August 25, 2006

September 17, 2007

Ted Schmitt
Consultant
National Academy of Sciences
500 Fifth Street, NW
Washington, DC 20001

Dear Mr. Schmitt:

On behalf of the HIMSS EHR Vendors Association (EHRVA), I want to thank the Institute of Medicine (IOM) for the opportunity to provide comments as part of its review of the Office of the National Coordinator’s (ONC) standards activities. The EHRVA represents more than 40 electronic health record suppliers committed to making EHRs interoperable and accelerate EHR adoption in hospital and ambulatory care settings.

EHRVA supports, both in principle and through its members’ participation, the federal government’s work to improve the quality, safety and efficiency of patient care through the appropriate use of information technology. As organizations that represent thousands of person-years of experience with this technology, and supporting an estimated 90% of the market of operational EHRs, we understand just how complex and challenging the initiatives being coordinated by ONC are.

EHRVA members have been deeply engaged in standards development and harmonization work, as well as certification efforts that are part of the ONC Framework for Establishing a Nationwide Health Information Network.

- They have served on the Certification Commission for Healthcare Information Technology (CCHIT), the Healthcare IT Standards Panel (HITSP) and the American Health Information Community (AHIC) panels, task forces and work groups since the inception of these activities. Our members and industry colleagues have contributed thousands of hours in support of these initiatives, working on behalf of our collective customers – hospitals and physicians’ practices large and small across the US.

- EHRVA members are long-standing supporters of Integrating the Healthcare Enterprise (IHE), an industry-led initiative that is creating a standards-based framework for clinical IT, now recognized by the International Standards Organization (ISO) for its use case process. The IHE process allows multiple standards to be specified in a precise manner to support variations in clinical workflow while achieving plug-and-play compatibility. IHE’s interoperability showcases encourage competing vendors to build and demonstrate data exchange among their products. In 2007, 20% of the 75 participating vendors were EHRVA members, including large companies with diverse healthcare products and services as well as small, EHR-focused companies that serve the smaller hospital and physician practice markets. Some of the EHRVA members who supported the IHE Showcase at HIMSS07 include:

  AcerMed
  Allscripts Healthcare Solutions
  BlueWare
  Bond Technologies
  Cerner Corporation
  CHARTCARE, Inc.
  CPSI
  Dairyland Healthcare Solutions
digiChart
  Digital MD Systems
eClinicalWorks
  Eclipsys Corporation
  e-MDs
  Epic Systems Corporation
  GE Healthcare Integrated IT Solutions
  GEMMS, Inc
  Greenway Medical Technologies
  Healthcare Management Systems, Inc.
  HealthPort
  iMedica, Inc.
  InteGreat
  Lake Superior Software, Inc.
  McKesson Corporation
  MedcomSoft
  MedHost
  Medical Informatics Engineering, Inc.
  Medical Information Systems
  Medinformatix
  MediNotes Corporation
  MediServe Information Systems
  Meditech
  Missy Healthcare Systems
  NextGen Healthcare Information Systems
  Noteworthy Medical Systems
  Pulse Systems Incorporated
  RemedyMD, Inc.
  Sage Software
  Siemens
  SOAPware
  Spring Medical Systems, Inc.
  Workflow.com
  Xpress Technologies
EHRVA members worked collaboratively to publish the *EHRVA Interoperability Roadmap* which articulates an achievable path to interoperability. The roadmap, published in 2005, sets out a timeline for the interoperability needed to implement a nationwide health information infrastructure (NHIN). The first phase of the EHRVA roadmap was demonstrated at the HIMSS Conference in 2006, with EHRVA members joining other IT vendors, including the VA and DOD, in showcasing multiple interoperability use cases. One of the NHIN pilot implementations used several aspects of the roadmap. Those experiences, as well as our customers’ input to requirements, will inform the *Roadmap* as it evolves. EHRVA continues to reach out to other stakeholders to encourage further implementation and convergence of the *Roadmap* into national and local projects.

