as defined in ONCHIT's July 21, 2004 Framework for Strategic Action, will become a valuable asset to the NHIN as local healthcare practices, cultures and systems can inform and be informed by the national efforts. A RHIO can

support a local healthcare stakeholder that desires to organize an interoperable health information technology initiative in the region and facilitate collaboration with other local stakeholders when appropriate, or merely provide a set of best practices learned from other projects within the region or from being associated with national efforts.

The role of healthcare stakeholders in regional and local healthcare technology adoption and utilization initiatives have some common elements and also differ somewhat by their specific corporate goals. The following roles are common to all:

- Provide access among healthcare providers in a wide range of care settings to a standard set of clinical data (e.g., current problem list, current diagnosis, allergies, current lab results, current medication list, immunization, health and medication insurance benefits, visit history and summary) on patients to support quality, cost-effective care management
- Promote adoption and utilization of interoperable healthcare technology solutions through public statements, testimonials, press releases, internal newsletters and other means
- Reach out to providers in the community with which it has a trusted relationship and provide education about the benefits of interoperable health technologies
- Invest capital to provide incentives to adopters and to support development of a community-wide effort
- Measure the impact of the technology initiative and report results to the community

Each local and regional stakeholder, however, may have some unique requirements for embracing an initiative focused on interoperable health technology:

- Health plans may focus on how the technology can deliver formulary, benefits information and clinical guidelines to the point of care and how to effectively share the history in its databases with practicing clinicians
- Hospitals and health systems may focus on automating physician practices it owns and those closely aligned and to make laboratory and other services more available to community practices
- Independent practice associations (IPAs) are encouraged to adopt interoperable clinical technologies to meet guidelines for a clinically integrated practice to negotiate managed care contracts
- Primary care physician practices are embracing interoperable EHRs to lower practice operating costs, coordinate better with other providers and participate in pay-for-performance programs for increased revenue

In many ways, the RHIOs represent the environment of the national network in that they are oftentimes sub-networks that over time can be integrated to handle the requirements of inter-regional communications. Until integrated, the NHIN can support these regional sub-networks (RSNs) by offering both a starter set of basic transactions and a service than can connect providers to out of region resources.

Regional versus national data sources: some recent experiences

One key question is: What data sources can be accessed directly via a single national health information network (NHIN) vs. indirectly via a regional sub-network (RSN)? Data sources with

national scope, such as large payers, PBMs, and reference laboratories can be accessed nationally via a NHIN. A good example of this with several years of production experience is access to PBM eligibility, formulary, and prescription claims data via RxHub.

It is also helpful to separate out issues of data source connectivity from issues related to end-user, or provider organization, connectivity (the latter can be considered to be a service distribution problem). For instance, the NHIN must be prepared to support connectivity at the local/ regional level to provider organizations that need access to the data. Alternatively, if the NHIN cannot support direct connectivity to individual provider institutions at the regional level, it must rely on regional "distributors" – most suitably a RSN – that can connect to multiple local / regional institutions on one side via multiple individual connections and to the NHIN via a single connection on the other side.

RxHub's experience is illustrative. Hospitals in Indianapolis that want prescription history reports from RxHub (the analog for NHIN in this example) will get them via Regenstrief / Indiana Health Information Exchange, or IHIE (the analog for a RSN in this example). This allows the NHIN to focus on MPI performance/maintenance and expanding coverage by enlisting participation of (and engineering with) additional data source providers (e.g., more PBMs and payers in RxHub's case), while the RSN focuses on enrolling and connecting to local/regional provider institutions. The same phenomenon of a RSN accessing and distributing data from a NHIN is occurring in Boston via the MedsinfoED project (again, the NHIN in this example is RxHub, while the regional entity is the Massachusetts Health Data Consortium or MHDC).

This model works well because it is both politically and technically (from a human resource perspective) more efficient for a regional entity to enroll regional institutions, connect to them, and provide related monitoring, and onsite training and support than it is for the NHIN. However, this may not always be the case.

It is possible that a NHIN could manage distribution, connectivity, and support directly to provider institutions regardless of region without relying on RSNs as distribution intermediaries, but this would require a far greater resource commitment by the NHIN and potentially increase transaction resources to the provider institutions, at least in the short term.

