Written Testimony by
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Standards for Health IT: Meaningful Use and Beyond
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Good morning. My name is Joyce Sensmeier and I serve as Vice President of Informatics for HIMSS, where I oversee the clinical informatics, standards, interoperability, privacy and security initiatives for the Society. It is a pleasure to be with you today before this Subcommittee and alongside these distinguished panelists.

Background

I present these comments today on behalf of HIMSS, a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded 50 years ago, HIMSS and its related organizations have offices in Chicago, Washington, DC, Brussels, Singapore, Leipzig, and other locations across the U.S. HIMSS represents more than 30,000 individual members, of which two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 470 corporate members and more than 85 not-for-profit organizations that share our mission of transforming healthcare through the effective use of IT and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, and research initiatives designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

I have been deeply involved in the harmonization and adoption of health IT standards during my decade at HIMSS. With co-sponsor, the Radiological Society of North America, I led HIMSS' effort to develop and manage Integrating the Healthcare Enterprise (IHE), a global initiative that

drives the adoption of health IT standards for clinical needs. I also led HIMSS' involvement with the Healthcare Information Technology Standards Panel, or HITSP, a federal standards harmonization initiative, while also collaborating with another organization to form the Alliance for Nursing Informatics, a collaboration of 27 distinct nursing informatics organizations that I co-chair.

I became Board Certified in Nursing Informatics in 1996, and am an adjunct faculty member at Johns Hopkins University in Baltimore. This year, I am honored to be recognized as a Fellow of the American Academy of Nursing, a credential held by more than 1,600 nursing leaders throughout the world.

On behalf of HIMSS members, we commend Congress and President Barack Obama for their vision and commitment to transform our national healthcare delivery system through the use of IT.

HIMSS and HITECH

I was asked to come before the Subcommittee today to share HIMSS perspective on the progress of federal efforts in the standards arena to support the first stage of Meaningful Use. In this testimony, we will aim to address the specific questions posed by the Subcommittee.

The American Recovery and Reinvestment Act of 2009 (ARRA) includes billions of dollars in Medicare and Medicaid incentive payments to providers and hospitals for the "Meaningful Use" of certified health IT products, which are addressed in the Health Information Technology for Economic and Clinical Health (HITECH) Act portion of the statute. The HITECH Act requires the Department of Health and Human Services (HHS) to take regulatory action in several areas, including electronic health record (EHR) incentives for eligible professionals and hospitals (Meaningful Use), standards and certification criteria, a Certification Program, and privacy and security.

The HITECH Act also requires the Secretary of HHS to establish certification criteria and standards for achieving Meaningful Use. HHS and the Office of the National Coordinator for Health Information Technology (ONC) established a Final Rule on the Standards, Implementation Specifications, and Certification Criteria that are being used to support Meaningful Use for the start of the incentive payment programs in 2011.

The HHS/ONC Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final Rule were published in the *Federal Register* in January 2010. After receiving more than 400 responses from HIMSS and other organizations, ONC released its Final Rule on July 28, which included the resolution of technical challenges related to some of the standards and implementation specifications. The Final Rule went into effect on August 27, 2010.

Response to Subcommittee Questions

Supporting the adoption and Meaningful Use of health IT is a key focus for the HIMSS membership. It is in that vein that we have addressed the questions posed by the Subcommittee. We were asked by this Subcommittee to particularly address two issues, the first of which is:

> "What progress has ONC made since the passage of the HITECH Act in meeting the need for interoperability and information security standards for electronic health records and health IT systems?"

Prior to the passage of the HITECH Act, and for many decades, standards development organizations (SDOs) used an open, consensus-based, volunteer-driven process, working in silos to develop health IT standards. While this is important work that is being leveraged by healthcare entities today, each SDO has its own priorities, goals and objectives. As a result, while many standards are available, there are multiple gaps, redundant efforts, and limited adoption in live health IT systems.

Also, standards are often not implemented consistently enough across individual organizations or products to enable interoperability. By necessity, hospitals and clinical practices invent one-off integration "solutions" when implementing IT products, which is a major impediment to interoperability. Implementation guides or specifications are also necessary to ensure that standards are implemented in the same manner to allow multiple systems to share data. These implementation specifications are typically developed by SDOs, such as Health Level 7 (HL7) or SNOMED, and standards-profiling organizations, such as IHE.

