January 18, 2005

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

Re: National Health Information Network Request for Information

Dear Dr. Brailer:

On behalf of the American Hospital Association (AHA), our 4,700 member hospitals and
health systems, and our 31,000 individual members, we appreciate the opportunity to comment
on the Request for Information (RFI) on how widespread interoperability of health information
technologies and health information exchange can be achieved through a National Health
Information Network (NHIN), published in the *Federal Register* on Nov. 15, 2004.

We applaud the Bush Administration for recognizing the value and the promise of using health
information technology (HIT) in providing care to patients. For many years, health care
providers have talked about the amazing potential for using HIT, but progress has been slow
and the struggles many. American hospitals are varied in their size, capacity and financial
resources to invest in HIT. For many hospitals, the money simply isn't there to invest. For
others, choices need to be made based on challenges they must confront in their communities.
To accept the risk, make the initial investment, and fund the ongoing costs, means carefully
selecting which projects to fund based on a thorough assessment of community needs. For
example, some hospitals may establish HIT as a top priority because typical "bricks and
mortar" improvements are not as critical at this stage of their operations, while others may have
trouble accessing capital for building projects let alone IT. The progress made by hospitals
across the country in implementing HIT also varies greatly. While some hospitals have
adopted very sophisticated and extensive components of an electronic health record, most are
simply in the beginning stages of considering or planning such systems.

Hospitals are fundamental to the health care system within their communities. Because they
provide care 24 hours a day, hospitals will be the source and custodians of significant portions
of the data available within the NHIN. In addition, hospitals will be one of the primary users
of the data. Thus, hospitals must play a prominent role in the development of the NHIN
infrastructure. Moreover, the committees and commissions that will be setting standards,
certifying products, etc., must be accessible to all stakeholders. The process cannot be confined
to the input of organizations that are able to pay a membership fee. An open and transparent
process is key to the success of a NHIN.

As policy leaders and decision-makers move forward in working toward creating a NHIN, the AHA will focus on a few guiding principles:

- Health care and the implementation of HIT is a public utility and, therefore, must be a shared investment;
- Although providing care is done at the local level and the needs of communities differ greatly, the creation of a NHIN must be based on national standards and a common framework;
- The success of a NHIN requires a public/private partnership with all stakeholders at the table; and
- The success of a NHIN ultimately will be judged based on whether it makes a difference in the care provided to patients at the bedside.

In an effort to limit our comments to those questions most applicable to hospitals, we have chosen to focus on four questions. However, we stand ready to discuss these and others in more detail at a later date.

Question 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.

Definition: A NHIN is a public/private infrastructure used to connect providers, employers, insurance plans, public health authorities and patients in order to share information, provide greater quality care, reduce errors, and gain efficiencies in the secure transfer of information. A NHIN should be flexible, scalable, reliable and interoperable. It is built on a "common framework"[1] that enables the creation of standard interfaces at the local, regional and national levels. This common framework is necessary to ensure the creation, interoperability, scalability, efficiency and ongoing evolution of this environment. In addition, it is a system based on the premise that the patient is the owner of the information and that patient information will be protected. The design's ultimate goal is to benefit the patient and allow providers access to the tools and information necessary to provide higher quality patient care. Identifiable patient data should be decentralized; data must reside where it was created and be accessible to providers who are granted access by the patients. We support the aggregation of nonidentifiable information for the purposes of improved public health improvements. Two absolute requirements for a fully functional electronic health information network are:

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[1] The AHA is not supporting one particular framework, but rather using the term in a general context.

1. A precise set of technical communications protocols for transmission of data among all relevant parties. This is a connectivity issue.
2. Detailed business standards to make sure all data is being defined and used the same way. For example, since hospitals routinely define swing bed patients and observation patients differently, any epidemiological research using these data points will be severely compromised until consistent definitions are implemented.

The health care industry's experience with transitioning to the Health Insurance Portability and Accountability Act (HIPAA) transactions and code sets showed that even though HIPAA tightened up definitions to a certain level, the business rules were not adequately addressed, thereby allowing each health plan to continue to define and populate numerous fields in their own ways, thus crippling the intended endpoint of the HIPAA standards.