There is no technical reason why an existing RSN or some other third-party intermediary couldn't provide access to the NHIN beyond regional boundaries. For instance, if IHIE or MHDC were willing to take on the resource requirements associated with broader distribution of RxHub prescription history data services, then a hospital in California or New York could potentially hook up to RxHub in St. Paul by connecting to a distribution intermediary in Indianapolis or Boston. This would accelerate service availability in these new regions, since the non-trivial connectivity engineering between the existing regional entities (IHIE, MHDC) and RxHub is already complete and can be leveraged. This model – whereby a RSN broadens its health data exchange services beyond traditional regional boundaries – is far more plausible if it is acting in "transaction-only" mode rather than storing the data passing through it in a CDR (see responses to questions 1 and 2 above).

The issue of national distribution of data made available by the NHIN is of more than academic

interest, since there are relatively few markets around the country with regional sub-networks that are mature enough to support regional distribution as described in the last paragraph, and many regions with no existing health information exchange entity whatsoever. An alternate, or perhaps complementary, distribution strategy is via healthcare IT vendors. Under this model, the vendor would support a single central connection to the NHIN, and then distribute the data as a value-add service to their existing customers. This is occurring today in the ambulatory setting with formulary and prescription claims data being delivered via a number of point-of-care EMR and electronic prescribing vendors connected to RxHub.

Unfortunately, vendor-based distribution may be years away on the acute care (hospital and emergency room) side of the industry. For example, while it would be technically easy enough for some major vendors to offer RxHub prescription history services to their customers, there are business model challenges and competing priorities that have kept this from happening. Moreover, many hospitals would prefer to handle simple HL7 transaction engineering themselves, and see no reason to have one of their IT vendors get in the middle. The other limitation of vendor-based distribution of data services from the NHIN to hospitals is that it doesn't allow for "blanketing," making the data service available to all of the hospitals in the region, except in relatively rare markets where a single vendor dominates the region.

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?

Specifically, the NHIN could be developed from a core collaboration among SureScripts, RxHub and ONCHIT to combine a set of foundational transaction capabilities with connectivity. Another potential participant could be a similar type of organization founded by clinical laboratories to manage orders and results transactions between healthcare providers and labs. Additionally physician organizations and associations could collaborate on the provider to provider communications provided by the NHIN for referrals, consultations, and requests for information from a patient's record from other providers.

Leveraging the technology/infrastructure, intellectual property, business models, customer relationships and implementation services of RxHub and SureScripts is the most cost effective way to form the foundation of the NHIN.

- The message routing capabilities combined with the MPI capabilities are well matched to extending services beyond prescribing to include laboratory orders and results, referral transactions and retrieval of EHR data from regional sub-networks.
- The relationships both companies have developed with key stakeholders including PBMs, health plans, community pharmacies, health systems, physician organizations and community collaborative initiatives, as well as the major physician and hospital technology companies are immediately applicable to the work of the NHIN.
- The implementation services of both companies are important capabilities for the NHIN, in that, it is likely that new functions will need to be defined and rolled out through clinical systems suppliers and subsequently certified. Both companies have considerable national experience in this regard.

SureScripts and RxHub have significant knowledge and experience in utilization and adoption of clinical health technology that are relevant to accelerating the use of NHIN for mainstream care. Both companies have experience in designing incentive programs for technology vendors and both are currently engaged in working with health plans and other stakeholders on plans for provider incentives. SureScripts has entered more than two dozen major US markets with its community adoption programs and has methodologies and tool sets to energize and bring together communities to focus on technology adoption and utilization that will help improve patient safety and practice efficiency. Key learnings include:

- Provide regional programs that are collaborative, but allow individual stakeholders to initiate programs independently
- Discourage single vendor and limited assortments in favor of an open invitation to all certified solutions
- Provide decision-making support to providers about the different solutions available and manage expectations through adoption and implementation
- Adoption incentives should be pay-for-utilization and not just for procurement
- Automate work environments and not individual providers
- Focus on workflow improvements and outcomes which may require onsite training and support and not on the technology itself
- Ensure end-to-end whole products that work out of the box without asking providers to do workarounds
- Link incentives to technology providers to include a focus on utilization within respective client bases to encourage current users to upgrade to the latest release
- Use tipping point methodologies by focusing on key opinion leaders in a first wave of adoption / utilization and develop proof points in the language of the provider to seed and accelerate widespread adoption and use by leveraging peer to peer influence. Apply the science of diffusion of innovation to adoption programs, e.g., offer low-cost trials, get local testimonials from direct peers, ensure a significant short term benefit for adoption, etc. (see Diffusion of Innovations by Rogers, Crossing the Chasm by Moore, Tipping Point by Gladwell, etc.)
- Give equal attention to the environments that have already taken significant steps in adoption and focus on utilization

