

**U.S. House of Representatives
Committee on Ways and Means
Subcommittee on Health**

**Hearing on Promoting the Adoption and Use of Health Information Technology
July 24, 2008**

**LeRoy (Lee) Jones
Principal & Chief Executive, GSI Health**

Mr. Chairman and distinguished members of the Subcommittee, my name is Lee Jones, and I am the founder of GSI Health, a healthcare information technology consultancy. In that capacity, I am involved in a number of industry and government-sponsored initiatives to bring about large-scale interoperability among healthcare applications and enterprises. One effort I currently support is the very important work happening in New York State to create shared policies and technical protocols for interoperability. This effort has over \$100 million invested in a statewide collaborative process to develop a standards-based health information exchange network among a number of regional efforts within the state. Additionally, I currently serve as the program director of the Healthcare Information Technology Standards Panel (HITSP), a volunteer-driven cooperative partnership between the public and private sectors that is working to ensure the interoperability of electronic health records in the United States. I am grateful for the opportunity to testify before you today on the need for harmonized electronic data exchange standards and infrastructure to empower patients and healthcare providers.

The Current Landscape of Healthcare Information Technology

Through my years of work in healthcare information technology, I know that patients are often treated by doctors with incomplete medical information. Patients often do not know their medications, their medical history or their latest laboratory results. Patients seek care from a wide variety of primary care providers, specialists, hospitals, clinics, laboratories, imaging centers and pharmacies—all of which have disconnected pieces of their medical record.

Patients, providers and payers believe that communication among caregivers is key to delivering quality, personalized medicine. Many think that electronic records shared across the entire community of clinicians is key to care coordination.

According to a national survey published earlier this month in *The New England Journal of Medicine*, only 17% of clinicians in the U.S. have a basic system of electronic health records in their offices. Among the doctors who have access to electronic health records systems, 97-99% report using all of the system's functions at least some of the time.¹ However, data does not flow among all these systems partly because of the inconsistent use of data standards, lack of a consistent architecture for exchange of data, the lack of a trusted means to validate consistent and compatible implementations of standards and architecture, and the lack of agreement on privacy policies held by different jurisdictions.

The Need for a Coordinated Approach Toward Interoperability Enablement

¹DesRoches et al (2008). "[Electronic Health Records in Ambulatory Care — A National Survey of Physicians.](#)" *The New England Journal of Medicine*, Volume 359(1):50-60.

Consumers in today's global economy have become accustomed to instant access to information. News, music and movies can be accessed real-time on a handheld device. Products and services from multiple providers can be located, compared and purchased online. Financial accounts can be managed, bills can be paid electronically, and funds can be withdrawn at ATMs anywhere in the world.

When it comes to their personal health information, however, patients have felt a speed bump on the information superhighway. The records exist, but doctors, pharmacies, and insurance companies use disparate systems that make the exchange of information slow and cumbersome, thus retarding timely access to the information in the routine delivery of care.

But all of this is changing.

U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt has established the American Health Information Community (AHIC), a group of eighteen government, business, and non-profit organization leaders charged with fostering adoption of interoperable electronic records throughout the country. The AHIC has been essential to moving national interoperability efforts forward by articulating and prioritizing specific scenarios, often referred to as "use cases", which focused industry efforts on specific and tangible areas where healthcare interoperability is needed and can be achieved through concerted work. Equally as important, the AHIC has served as a conduit to the Secretary of HHS to identify the results of the industry's work to achieve interoperability in the areas of those use cases, so the Secretary can hold up said results for all Federal agencies and initiatives to leverage appropriately. These standards that the Secretary holds forth are known as "recognized standards" and have an appropriate lead time that enables testing and evaluation before achieving recognized status, which is when Federal partners are expected to use these standards. Thus, the first generation of recognized standards have had that status for only slightly more than 6-months, and so we anticipate increasing adoption and system interoperability as these standards are given a chance to be planned for and implemented in Federal and private-sector systems in an ongoing fashion over the coming months.