Until both of these areas are fully defined, a truly interoperable network is impossible. Vendors of health data products will continue to develop their own products and approaches, many of which will ultimately become obsolete once the industry coalesces around the final system-wide approach. Due to the very costly investments required, many hospitals will purchase expensive systems in 2005, 2006 and 2007 that will ultimately become outmoded, but which will still be used for many years to come because they are too expensive to replace. In other words, until both aspects of the interoperability standards are fully defined, vendors will continue to produce and hospitals will continue to purchase what will be tomorrow's outdated "legacy systems."

Barriers
Currently, there are probably more barriers—either real or perceived—than enablers that will lead to the creation of a NHIN. Most important are the lack of national standards that define terminology, vocabulary and messaging of data content.

As a starting point for implementation, the following are recommended for <u>terminology standards</u>:
*   Adopt ICD-10-CM and ICD-10-PCS to replace ICD-9-CM for hospital inpatient (acute care) services;
*   Continue to support the use of CPT and HCPCS designated for outpatient procedures/services;
*   Further study is needed on the feasibility (cost/benefit) of adopting LOINC and SNOMED.

For <u>vocabulary standards</u>, we recommend establishing a dictionary of commonly used medical record terms, as well as assigning common names, titles for medical record documents and components contained within those documents.   For <u>messaging standards</u>, we recommend selecting electronic format designs to encapsulate medical record information. These must be scalable and capable of integrating simple messages for specific tests, imaging, text, voice, and communication protocols (operating systems, internet, Bluetooth, wifi, etc).

In addition, there currently lacks a well-documented common business model that is necessary

to support the NHIN: the business model must take into account the use of the various applications of the NHIN by entities of the same type (e.g., internal provider operations); among entities of like-type (e.g. the ability of a hospital to exchange information with a physician office, or from one provider to another provider); and among interested entities (e.g., health plans, government agencies, accreditation organizations, public health reporting, etc.).

The sheer number of providers, patients, and interactions/transactions between them make creating a NHIN a challenge. The ultimate coordination and buy-in among stakeholders is complicated and likely to be a lengthy process. Without an architectural blueprint present, the system will seem directionless and unstable. For many who have legacy systems in place, problems will arise in the ability of these systems to read information from each other. Initially there will be a natural reluctance for providers to give up their legacy systems, many of which are relatively new and required extensive investments. Establishing standards for terminology, vocabulary, and messaging standards will give vendors that build many of these systems for providers a clear direction about baseline specifications. It would also give providers who plan on spending HIT monies in the near term some confidence that these investments will employ components that conform to a future vision of the NHIN.

Once the framework is defined and the supporting standards named, there will be enormous educational efforts that must take place — for providers of patient care, for patients, and for policy makers — to understand the attributes necessary for the successful creation of a NHIN. In the past, we have heard from many hospital leaders about the great reluctance on the part of clinicians to initially learn new technology systems and to familiarize themselves with new standards and processes, even though these are a necessary part of a new HIT system. Although the potential is great for HIT, its value must be appreciated before the benefits can be fully realized.

For many hospitals, navigating an often unstable vendor marketplace proves to be a barrier to HIT investment. Many hospitals face a dearth of reliable information about vendor products. Products may have a short halflife, and after HIT is adopted, hospitals often discover vendor support is limited. If these hurdles are not cleared, investment in HIT will be an insurmountable challenge for many.

Additionally, to date, many hospitals have been unable to demonstrate a return on investment for their HIT outlays. The promise of efficiencies and savings to hospitals may exist in the long term. Numerous studies are underway to analyze the evidence for such savings. Assuming that savings are achieved, they will likely be realized by insurance plans paying lower rates to hospitals and employers paying lower premiums. Hospitals and patients will benefit, if not financially, through improved quality and outcomes; this alone is sufficient to drive hospitals to the procurement of new technologies. However, such benefits will not help fund the HIT systems.

Enablers
With that said, many enablers either currently exist or are somewhat available to encourage providers to invest in HIT. Not to be underestimated is the role of the federal government and

policymakers to continue the focus on HIT. Drawing attention to the value of systems that help with patient safety, care management, and efficiencies in providing care remind people that this issue is important, has promise, and that change is needed. Patients will soon demand technology, and the market may dictate how care is delivered and communicated. Although government attention to the issue is important, we strongly believe that the creation and use of HIT and participation in a national system, must be voluntary and incremental in its approach to the way care is delivered. The role for the federal government is to serve as a catalyst by adopting national standards and providing an incremental roadmap that enables creation of a NHIN.