- Encourage smaller, more elegant solution sets for smaller physician practices realizing that not all provider environments need the same thing (e.g., smaller practices are more concerned about connectivity than chart pulls)
- Ensure that clinical practice administrators are involved in decision-making and implementation and not just clinicians

One example of a quick win in adoption

A new regional or national exchange could begin transacting prescription history reports within months to participating hospitals throughout a region or across the nation. Transaction requests can be routed to RxHub who would funnel the resulting responses back to the requesting institution. Organizational and political issues – often more difficult to get past than technical ones – are largely simplified by not having to build a CDR just for this purpose.

We believe that prescription history reports and other types of clinical data will be viewed as valuable to hospitals and they will thus be willing to pay reasonable transaction fees for the data. For instance, a recent JCAHO National Patient Safety Goals for Hospitals calls for full implementation by January 2006 of a solution that addresses the problem of prescription history reconciliation upon admission to the hospital, (reference 3rd bullet from the bottom at :http://www.jcaho.org/accredited+organizations/patient+safety/05+npsg/05_npsg_hap.htm)

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.

We believe our proposed approach to be the most cost effective model to create initial NHIN capabilities by leveraging the transaction-oriented business models and infrastructure that has already been built by RxHub and SureScripts.

Alignment of incentives and federal investment

While we are promoting the NHIN be financed largely by the private sector, in order to continue to move towards an electronic health information infrastructure and the adoption and widespread use of health information technology, it is critical that policy options that both align incentives and provide federal investment be developed and implemented. These activities will not only accelerate progress, they will also serve to stimulate private sector innovation and investment in these activities.

Current and emerging federal programs should be leveraged to test and evaluate these policy options. The capacity of healthcare information technology to reduce medical errors is clear and wide-scale demonstrations have shown they can lead to reduction in overall health care costs. A CITL study showed that nationwide adoption of computerized order entry systems in ambulatory care would eliminate more than 2 million adverse drug events and 190,000 hospitalizations per year, resulting in savings of close to $44 billion per year in reduced medication, radiology, laboratory and hospitalization expenditures.

Most of the fundamental health care information technology systems are capital intensive both from a hardware, software, implementation and maintenance perspective. Hospitals and physician

groups generally lack substantial capital or sufficient positive cash flow to finance these large investments, particularly the smaller ones where much of healthcare is actually delivered. Through comprehensive investments using a variety of financing efforts, the promise of information technology can be made a reality in the daily interaction of the health care system with the American people. Without such an investment program, we fear healthcare information technology may continue to flourish only in isolated silos to haphazard effect, and most of the population will remain largely untouched.

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 key element of a sustainable business model for the core components of the NHIN is that transaction and/or subscription fees are paid by all participants connected to the infrastructure. Other sources of revenue to support the model that are not currently in place but may be considered are:

- Service fees and/or transaction fees from industry participants for data analyses related to their own information (not data sales)
- Administrative and program management fees from stakeholders for health technology associated programs in patient compliance, care management, health risk assessment, etc.
- Nominal fees from technology vendors and regional sub-networks for adoption and utilization toolsets representing best practices

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 are considerably simplified under a transaction-only model. For one thing, while the CDR model creates better opportunities for cross-organizational aggregate data analysis and reporting, it creates its own set of obstacles related to secondary use of data. In particular, many "source" data providers are reluctant to participate in the CDR model unless they can control and restrict data use. A large, centralized clinical data pool is also a far more appealing target for attack than a demographic-only repository (i.e., the MPI under the transaction-only model).

Under the transaction-only model NHIN, clinical data exchange is usually triggered at the time of a patient encounter. This is important because HIPAA is relatively flexible when it comes to clinical data exchange in the context of a clinical encounter. This exchange is usually exempt from HIPAA privacy restrictions under the treatment exception (in other words, the clinical data exchange is important for treatment decision making, and is in the best interest of the patient).

Under the CDR model, on the other hand, clinical data may need to be exchanged from the data source to the CDR whenever the data is first produced (irrespective of timing relative to a patient encounter), in order that the data be available in the CDR whenever the need arises (presumably, at the next patient encounter). As such, the data exchange in the CDR model may not fall under the HIPAA treatment exception, at least not for the initial exchange between the data source and the CDR.