In order for the objectives of the AHIC to be met in a purposeful and directed way, the HHS-based Office of the National Coordinator for Health Information Technology (ONC) has funded a coordinated effort to accelerate electronic medical record interoperability efforts. This effort is comprised of several symbiotic initiatives, four of which I will mention here:

The first is to harmonize all the electronic standards for healthcare in the country. Currently there are more than a dozen organizations creating healthcare information standards in the U.S. These standards are at times redundant, competitive and non-interoperable. Further, sometimes there are no appropriate standards available to enable particular kinds of healthcare transactions. To achieve the kind of universal functionality our ATM cards provide today, the country must agree on a common set of healthcare information standards, implemented consistently by vendors and healthcare providers alike. The organization I support, the Healthcare Information Technology Standards Panel, or HITSP, has been sponsored by ONC to harmonize the relevant information standards, working with the various authoring organizations of these standards, industry stakeholders of all types, and affected Federal partners to disambiguate the use of standards when several compete, and to push for establishment of needed standards where none exist.

The second key initiative is to ensure electronic medical records provide the basic functions needed for a doctor to record and transmit patient medical information. The average patient over 80 years old has ten medications and three clinicians. Rarely is there any coordination of care among caregivers to assist these patients, and others, with bringing to bear a correct picture of their health status (history, treatments, medications, current issues, etc.) into each new healthcare encounter. But in order for care providers to more easily share patients' clinical information which may be held in their particular electronic health

record systems, objective criteria to certify that an electronic record system meets the basic requirements for data capture and exchange is essential. The Certification Commission for Healthcare Information Technology, or CCHIT, provides certification and validation services that enable healthcare IT vendors and implementers of various kinds to verify the correctness of their implementations of interoperability standards and key system functions.

The third key initiative is to catalogue privacy and security policies across the nation toward the end of reconciling their variances in a manner that enables interoperability. In Massachusetts, for example, doctors cannot retrieve a complete electronic medical list from insurance companies, even with patient consent, if a medication related to mental health, substance abuse or HIV treatment is present. In Ohio, doctors must use a cryptographic electronic signature to prescribe medications electronically. In California, only paper signed consent forms (not electronic forms) are considered a valid patient consent. The laws that created many of these regulations were appropriate 30 years ago when electronic systems lacked the sophistication available today, but now are an impediment to delivering safe, patient focused care. The Health Information Security and Privacy Collaboration, or HISPC, has begun this cataloguing effort and has spurred many efforts to remove key barriers to interoperability related to divergent privacy and security practices.

The fourth key initiative I will discuss here is to ensure that a real health information exchange network is established which both demonstrates the feasibility of implementing interoperability standards in an effective way, as well as propagates their use broadly by connecting real systems. All standards are merely theoretically useful until proven through real implementation. The Nationwide Health Information Network, or NHIN, orchestrates implementation of interoperability standards within the context of real-world health delivery environments across different regions in the country. Often, these implementations involve a number of vendor products and platforms that adopt the desired standards through NHIN, and subsequently spread them through their normal channels in the marketplace.

These four ONC initiatives plus the AHIC are critical to the rapid advancement of healthcare interoperability for several reasons.

First, prior to the government becoming actively involved in this type of public/private partnership through the activities of ONC, interoperability efforts through the standards development organizations' activities alone led to a highly fractured system that was not converging in any meaningful way. Therefore, the Federal government must stay involved in the process for ultimate success to be achieved in moving the entire industry.

Second, the model AHIC and ONC have been cultivating over the past few years has shown that it matters *how* the Federal government participates, not just *that* it participates. Leveraging the familiar paradigm of consensus-based development and adoption of standards in the United States has led to wider participation and buy-in than has been achieved through other methods such as unassisted market forces or heavy-handed mandates. It is important to allow private sector entities have ownership in the process of developing the interoperability solutions they will need to implement. It is most effective when they can innovate around, and adopt standards and architecture in a manner where their incentives are aligned with the collective goals.

Third, these efforts have now established complementary and coordinated systems that have set the dominant design for how interoperability will be continue to be achieved in an on-going fashion whereas there were no such systems prior to AHIC and ONC. We now have a system in place to harmonize and advance appropriate standards. We now have a system in place to verify correct implementation of those standards. We now have a system in place to develop and proliferate the technical network to interconnect

healthcare partners. And lastly, we now have a system in place to identify and ultimately remove barriers posed by divergence in privacy and security practice.

Lastly, the efforts of the AHIC and ONC have inspired smaller-scale replicas to emerge around the country. The AHIC use cases are reused or customized for local interoperability efforts. The consensus processes used for standards harmonization are mimicked by regional efforts that need to arrive at their own technology blueprints. In the parlance of the internet community, the current national interoperability initiatives are “viral”.

For the balance of this testimony, I will provide further details around the areas I am most involved in, namely establishing interoperable networks and architectures, and harmonizing interoperability standards. The intention here is to convey a greater insight into how these initiatives are operating to foster understanding of why the current efforts are working well.