Secondly, financial assistance and incentives for providers are needed. As will be discussed later on in this RFI response, this should be a shared investment because providers bear most of the initial cost without much return on investment (ROI), financial incentives must be available, and made available over a long development period.

Finally, providers must have confidence in their investments. Because this technology is rapidly changing, the adaptability of technology systems and the ability to upgrade HIT without penalty or loss of investment will help ensure continued provider participation and ultimate success of the NHIN.

Question 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.)

As NHIN and downstream Regional Health Information Organizations (RHIOs) are created, some responsibilities will be shared while others will have a place at a national, local or regional level.

National
At the national level, the first and foremost goal is to create a common framework that defines components as national standards, as well as provides a certification process to assure providers that what they are purchasing is compliant with national standards or specifications. The components for national standards are terminology, vocabulary, and messaging standards. There may however be specific components that can be added to recognize regional or local health needs or local regulations (public health reporting, accreditation, and other). In addition, the establishment of communication protocols should provide flexibility to allow for geographic disparities in communication capabilities or technologies (factors influencing communication capabilities are geographic distance, phone line infrastructure, Internet availability, etc).

Initially, the federal responsibilities may seek to include incentives for early participation, but it requires a clear articulation of the strategy for a NHIN and the establishment of oversight and enforcement agencies to ensure adherence to the component standards. Additional

guidance/policy changes on issues related to HIPAA and Stark Anti-kickback laws should be provided at the national level to remove impediments to participating in both a RHIO and a NHIN. Standards and guidelines concerning warehousing the data should also be created at the national level.

Local
Because most health care is local, the bulk of information transfer occurs in a patient's own community. However, as patients move about, information must be able to flow across state lines and other regions. The national standards must provide a performance baseline but should also allow some flexibility to fit differing needs at the local level. However, in the end, the functionality of performance should be similar across localities. Local entities should have responsibility for applications of technology; supervising uniform adoption of information-sharing policies by participating entities; and establishing a multi-stakeholder governance structure.

Question 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. The kind of financial model required to build a NHIN (potential sources of initial funding, relative levels of contributions among sources and implications of various funding models).

Significant attention on financing the NHIN, the RHIOs, and individual HIT systems is essential as we move forward on this issue. Each community's needs differ based on market conditions, existing infrastructures, regulations and other variables. All stakeholders will need to contribute and share in the investment. We believe that the use and purchase of HIT is a public utility, and, therefore, needs to be a shared investment. The upfront cost is significant and must include a federal contribution toward the infrastructure.

It is important to also note that certain federal laws present barriers to the adoption of HIT. Most notably, the Physician Self-Referral (Stark) Law and the Anti-kickback Law hinder the establishment of arrangements between hospitals, physicians and other providers interested in establishing mutually beneficial relationships around HIT investment and implementation. In general, anti-kickback laws prohibit payment, solicitation or remuneration between certain stakeholders in exchange for referring another individual for a service, purchasing or leasing an item or service or arranging for or recommending the purchase of an item or service. While these laws do not directly address HIT arrangements, health care providers are concerned that certain arrangements could violate existing laws. As a result, health care providers are reluctant to make significant investments in HIT when the legal consequences remain uncertain. By modifying existing law, loosening the standards or expanding the definition of safe harbors, the federal government could create new incentives for physicians, hospitals, and other providers to establish beneficial relationships to promote investment in HIT.

In addition to these suggested modifications, certain financial incentives should be considered to further HIT adoption and implementation. These incentives are vital to HIT adoption as evidenced by the Medicare Payment Assessment Commission's (MedPAC) latest estimates

that in the year 2005, hospitals overall Medicare margin will be *negative* 1.5%. And one-third of nation's hospitals today—large and small, urban and rural—are losing money overall treating patients. Hospitals are already facing difficulty accessing the capital needed to meet growing demand, replace aging facilities, and update technology. With more bond downgrades than upgrades (Standard & Poor's, 2004), hospitals are finding access to capital difficult. Moreover, once the systems are in place, the maintenance costs are also significant.