Whether or not the HIPAA treatment exception can be invoked, state medical record privacy regulations tend to be more restrictive than HIPAA and thus supersede it. In some care settings in some states, this is not a major obstacle to clinical data exchange. Often, existing consent language on the organization's existing registration form is deemed to be adequate to cover the exchange, or only minimal changes or additions to the form are needed. However, if major consenting language changes / additions are required and/or if significant changes to an organization's existing consenting workflow need to be pursued, this can be a major barrier to clinical data exchange.

Some states, for instance, have special restrictions and consenting requirements for the exchange of "sensitive" clinical data, such as prescription history related to HIV, STD, and mental health treatment. Massachusetts is one such state, and a pilot study conducted earlier this year at Partners found that 34% of prescription history reports had sensitive drugs filtered out of the report (David Bates, personal communication, September '04). This is actually quite dangerous clinically, and may represent an example of well-intentioned patient privacy regulations gone awry.

Any NHIN effort should address the interstate variability issue described above, and should seek to eliminate irrational consenting requirements for which there is no practical workflow to accommodate.

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

Guiding principles should be established that support operation of the NHIN itself. These guiding principles will provide a framework for decision making, setting of policies and procedures, rules of engagement by stakeholders, and public messages. These should include at a minimum the following:

- Open support of standards
- Open participation
- Promotion of open choice
- Accountable to the public
- Foster innovation

A standards and policy setting entity should be created with the following characteristics:

- Public and private partnership to include a wide range of industry stakeholders
- Able to pull together and coordinate all the relevant standards setting bodies, identify and fill gaps, and address potential inconsistencies
- Responsible for setting standards and policies necessary to ensure interoperability

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 construction and implementation of a NHIN would create market opportunities for private sector investment and innovation, particularly among technology companies capable of offering products and services related to clinical data management and exchange, the ability to support effective interfaces of diverse information systems in a wide range of care settings, providing connectivity to support electronic data exchange, and more. Savvy technology companies are likely to compete on the open market for their share of the business opportunity created by the development of a NHIN as well as regional collaborative efforts around health information exchanges.

This competition should be encouraged. However, it is important to mention that one of the frequently cited barriers to physician practice adoption of electronic medical records is the difficulty in evaluating their many options, a recognition that none is perfect and each have particular strengths and weaknesses, and probably most importantly, the fear, often realized in recent years, that the chosen solution would go out of business leaving the physician without a sustainable solution after investments are made. Given this challenge, it may be appropriate for the NHIN or a newly created policy and standards setting body to certify or accredit vendors based on some key criteria such as functionality, interoperability with other systems, and financial sustainability.

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.**

Key principles should include at a minimum:

- Encourage private investment by educating the business community on the benefits of a health information technology infrastructure on care quality and costs
- Provide incentives to drive its creation and use. These incentives must be funded by private investment and the return on that investment will be derived from increased adoption by physicians.
- Stimulate competition and innovation among technology companies and other players in the industry
- Set standards for interoperability that create consistencies between the NHIN and regional collaborative efforts as well as between regional collaborative initiatives.

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?

If the NHIN provides access to clinically useful information in a manner that isn't too disruptive of typical clinical workflow, then clinicians will use it regardless of their practice size and location. This was demonstrated nicely by Gold Standard Multimedia's (GSM) recent successful experience with making prescription claims history available to physicians seeing Florida Medicaid patients in the clinic, regardless of practice size or location (Medvedeff, D. Testimony before NCVHS Subcommittee on Standards and Security, May 25, 2004: http://www.ncvhs.hhs.gov/040525ag.htm

While this example utilized a "slick" modern technology approach (including PDAs that had wireless WAN access), the provider-side solution does not have to be high tech or particularly elegant from an informatics perspective in order to be useful and be used. For instance, the NHIN does not have to be accessed directly on-line by a provider or be integrated into or tightly coupled to a point-of-care IT application. Rather, the NHIN could be accessed by an authorized registration clerk or nursing assistant who would then print a clinical summary report at the time of a patient encounter and place it on the patient's paper chart for the provider to review off-line. A controlled trial at Henry Ford Health System showed how easy and effective this approach can be, at least for prescription claims history (Bieszk, N. et. al. Am J Health-Syst Pharm. 2003; 60:360-366).

