PATIENT SAFETY INSTITUTE
Partners Working Together for the Good of Patients

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January 18, 2005

David J Brailer, MD, PhD
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert H. Humphrey Building, Room 517D
200 Independence Avenue, S.W.
Washington, DC 20201

RE: NHIN RFI Response

Dear Dr. Brailer:

On behalf of the Patient Safety Institute (PSI), I am pleased to submit this response to the Request for Information that your office issued on November 9, 2004. We would like to thank you for this opportunity to participate in this important discussion.

PSI is a national non-profit, 501(c)(3) organization that is dedicated to supporting communities across the nation in their development of clinical information sharing networks. PSI is governed by leading consumer, physician and hospital advocates, and believes strongly in the promise that applying existing, scalable and inexpensive technology holds for improving healthcare quality, safety and cost. Attachment A is listing of the members of PSI's Board of Directors.

Our response is targeted at the major issues surrounding the development of a National Health Information Network. I will be glad to provide you with additional information on our views of the subject or to answer any questions that may arise. If you have any questions, please do not hesitate to call me at 972-516-4260, or Jack Lewin, MD who serves as the Chairman of our Board of Directors. Dr. Lewin can be reached at the offices of the California Medical Association, 916-551-2020.

Best Regards,

   /s/ Johnny Walker

Johnny Walker
Chief Executive Officer
Patient Safety Institute

Central Thesis

The primary obstacle to creating the NHIN has not been the absence of suitable technology. Rather, what has been lacking is a sustainable economic model and a governance and administrative infrastructure that is acceptable to all of the important constituencies.

More than 35 years ago, a successful technology solution was pioneered in the banking industry to link otherwise unrelated consumers, merchants and banks to facilitate commerce. Many parallels have been drawn between the circumstances and architecture that VISA uses to address its interoperability challenge and the circumstances that consumers, physicians, hospitals, payers, nursing homes, home health agencies, retail pharmacies and others currently face during healthcare encounters. The VISA network and organizational model is a time-tested means of delivering highly reliable and secure data to the point where it is needed quickly and at a very low cost per transaction.

At Patient Safety Institute, we have successfully developed and deployed a technological model using the latest open-architecture technology that links patent-centric clinical information from disparate healthcare providers at the point of clinical contact. This technical solution has been in continuous service in the Seattle area since early 2003 and continues to expand its reach, providing otherwise unavailable clinical information to physicians quickly and securely. The technology has been vetted by senior government officials and experts from across the country who have affirmed that the model is viable and scalable to meet the needs of the US Healthcare system (or larger, if needed).

Whether PSI serves as the vehicle to facilitate the NHIN or not, we believe these issues will need to be addressed by whoever accepts the responsibility for the NHIN.

Economic Model

Because PSI has already created a model governance system, the key remaining obstacle is to find a sustainable economic model that will cover the costs to implement and operate the governance and technical model on a regional and national scale. Like Secretary Thompson and many other noted industry experts, we believe that the NHIN--if constructed in a way that fosters rapid adoption by providers and facilitates easy sharing of clinical information--will produce significant economic benefits for a variety of constituencies. Most of the savings will be as a result of significantly reducing the number of unnecessary duplicative diagnostic tests, reducing or eliminating duplicative medication orders, reducing unnecessary hospitalizations, streamlining certain aspects of the clinical trials process, etc.

Based on our research and early projections, the total cost to build and operate the NHIN will be a small fraction of the economic benefits that will accrue from its deployment. Therefore, the most significant funding hurdles to overcome are:

- demonstrating that the economic benefits are attainable and quantifiable;
- establishing an equitable model for allocating costs based on net realizable benefits; and
- finding source(s) of capital that are willing to finance the initial infrastructure deployment in return for a reasonable rate of return.

To this end, we have developed a business model (based on the existing literature) that equitably distributes the costs associated with building and maintaining the NHIN among those who reap the economic benefits. We are in the process of initiating a demonstration project to measure and validate the economic model across a region.

We have received proposals from four large urban communities that wish to participate in the demonstration and will finalize our selection shortly. We are also in discussions with a number of organizations and agencies who have expressed an interest in financing the demonstration project.

If our hypothesis regarding the self-funding model is supported by the actual results of the demonstration project, we will have solved one of the most significant challenges that communities across the country face as they look to find ways to fund the development of local clinical information sharing networks. Further, we will be able to provide the healthcare industry with a model for financing the NHIN using private funds in a way that does not create any potential for conflicts of interest with regard to maintaining patient privacy. The alternative to PSI's self-funding approach, (which follows VISA's successful model of value-based user fees) is continuing the current model of capital-intensive and time-consuming financing by state and federal government agencies. This leaves the communities (or government) responsible for the continuing operating costs once the implementation program has been completed.