Noting these difficulties, we would encourage the government to consider offering federal seed money and tax credits for HIT investments. The AHA strongly supports grants and low-interest loans for providers and communities to create RHIOs as part of the NHIN. These programs would help provide incentives for early adopters and would increase participation in the RHIOs. In order to receive funding, providers would be accountable to the government for complying with the new standards of the RHIO/NHIN. This effort is just as important as past government efforts, such as the Hill-Burton program that provided low cost loans to hospitals to expand their facilities to accommodate the health care needs of their community.

After the NHIN and the RHIO are established, a business practice model must be defined and an assessment of the costs involved along with the benefits derived need to be established. The process should not proceed until there are several regional demonstration projects that can provide findings on the costs, the hurdles, the successes and the benefits derived.

Numerous private sector and governmental pilot projects are currently underway to test the feasibility of implementing "pay-for-performance." Of the models being discussed for the future, many rely on a complex HIT framework. While we support the use of HIT, we would strongly encourage more thought and analysis in the application of this approach. It is not enough to simply reward providers for the presence of HIT designs, rather, the rewards should be based on the use of HIT and the improvement in patient outcomes. The AHA has experience in creating a "pay-for-performance" structure using quality indicators and other data. We know the obstacles but also realize the promise and stand ready to participate in further discussions about this approach.

As the funding for HIT is debated, special attention to the needs of smaller hospitals must be considered. The larger hospitals and medical groups will likely have a stronger infrastructure as well as greater staff support (both technical and administrative), therefore, they are more likely to be technologically connected and can better support broader HIT adoption.

In addition to legal modifications and financial incentives, certain market-based incentives should be created. For example, the reduction of medical malpractice insurance rates based on HIT use and the creation of collaborative HIT vendor-provider relationships that minimize upfront HIT costs should be considered.

Question 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 AHA, as part of the Healthcare Leadership Council (HLC), has signed an HLC comment letter on behalf of its privacy coalition members. Please note that letter and associate our comments with that document.

Question 11: How could a NHIN be established so that it will be utilized in the delivery of care by health care 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 AHA, working with all the state hospital associations, is in a unique position to help bring this vision to a reality. As previously mentioned, communities differ greatly in their makeup and their needs. Individual systems currently exist that meet the needs of specific communities. The establishment of a RHIO and the NHIN has the potential of limiting the operating overhead for individual hospitals or group medical practices. Once these networks are established, they will require ongoing infrastructure and organizational support. It is important to carefully monitor the creation of these components and make available the lessons learned, so that the "wheel" is not recreated. This should prevent unnecessary vendor costs.

The process should include logically placed building blocks to prevent wasting already scarce resources. Community needs should be well defined at the onset. We also realize that these needs will periodically be redefined, issues of feasibility and cost will also need to be revisited. The design of the system envisioned should also be flexible and capable of taking advantage of already existing infrastructures, thereby reducing the degree of modification to legacy systems. It is important to create a framework that is not complicated but is well defined. This would help hospitals and individual providers understand what it will take to participate as well as their investment in the community network. Simplicity and cost- effectiveness must always be at the forefront in the decision-making of a NHIN.

Several of our member hospitals have already created local or community HIT networks prior to knowledge of a future NHIN. For those who have already made investments in community HIT networks, funding should be available as needed to alter these systems.

Participation in HIT networks must provide access that is scalable. It must be possible for providers with a low level of technical sophistication to access the NHIN with an Internet browser. Having limited access choices removes too many people from the NHIN and diminishes its value. In addition, financial help should be given to establishing "support centers" to help those smaller, more rural, or underserved areas. Without technical help, these providers are likely to miss the opportunity to participate, and thus be counterproductive to the ultimate goal of a NHIN.

The AHA appreciates the opportunity to comment on the Request for Information. Thank you for your consideration of these comments. If you or your staff have any questions regarding our comments, please feel free to contact Kristin Welsh, Executive Branch Relations, at (202) 626-2322, or e-mail at kwelsh@aha.org.

Sincerely,

Rick Pollack
Executive Vice President