An important security caveat should be kept in mind when considering a low-tech, non-integrated approach. If patient lookups on the NHIN are triggered at the point-of-care by free-form data entry of basic demographic data into a web form, it will be extremely difficult to prevent and/or detect inappropriate lookups by otherwise authorized users. This is unfortunate, since distributing NHIN access via a non-integrated web browser will remain an otherwise extremely attractive approach for the small, independent practice market generally, and for settings in low income rural and urban areas especially.

The national coverage issue – particularly for low income rural and urban areas – is highly dependent on participating data sources. In many respects, this data source issue is more straightforward to resolve for underserved populations than the issue of how to deploy NHIN access to the providers that service them (unless one is willing to accept the security risks of a free-form web-browser distribution approach, as outlined in the last paragraph).

For instance, prescription claims history can be easily made available via a health information exchange service for Medicaid patients (or Medicare patients with a prescription benefit). All the Medicaid claims processor needs to do is participate with the NHIN MPI so that information requests to the MPI can identify that data is available for Medicaid patients and know where to go to get it. RxHub is doing this today for many managed care Medicaid patients whose prescription benefit is managed by either Express Scripts, Medco, or AdvancePCS (Caremark), and the model could easily be extended to include the few major processors of most other state Medicaid prescription claims (e.g., ACS, EDS, FirstHealth, and CSC).

As noted earlier, Gold Standard Multimedia has connected to Florida's Medicaid claims data and demonstrated that the data could be made available, in real-time, to providers caring for Florida

Medicaid patients. However, it is important to note that a better model would likely be a NHIN connection as opposed to a vendor-specific one.

Of course, accessing payer-based data, such as prescription claims, does not provide a complete clinical picture. Moreover, many if not most of the nation's 40 million plus uninsured live in lower income rural and urban areas, and exchange-based access to Medicaid or other payer data would do nothing to help them or their health care providers. Ultimately, in order for the NHIN to truly be able to deliver comprehensive clinical data for the majority of patients residing in these areas, provider organizations that care for these patients would themselves need to be a participating data source in the NHIN, either directly or, more likely, via their IT vendor(s). Initially, this would probably include only local hospitals and emergency rooms (the latter being where many of these patients receive their primary care, particularly in urban poor neighborhoods), and perhaps local pharmacies, reference laboratories and radiology service providers, but ultimately should include all care delivery settings.

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

The development and implementation of the NHIN should support, inform and help to accelerate community and regional health information exchange projects by providing an infrastructure that supports connectivity and interoperability across clinical settings, systems and services, as well as a core set of data and transactions that are most critical to delivering quality, cost effective healthcare services. The NHIN would also support the community and regional health information exchange projects by providing standards, policies, best practices, guidance on technology requirements and viable solutions so each initiative does not have to start with a blank sheet of paper in its planning, development and implementation. Potentially some funding could also be made available to support local and regional initiatives. Another benefit of the NHIN to local and regional projects could be the visibility and public awareness gained from the national initiative that would help to overcome potential concerns about privacy, security and other issues.

One risk would be that local and regional efforts would stall while they watched the national initiative rather than pressing ahead. This risk could be overcome through a strong communications campaign that would encourage local and regional initiatives to proceed because their projects are important and can inform and be informed by the national initiative.

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

The implementation and broad adoption of the NHIN would lead to business opportunities for savvy HIT vendors. However, the integration of both business and clinical data made available through the NHIN into applications that fit into the workflow of clinicians serving patients will not

be a trivial task. Opportunities will largely reflect the ability of the health information technology market to take raw data available through the NHIN and make it relevant to clinicians at the right time, right place, based on the right information for the right patient. The resulting effect for technology companies that can deliver this content would be increased demand for products and services.

For instance, many ambulatory care ePrescribing and EMR vendors are already integrating prescription claims history—obtained in real-time by transacting with RxHub into their applications' core data structures and user interfaces. This capability, along with the companion functionalities of eligibility-based formulary services and prescription routing, is beginning to differentiate vendors in the marketplace. In fact, we are aware of several recently issued RFPs for EMRs from major institutions (e.g., Duke, Ohio State) that specifically call for these capabilities.

On the acute care side, vendors will initially differentiate themselves by whether or not they can deliver non-integrated, free-text prescription history reports to their customers for admissions, ER visits, or other hospital-based encounters. Eventually, however, their customers will call for tighter coupling between the prescription claims history reports and the vendor's core clinical applications (imagine the frustration of the clinician who has to toggle back and forth between a standalone prescription history report on one screen and a CPOE application on another screen in order to manually enter a patient's home medications). At that point, market differentiation will occur at the level of which vendors can most successfully couple NHIN-accessible patient data with their applications and workflow.