We bring the cumulative experiences of our member firms to bear in a collaborative effort to achieve the promise of better healthcare for all Americans as described in ONC’s *Strategic Framework for Health IT* published in 2004 and reinforced by President Bush in his last three State of the Union addresses. In this spirit, EHRVA would like to provide comments and suggestions regarding ONC’s work on interoperability standards.

ONC, through AHIC, HITSP and CCHIT, has made great progress toward interoperable health information with the potential to positively impact US healthcare delivery. However, some of the current functionality reflected in use cases is not focused on the needs of smaller physician practices, hospital/ambulatory setting referrals nor specialties.

- **Going forward, ONC should work with AHIC to focus on use cases that are relevant to family practice physicians and caregivers, as well as specialty providers.** We recommend that ONC take advantage of IHE’s work in creating the Patient Care Coordination Domain which is based on several foundational use cases including ambulatory referral to inpatient settings, inpatient discharge summary and emergency department referral to ambulatory settings. These use cases are championed by leading provider associations such as the American College of Physicians (ACP), the American College of Emergency Physicians (ACEP) and the American College of Cardiologists (ACC). In contrast to AHIC use cases, the IHE use cases incorporate all the information that is necessary to support the entire interaction that occurs in clinician-patient workflow between care settings because they include multiple data types and terminologies that vary from specialty to specialty and even from one hospital to the next.

- **HITSP, in our view, is the most successful of the ONC initiatives.** It is both transparent and supported by stakeholders from provider organizations, health IT vendors, standards development organizations (SDOs) and government. HITSP is providing an effective forum for public/private collaboration, essential for achieving interoperability among disparate technologies and care settings. HITSP has leveraged the work and experience of the key stakeholders, addressing the larger-scale market for HIT interoperability and likely reducing the costs and risks to both suppliers and buyers. And HITSP has delivered results as evidenced by the ASTM CCR/HL7 CDA harmonization and efforts to promulgate semantic interoperability in lab transactions. EHRVA is developing a “quick start guide” to help its members and other HIT suppliers implement the HITSP-supported Continuity of Care Document (CCD).

- **CCHIT should synch certification cycles with HITSP’s phased-in strategy to achieve interoperability.** Because CCHIT’s initial interoperability requirements preceded final HITSP requirements which are more market-driven, it may not be practical for vendors to develop nor for provider organizations to implement these requirements on an annual basis.
• The Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), and Medicare and Medicaid with the Executive Order Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs should ensure future HIT-related grant requirements are based on HITSP specifications where applicable.

• HITSP should be allowed to work directly with NHIN contractors, rather than being forced to work through ONC.

• HITSP should encourage collaboration with state chief information officers (CIOs) in order to foster the development and coordination of interoperability solutions within state HIT infrastructures. EHRVA will present its Interoperability Roadmap to the National Association of State CIOs (NASCIO) in October and will reinforce EHRVA’s support of HITSP and its work.

Several studies have detailed the potential impact of interoperability to improve patient care by making it safer, more timely and effective, and more efficient. Health information technology has the potential to save more than $77 billion a year in the US from increased efficiency and productivity, as well as avoided costs of preventable medical errors. EHRs are the essential foundation needed to achieve these results. We cannot, however, achieve sufficient EHR adoption nor sustainable health information exchange among providers without aligning market forces that govern healthcare.

• ONC should work with AHIC to provide use cases that will be relevant to family practice physicians and caregivers, as well as specialty practices, recognizing that 90% of care is delivered in outpatient settings. This will give these clinicians a reason to invest time and money in EHR systems.

• ONC should adopt EHRVA recommendations as stated in its August 20, 2007 letter to Dr. Mark Leavitt, CCHIT Chairperson (attached here) to focus on interoperability solutions between the inpatient and outpatient settings that do not require health information exchange. This approach will leverage HITSP standards in a manner that allows evolution to a health information exchange and the NHIN when communities or states are ready. Several customers of EHRVA member companies already see the benefits of using the HITSP specifications to build out their existing network infrastructures, making these investments with the confidence that the HITSP specifications are being adopted in the EHR vendor community, as well as being required in federal HIT efforts.