Health Information Exchange Networks

I am currently involved in two significant efforts to establish networks that enable the exchange of healthcare information among various healthcare software applications. These efforts are to build the Statewide Health Information Network of New York, called the SHIN-NY (pronounced “shiny”), and the Nationwide Health Information Network, called the NHIN. These efforts are actually related inasmuch as the SHIN-NY is intended to be a microcosm of the NHIN in New York. The development of technical infrastructure through these projects is catalyzing the adoption of interoperability standards and actual data sharing among providers.

Building these networks is a complicated undertaking. Not only do different sets of standards need to be integrated, but additional elements beyond information standards need to be “standardized”, such as technical methods associated with all networks (e.g. – ensuring the reliability of the and availability of the network). It involves deciding what technologies are ready for implementation, what level of backward compatibility will be supported, and what emerging technologies are likely to persist enough to include in the technical plan.

The NHIN has published a number of technical specifications regarding the detailed handling of not only healthcare standards, but also methods for communication in the transmission of messages, security techniques, as well as paradigms for distributing functionality across the network without centralized control (critical for quick adoption where policy hurdles regarding centralized control may abound). The NHIN has also established a shared testing environment that may be leveraged broadly to ensure accurate utilization of interoperability standards. There are over ten participating regions and entities in the NHIN, including Federal partners, volunteer organization, and regional teams funded by ONC. This pioneering is an important step in realizing ubiquitous interoperability.

The SHIN-NY is leveraging the work of a number of different efforts to achieve its goals in New York. It has modeled its local business cases on the published AHIC use cases, and has even extended them to encompass local concerns such as the utilization of Medicaid data in data exchange. It has also taken the HITSP interoperability standards and incorporated them into the design of statewide network, further entrenching these important specifications. New York is participating in an initiative sponsored by the Centers for Disease Control and Prevention to implement a biosurveillance system using the corresponding AHIC use case and HITSP standards, and this work is integrated into the SHIN-NY effort as well. And finally, as a participant in the NHIN, New York is leveraging the technical specifications, testing environment, and experience the NHIN has amassed over the past few years. In addition to all of this leverage of existing work, the SHIN-NY will contribute its own technical protocols and services that will be usable across New York and beyond.

These efforts both have designs to not only establish technology that will be interoperable, but also to serve as reference implementation models for other efforts to learn from and to reuse. The learning, including much of the design and some of the new software from these initiatives will be made available in the public domain. This will fuel the fledgling open source projects in healthcare as they are the most likely to leverage these new assets. Whether it is bolstering the open source assets, or transforming the landscape of commercial products as they integrate into the network, these significant initiatives to build networks for information exchange are propelling the industry forward into a more interoperable state.

The Role of the Healthcare Information Technology Standards Panel (HITSP)

“Within ten years, every American must have a personal electronic medical record...”
- President George W. Bush, April 26, 2004

When President Bush called for every American to have an electronic health record by 2014, he was outlining his vision for a healthier nation. To help make this vision a reality, the public and private sectors are working together to define and build an information network that would support the secure exchange of health data across the United States.

In the fall of 2005, the HHS Office of the National Coordinator for Health Information Technology (ONC) awarded multiple contracts to advance President Bush's vision for widespread adoption of interoperable electronic health records (EHRs). The contracts targeted the creation of processes to harmonize standards, certify EHR applications, develop nationwide health information network prototypes, and recommend necessary changes to standardized diverse security and privacy policies.

As coordinator of the U.S. voluntary consensus standardization system and proven provider of standards-based solutions to national and global priorities, the American National Standards Institute (ANSI) was selected to administer the standards harmonization initiative, in cooperation with strategic partners the Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI), and Booz Allen Hamilton. The resulting collaborative, known as the Healthcare Information Technology Standards Panel (HITSP), brings together representatives of the private and public sectors to make possible the interoperable exchange of health care data across the United States.

The Panel's work is driven by a series of Use Cases (i.e., business needs) that are issued by AHIC. Based on the needs outlined in each Use Case, HITSP develops guidance documents known as Interoperability Specifications (IS) that recommend the standards that will meet the defined clinical and business requirements for sharing information across organizations and systems. During this process, HITSP also identifies and documents any gaps in standards which must be resolved.

Once an IS is recognized by Secretary Leavitt, agencies administering or sponsoring federal health programs are required to implement the standards where applicable. These work products (IS) are intended to be supportive to the developing Nationwide Health Information Network (NHIN) for the United States and also to community and regional health information exchange networks.