Could the ensuing market opportunities be significant enough to merit the investment in the NHIN by the industry?

This is a difficult question to answer and is dependent on the anticipated level of investment. Although the potential market opportunities may be large, monetary investment on the front end is only possible from a limited number of companies with strong balance sheets. Investments from the technology sector should be viewed through a different lens. The technology sector can and should make significant investments through R&D, product development, connectivity, and market development.

To what entities could the benefits of these market opportunities accrue?

Although there would be differences in scope and magnitude, beneficiaries from the adoption of the NHIN would represent all stakeholders in the market. Certainly, technology vendors benefit through market development opportunities presented as a result of the NHIN. Local and regional integration resulting from system interoperability would drive demand for products and services in the private sector. The resulting competition for business would drive cost down and empower consumer choice. Payors would accrue benefits through streamlined connectivity to providers, improved messaging, and real time interaction. Improved coordination of benefits (COB) is a prime example of how the NHIN could benefit the payor market at large. Other entities such as labs, pharmacies, radiology centers etc. realize significant benefit as a result of improved efficiencies through information sharing. Provider groups such as hospital systems and physician organizations would accrue benefits through operational efficiencies and decreased liability. Broad adoption of information technology will produce opportunities to improve and reengineer

workflow for optimal performance. Employers should see benefits through a reduction in healthcare expenditures and increased employee productivity.

As described in the response to question 2 in the section entitled Healthcare Vendor Support, while creating an environment that promotes new market opportunities, the NHIN has an important role and responsibility to ensure neutrality by prohibiting commercial messaging and pop up advertising (defined as messages that pop up during the care process that are not specific to the patient's safety or an improved clinical decision and are intended to change a clinical decision) at the point of care in e-health platforms. By prohibiting this type of commercial messaging, healthcare providers can be assured that pharmacies, manufacturers, labs, payers, etc. are prevented from paying software vendors to highlight products or services and attempt to persuade clinicians to change their decisions. Information on formulary and benefit plan design should be allowed so long as all medical options to a physician and patient are available.

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?

Up front monetary investment on a large scale from the healthcare technology sector although desirable, is unlikely. Front end investment through activities described above would be a more likely scenario. Operational support to maintain an NHIN through ongoing service fees would be a reasonable expectation. However, any fees would have to be validated against current business and economic models and result in an appropriate return on investment for the technology sector.

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?

The NHIN should establish a Standards and Policies Committee made up of diverse industry stakeholders. This committee would establish the standards for operations of the NHIN and for participation by service providers and regional networks. The standards and policies developed should reflect the appropriate standards from the various Standards Development Organizations and those regulated by federal and state governmental entities such as the following:

- Standards organizations (NCPDP, HL7, etc.)
- NCVHS
- DEA
- HIPAA

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 NHIN will have to establish the necessary standards and policies as suggested previously. Service providers will have to contract with the NHIN where these providers will have to agree to the appropriate standards and policies in order to provide services or access services to/from the NHIN. In addition, the various network participants will have to complete an appropriate certification process to insure adherence to the NHIN standards.

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?

It is suggested that the most critical SDOs participate in the Standards and Policies Committee, if not as full members, at least in an advisory capacity.

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?

Management and business rules should:

- Ensure a neutral platform that serves the needs of diverse stakeholders
- Protect patient privacy
- Understand and address practice workflow issues and implications
- Prohibit commercial messaging at the point of care intended to change clinical decisions based on something other than patient safety or formulary and benefit design information
- Ensure a sustainable operating and financial model
- Provide agreed upon interoperability standards and support provider choice of software solutions that meet those standards

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?

- Requirements should be delivered to the appropriate ANSI accredited SDO for development of or enhancement to the appropriate standard.
- Specific version/releases should not be dictated as this will slow down business driven requirements from being implemented. Reference should be made to a base version/release of a standard but not prevent participants form implementing new version/releases of the standard as long as backward compatibility is maintained

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?

- Financial incentives will be needed in the initial phase to fund start-up costs, initial adoption and use
- Establish federal and regional matching funds to support initial start-up implementation costs.
- Ultimately incentives should be based on improved outcomes -- quality and cost performance such as the emerging Pay for Performance programs
- The NHIN and the RHIOs need to be financially self sustaining within a reasonable period of time (eg. 3-5 years)

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?