The current process for setting certification priorities for interoperability does not, as noted above, reflect the practical needs of providers using EHRs nor does it synchronize with HITSP’s work. Relaxation of the Stark regulations is an example of how misaligned requirements and priorities can impact EHR adoption. The interoperability deeming provision of the regulation limits participation by specialty ambulatory EHR vendors. The annual certification process in the Stark 12-month rule is unrealistic given typical product development timelines and the realities that customers do not upgrade systems on an annual basis, nor do they want to support multiple product release versions. Another example is the current specialty areas being addressed by CCHIT which leaves many of specialty vendors on the sidelines in EHR donation initiatives, hampering what has been a robust, competitive market. Lastly, requirements that eligible systems be certified as interoperable are out of sync with HITSP’s process for providing interoperability specifications that support the regulation.

• The CCHIT process for determining how requirements are prioritized should be more transparent and based on objective criteria already outlined in several studies regarding EHR capabilities and associated impacts.

• CCHIT should balance the requirements necessary to drive EHR adoption with those that may have an impact on a much longer horizon. The EHR used in today’s fee-for-service world is different than the one suited to clinicians who will be paid for performance.

• CCHIT must work to ensure that certification is not a cost burden to vendors, forcing them to pass these costs along to their customers. We are concerned that CCHIT has chosen to create its own infrastructure for testing interoperability requirements instead of leveraging existing robust, open source, globally-tested capabilities developed by IHE or NIST. Harmonization and its costs should not be limited to standards but must include the entire set of tools used to develop and maintain them.
• As we noted in our recommendations above, collaboration between HITSP and CCHIT in establishing interoperability specification deployment should be strengthened. That includes coordination of public comment periods to allow more time for stakeholders to evaluate these complex specifications and provide detailed input.

Our shared objective should be to enable market forces to drive adoption of interoperable EHR solutions. While use cases currently being promulgated by AHIC include consumer empowerment using personal health records (PHRs) and syndromic biosurveillance, the essential foundation of wide-spread use of EHRs that can ensure accurate and timely clinical information that these downstream applications require is not mandated.

• ONC should mandate interoperability in EHRs and make interoperability financially desirable by rewarding providers for sharing information electronically. HIPAA created a mandate for efficient electronic payment systems. A similar mandate could be imposed for clinical information exchange.

• Where HIT is used as part of an overall strategy to improve the quality of care, pay-for-performance programs should be expanded to reimburse at higher rates for improvements in operational efficiencies or for better outcomes resulting from interoperability.

In summary, EHRVA member organizations will continue to work collaboratively in a non-competitive effort to accelerate the realization of interoperable EHRs and the adoption of this transformative technology. We wholeheartedly endorse ONC and its work through AHIC, HITSP and CCHIT as having the potential to help drive healthcare delivery improvements that can positively change the system for all Americans. The inclusion of EHR vendors in all aspects of this important work is essential – not only to ensure that our collective experiences are considered in solving these complex challenges, but also to encourage public/private ownership of the systems and standards that result in true interoperability and widely-adopted EHRs.

We applaud Dr. Kolodner’s work to move forward with AHIC 2.0, the successor organization that will ensure that the hard work that has been done to date will not be compromised to the change in administration in 2009. We suggest that EHRVA must be at the table with other AHIC 2.0 participants as first-tier contributors to support the ongoing and important work of ONC.

Speaking for EHRVA members, thank you for this opportunity to provide commentary to the IOM in its assessment of ONC’s work on standards and interoperability.

Sincerely,

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CEO, MediNotes     GE Healthcare
HIMSS EHRVA Chair     HIMSS EHRVA Vice Chair

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Justin T. Barnes     Steven Starkey
HIMSS EHRVA is a trade association of Electronic Health Record (EHR) vendors that join together to lead the HIT industry in the accelerated adoption of electronic health records in hospital and ambulatory care settings in the US. Representing an estimated 90% of the installed EHR systems in the US, the association provides a forum for the vendor community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the USA. The association, comprised of approximately 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit http://www.himssehrva.org.