HITSP is a volunteer-driven, consensus-based operation. The Panel's 480 member organizations represent consumers, health care providers, public health agencies, government agencies, standards developing organizations, and other stakeholders – all working together to identify the most appropriate standards for specific use cases involving patients, providers, and government agencies. HITSP is committed to an open and transparent mode of operation and to facilitating standards harmonization efforts that support interoperability, accurate use, access, privacy and security of shared health information.

The Standards Harmonization Process

HITSP's most important work is the development of a well-defined, repeatable process to identify the most appropriate standards for each AHIC use case.

A standard specifies a well-defined approach that supports a business process and has been agreed upon by a group of experts, has been publicly vetted, provides rules/guidelines/characteristics, helps to ensure that materials, products, processes and services are fit for their intended purpose, is available in an accessible format, and is subject to an ongoing review and revision process. Harmonization is required when a proliferation of standards prevents progress rather than enables it.

In some cases, redundant or duplicative standards will be eliminated. In other cases, new standards may be established to span information gaps. In all cases, the resulting standards serve the consumer and other healthcare stakeholders by addressing issues such as data accessibility, privacy and security.

Our process to date is:

- a. AHIC and its working groups develop Breakthroughs.
- b. AHIC Working Groups or other customers prepare a HITSP Harmonization Request.
- c. HITSP Technical Committees identify candidate standards, which are harmonized into a final list of standards. They also identify overlaps and highlight gaps. Gaps are forwarded to standards developing organizations for their guidance as to emerging candidate standards or new standards requirements.
- d. HITSP Coordinating Committees provide technical committees with important background information to support their work, such as objective criteria to evaluate the appropriateness of standards for a given purpose.
- e. The final chosen standards produced by the Technical committees are discussed and ratified by the full Panel.
- f. These standards are made available for public comment and feedback.
- g. Technical committees work with standards developing organizations and other groups to produce detailed specifications, an unambiguous "cookbook" for the implementation of chosen standards. HITSP provides a convening and facilitation function for this activity.
- h. HITSP work products are delivered to AHIC for their endorsement.
- i. After AHIC endorses HITSP work, the Certification Commission on Healthcare Information Technology will include HITSP specifications in its certification work. Hospitals and clinicians will be more likely to buy products, which are certified as interoperable. This will lead to increased success of vendors, which embrace standards and interoperability.

Progress to date and next steps

The first priorities assigned to HITSP were in the areas of Electronic Health Records (EHR) (e.g., the electronic delivery of lab results to providers of care), biosurveillance (e.g., data networks supporting the

rapid alert to a disease outbreak), and consumer empowerment (e.g., giving patients the ability to manage and control access to their registration and medication histories). In January 2007, HHS Secretary Michael O. Leavitt accepted HITSP's recommended standards, known as "Interoperability Specifications (IS)", for a one-year period of implementation testing. In January 2008, the Secretary announced his formal recognition of the HITSP IS.

According to Executive Order 13410 signed by President Bush in August 2006, federal agencies administering or sponsoring federal health programs must implement any and all relevant recognized interoperability standards. These standards also become part of the certification process for electronic health records and networks.

Three additional sets of HITSP IS - Emergency Responder-Electronic Health Records; Consumer Access to Clinical Information; and Quality - were accepted by the Secretary for implementation testing in January 2008. And new IS on Medication Management was submitted to the Secretary for acceptance in Spring 2008.

New work is also underway to address interoperability needs in six additional areas: personalized health, transfer of care, remote monitoring, secure communications between patients and providers, public health case reporting, and immunizations and response.

The HITSP Education, Communications and Outreach Committee has strived to educate interested stakeholders on the future of healthcare information technology and how the public can shape the standards that will promote interoperability. This summer, the Committee is sponsoring an educational webinar series that informs the public of the work that is currently underway to support the exchange of healthcare information in the U.S.

Beyond 2008, HITSP will continue to produce recommendations and reports in Interoperability Specifications and related Constructs. These work products are intended to be equally applicable to the developing Nationwide Health Information Network for the United States (NHIN) and also to community and regional health information exchange networks.

From consumers to doctors, nurses and hospitals; from those who develop health care IT products to those who use them; and from government agencies to organizations that are developing the standards upon which these new health systems are based – everyone has a role to play in shaping the new U.S. healthcare IT infrastructure.

Thank you very much for your attention, and I look forward to any questions you may have.