Governance

Issues of governance for the NHIN must be resolved in a manner that is acceptable to all participants. Specifically, this means that no single individual, organization or stakeholder group is in a position of dominance or control. Additionally, history has shown that the nation's most influential consumer advocates will apply the toughest litmus test on this issue. Consumers must hold an equal or disproportionately larger share of the seats on the governing body. Due to consumers' strong positions on maintaining patient privacy, we believe that consumers will be naturally reluctant to support any solution owned by profit-driven firms or controlled by a government entity.

Accordingly, we believe that at a minimum, five core issues should be controlled at a national level by a non-profit, non-governmental agency that is governed by leading consumer, physician and hospital representatives. These five issues are:

1) establishment and ownership of the underlying technical architecture;
2) determination of the minimum set of operating policies and procedures that all participants must adhere to (including the power to charge [as approved by the membership] value-based user fees [e.g. VISA interchange fees] those members who benefit financially from the network);
3) maintenance of the master "switch" that contains information about the location of the clinical data sitting behind the firewalls of the various sources of clinical data, but not the actual clinical data itself;
4) maintenance of a library of interface specifications for various health information technology systems; and
5) leveraging economies of scale for the benefit of all community participants.

To ensure that the relevant federal government agencies have a strong role in advising and guiding this process, the national, non-governmental agency should have a close working relationship with the Office of the National Coordinator for Health Information Technology, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, Centers for Disease Control, Department of Defense and Veterans Health Administration. Further, the organization's governance structure should include representatives from the regional governing bodies (see discussion below); and should have a formal mechanism in place for obtaining advice and counsel from technology vendors and experts in the areas of privacy and network security.

Additional thought should be given to the role that the bio-pharmaceutical manufacturing industry should play, given the potential for the NHIN to facilitate the recruitment of patients for clinical trials, as well as post-marketing studies.

Beyond these fiver core issues, regional governing bodies should be empowered to:
- make decisions on incorporating additional technical functionality (e.g. incorporating context-specific guidance for practitioners based on locally accepted clinical pathways or inclusion of expanded clinical data elements);
- monitor compliance with national rules and regulations; and
- establish operating policies and procedures that address local issues.

Patient Safety Institute
The Patient Safety Institute was formed in 2001 to apply the "trusted third party governance" philosophy to the patient safety and clinical information sharing problems facing the healthcare industry. Since that time we have achieved the following:
- Organized a nationally respected, consumer-focused Board with VISA®'s founder and CEO Emeritus as a senior advisor to the Board;
- Raised approximately $15 million, using those funds to design the <u>vendor-neutral and standard-neutral</u> PSI national utility solution and implement a community demonstration project in Seattle, Washington.
- PSI's Seattle demonstration supports all existing industry standards, but does not require a user to comply with a standard before being able to connect. This Seattle project met with rave reviews from the participating physicians, who reported seeing a tangible positive impact on the care they provide and reductions in cost, often within their first few hours of using the PSI utility;
- Received support and endorsement from the Western Governors' Association for statewide implementations;
- Selected by national clinical data providers including RxHub, LabCorp and other major lab companies to distribute national data through the PSI network;
- Garnered strong national bipartisan political support.

Our organizational concept is open to all constituency groups including patients, physicians, hospitals, insurers and other payers, labs, and pharmacies. These groups can organize within PSI at any time, on any scale, in any manner and for any purpose consistent with PSI's purpose and principles.

As described in our discussion of the economic model above, we are in the final stages of selecting a community to serve as the demonstration site to test our self-sustaining economic model. We

have had discussions with a variety of both public and private entities who are interested in providing the $8 million in capital that will be required to test our framework. We hope to announce our choice of site in the coming months. We believe that the work we have done to date and our ability to move quickly could be of significant benefit to the various federal agencies that are wrestling with health information technology issues, including the Office of the National Coordinator for Health Information Technology. We stand ready to cooperate with ONCHIT and any other party that is interested in leveraging our work in this critical area.

Attachment A: PSI Board of Directors

Biographical information on each Director can be found at www.ptsafety.org/board/

Chairman
Jack C. Lewin, MD, Chief Executive Officer-California Medical Association.

Vice President
Don C. Black, President-Child Health Corporation of America.

Secretary/Treasurer
Jane L. Delgado, PhD, MS, President and Chief Executive Officer-National Alliance for Hispanic Health.

Twila Brase, RN, PHN, President-Citizens' Council on Health Care.

Richard F. Corlin, MD, gastroenterologist in private practice, and Past President and Executive Committee Member of the American Medical Association (AMA).

Karin Dufault, SP, PhD, RN, Vice-President, Mission Leadership-Providence Health System, Trustee of the Board of Catholic Health Association and former Board Chair of Providence Health System.

Linda F. Golodner, President and CEO-National Consumers League.

William F. Jessee, MD, FACMPE, President and Chief Executive Officer-Medical Group Management Association.

Daniel H. Winship, MD, Chief-Cook County Bureau of Health Services, and former Petersdorf scholar in residence at the Association of American Medical Colleges and Vice Chancellor of Health Affairs and Chief Executive Officer at University of Missouri Health Care.

Ex-officio
Johnny Walker, Chief Executive Officer-Patient Safety Institute.