- Financial incentives will be needed in the initial phase to fund start-up costs, initial adoption and use
- Ultimately incentives should be based on improved outcomes -- quality and cost performance such as the emerging Pay for Performance programs
- The NHIN and the RHIOs need to be financially self sustaining within a reasonable period of time (e.g., 3-5 years)

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?

Potential statutory and regulatory constraints on the formation, adoption and operation of a NHIN arise from various branches of law, including data privacy, fraud and abuse, tax, antitrust, and professional licensing. In addition, the threat of malpractice liability and similar litigation may chill adoption of a NHIN.

Data Privacy

Privacy and security legal requirements that were written with non-electronic health care systems in mind can be a barrier to the formation and operation of a NHIN. For example, some states have provisions that prohibit passing prescriptions from a physician to a pharmacist using an intermediary. Both SureScripts and RxHub had to review these requirements and obtain clarification from numerous state boards of pharmacy that these prohibitions do not apply to transmission of electronic prescriptions from physician to pharmacist using an electronic network.

In many cases, the state boards of pharmacy deemed that these prohibitions do apply to prescription transmissions using an electronic network, which in turn necessitated a variety of legislative and regulatory lobbying efforts by SureScripts and RxHub to remove these obstacles. The staff time and financial resources consumed by these efforts has been significant for both organizations.

Privacy and security legal requirements vary from state to state, with HIPAA providing a federal "floor" for protection. Developing a NHIN, which by definition is a nationwide system, requires complying with requirements in all fifty-plus states and other jurisdictions as well as federal requirements. Even collecting all of these requirements is a large task and interpreting them is a larger task.

Examples of additional privacy and security requirements that are a barrier to formation and operation of a NHIN are discussed in our response to Question 7 of the RFI.

Fraud and Abuse and Anti-Self Referral

Federal and state fraud and abuse provisions, including the federal Stark law (prohibiting patient referrals from physicians to entities with which the physician has a financial relationship), and the federal Anti-kickback law (prohibiting the provision of anything of value in exchange for recommendations, referrals or purchases), are a barrier to hospitals and other providers, insurance companies, manufacturers, suppliers or other parties providing financial assistance or technology to physicians for adopting a NHIN. Such financial assistance may be seen as (1) creating a financial relationship for purposes of the federal or similar state anti-referral laws or (2) being a kickback for the physician referring patients to services or items.

This barrier to creation of a NHIN has been recognized and there have been several initiatives to create exceptions or safe harbors to permit physicians to receive assistance in adopting health information technology. However, fraud and abuse laws are very broad and can have severe civil and criminal penalties, including the risk of exclusion from participation in state or federally funded healthcare programs. Unfortunately, proposed exceptions and safe harbors are also often limited in scope or not clear in their application. Physicians may choose not to participate in assistance unless an exception or safe harbor to fraud and abuse liability clearly applies.

Tax

Many hospitals are tax-exempt organizations. Tax-exempt organizations are prohibited from providing financial or other benefits to taxable entities (such as individual physicians), and may be wary of providing financial or technical assistance to physicians adopting a NHIN. Violation of these private inurement provisions can result in intermediate sanctions, including penalties to officers or directors and even loss of a hospital's tax-exempt status.

Antitrust

A NHIN will require the cooperation of many different health care entities, many of which are competitors. Cooperation among competitors raises antitrust questions. Although antitrust

sanctions should not apply when the benefits of cooperation to a NHIN outweigh any anticompetitive effects, the threat of sanctions remains and poses a barrier to formation and operation of a NHIN.

Professional Licensing

All states administer licensing schemes for health care professionals, including physicians and pharmacists. If a NHIN provides information about possible diagnoses, drug interactions, etc., there is a risk that the information will be deemed the unauthorized practice of medicine or the unauthorized practice of pharmacy.

State-based licensing also means that a physician or pharmacist licensed in one state is not licensed in all states. Consequently, physicians and pharmacists may be wary of providing advice or conclusions using a NHIN to patients located in another state for fear of violating licensing requirements in the patient's state.

Malpractice

Physicians are increasingly threatened by malpractice litigation, which can cause physicians to fear any change in health care delivery that provides plaintiffs' attorneys with easily discovered information, particularly in areas of peer and retrospective review.

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

Data Privacy

Specific technical recommendations are set forth in our response to Question 7. In addition, we recommend that a NHIN build on the work of existing nationwide health information systems. These systems have been designed to comply multiple state laws and regulations as well as federal HIPAA privacy and security standards. We also support efforts to make privacy and security regulations more consistent nationwide and more tailored to NHIN-specific issues.

Fraud and Abuse; Tax

Legal restrictions and uncertainties imposed by fraud and abuse laws and tax considerations (e.g., private inurement) need not affect the technology used for a NHIN. However, organizations sponsoring a NHIN will need to follow developments in these areas as exceptions and safe harbors are implemented (e.g., with respect to Stark, for community-wide health information systems and for Medicare Part D). We support broad, clear exceptions and safe harbors to promote a NHIN that, at the same time, are sensitive to the policy concerns behind fraud and abuse and private inurement.

Antitrust

We believe that cooperation, including between competitors, on developing and using consistent technological infrastructures for a NHIN provides clear benefits that should outweigh any concerns regarding anticompetitive effects. However, we support clarification by the appropriate governmental agencies that such cooperation is not a violation of antitrust laws. Just as they have in other areas, we suggest that Justice and FTC consider issuing antitrust "safe harbors" to apply to NHIN.

Professional Licensing

We believe that a NHIN does not itself require state licensing. We also believe that health care professionals licensed in one jurisdiction should not be penalized by another jurisdiction because a NHIN connects to other jurisdictions. We support legal clarification of these principles.

Malpractice

A NHIN has the potential to reduce medical errors and improve health care outcomes. We believe that some physicians will choose not to adopt a NHIN for fear that the additional information available through a NHIN makes it easer to file frivolous malpractice claims. We support legislation granting protection from medical malpractice claims for providers that adopt and appropriately utilize NHIN.

OTHER

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

The physical network that will support the NHIN will primarily be the Internet, with private connections as deemed necessary between organizations. The NHIN needs a mechanism such as a MPI to support patient identification as well as identification of providers and care settings (laboratories, pharmacies, physicians, etc.).

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?

Early success will be measured in terms of coverage and participation level. For example, the number of physicians/clinical caregivers, hospitals, payers, pharmacies, labs, etc., connected to the infrastructure. The next phase of success will be measured based on levels of utilization of the infrastructure. Additional measures that will be key include the satisfaction of those using the infrastructure and ultimately the impact on outcomes.

Attachment 1
Participating Vendors

Certified Technology Partners	
RxHub	**SureScripts**
Allscripts	**PHYSICIAN TECHNOLOGY PARTNERS**
Barnes Jewish Hospital	A4 Health Systems
Catalis Health (formerly ReCare)	Allscripts
CAQH (Formulary Only)	Cleveland Clinic (using Epic system as EMR)
▪ Anthem	DrFirst
▪ Aultcare	Gold Standard Multimedia
▪ Wellpoint	HealthRamp
DrFirst	InstantDx
eRx Networks	MedPlexus
Express Scripts	NewCrop
HealthRamp	SynaMed
HealthVision	University of NC Health System
InstantDx	
iScribe	**CHAIN PHARMACIES**
MA Share	Albertsons
▪ Beth Israel Deaconess Medical Center	Brooks/Eckerd
▪ Boston Medical Center	CVS
▪ Emerson Hospital	Longs
MDanywhere	Rite Aid
Medco Health Solutions	Walgreens
MedPlus	Wal*Mart
McKesson	
NewCrop	**PHARMACY SOFTWARE PROVIDERS**
NextGen	eRx / PDX / pc1
Phytel	Etreby Computers
Relay Health	HBS
RxRite	HCC – Synercom
SafeMed	HCC – Alpha PC
ScriptRx	Interactive Systems & Management Corp.
RxNT	McKesson – Pharmaserv
ZixCorp	NDCHealth – Condor
	NDCHealth PharmacyRX
	NDCHealth – Zadall
	QS/1 – RxCare Plus
	QS/1 - CRx

Attachment 1 (continued)
Participating Vendors

Contracted Technology Partners	
RxHub	**SureScripts**
A4 Health Systems *(in certification)* Bond Medical *(in certification)* CAQH ▪ Aetna *(in certification)* ▪ Cigna *(in certification)* ▪ First Health *(in certification)* Cardtronic MedKeeper (Formulary Only) PCN Regenstrief *(In certification)* Synamed (Formulary Only – *in certification*) WebMD Wellinx	Axolotl Bond Medical ChartConnect DOCS eClinical Works eMDs Health Systems Research HealthVision iMedica Kryptiq Lighthouse Medical Management McKesson MDanywhere MedicWare MedNet System MedPlus Physician Micro Systems Wellogic ZixCorp