Prior to enactment of the HITECH Act, U.S. health information exchange priorities were set by the American Health Information Community (AHIC), the Federal Advisory Committee established by HHS. These priority use cases were given to HITSP through a $22-million, five-year contract awarded to the American National Standards Institute (ANSI), which was funded by HHS and managed by ONC. In an open, consensus-based process involving 966 member organizations and more than 900 volunteer stakeholders, HITSP technical committees selected and harmonized standards to address the interoperability of the use cases. This stakeholder engagement was widespread across both federal and private sectors, and a number of the HITSP specifications, which are available in the public domain, are in the process of being tested and implemented. During its tenure, HITSP developed over 130 interoperability specifications that were subsequently accepted, recognized, and/or adopted by HHS.

With the passage of the HITECH Act, a new process for oversight of the health IT standards process has been implemented. During this transition period, a degree of momentum in the advancement, harmonization and implementation of health IT standards has been lost. The healthcare community was previously aligning with the HITSP process, and vendors and health information exchanges were adopting its recommended standards and specifications. Today, the HIT Standards Committee determines priorities and recommends standards to support the Meaningful Use criteria. While the Committee's efforts are not overtly based on an open, consensus-based process, it has designated task forces and work groups to execute specific tasks, and these groups invite testimony to incorporate feedback from the healthcare community. The regulatory process stemming from the HITECH Act includes designated comment periods to

accommodate public feedback, which allows "real world" experience and subject matter expertise to inform the final regulations. Compliance with the standards identified in the Standards and Meaningful Use final rules will be verified by the National Institute of Standards and Technology (NIST) testing procedures and the EHR certification process.

These inputs have informed the Standards, Implementation Specifications and Certification Criteria, as well as the Stage 1 Meaningful Use final rules, which incorporate a beginning set of standards and several implementation guides to enable interoperability. Leveraging the open, consensus-based work products of HITSP and using implementation guides from standards profilers such as IHE is essential for quickly, efficiently and cost effectively advancing health IT efforts to allow providers to realize the incentives. This type of reuse was accomplished with selection of HITSP/C32 as the implementation specification for the Continuity of Care Document (CCD) and the Continuity of Care Record (CCR) clinical summary content standards for Stage 1 Meaningful Use, and thus, is a positive example of leveraging previous work and ensuring the interoperability of those standards when implemented. However, there are significant gaps in standards for interoperability in Stage 1 Meaningful Use.

We would like to identify three specific areas of concern regarding standards selection for Stage 1 Meaningful Use. First, data transport and basic security are focus areas where selected standards are missing, yet necessary for achieving interoperability. We understand that Stage 1 is not intended to force interoperability on a healthcare community that is not technically ready to meet the requirement. However, identifying the accepted transportation method will have a dramatic impact on preparedness for Stage 2. For example, it is important to designate standards for documenting the content of clinical summaries, but if we don't know how to transmit these summaries or acknowledge their receipt, we will have limited interoperability. Until the recommended transport standards are identified, EHR vendors will be forced to support all available transport methods or risk developing software that may not meet future interoperability needs. This lack of guidance creates marketplace confusion and wastes existing resources, ultimately delaying progress.

Second, we would like to express concern regarding the selection of multiple standards for the same criterion, such as selection of two clinical summary content standards - CCR and CCD. When two standards are selected, vendors and providers have to choose to support one standard, or instead, support both, which is very costly, resource intensive, and minimizes interoperability capabilities across organizations. It is our recommendation that only one standard is selected for each criterion in future stages of Meaningful Use.

Our third area of concern is the timing of identifying and publishing the selected standards in subsequent rules, which is critical to ensure that the industry can appropriately incorporate the standards into the product development and implementation cycle. Thousands of EHR systems are currently being developed and upgraded by vendors and implemented by healthcare providers. Recent statistics show that sales of hospital EHR systems nearly doubled from 2008 to 2009.[i] To ensure optimal software development, testing, and safe implementation by providers, the final rules for Meaningful Use and certification criteria should be available 18 months before the next stage of Meaningful Use commences.

ONC has published a Standards and Interoperability Framework and has recently completed the long-awaited contracting process for promoting interoperability and Meaningful Use. The goal of this framework is to create a collaborative, coordinated, incremental standards process that is led by the industry in solving real-world problems. The selected contractors will each be working to complete specific components of the framework, including use case development, standards harmonization, implementation specifications, tools and services. It is ONC's stated intent to leverage the health IT community, professional organizations, government agencies and standards organizations to ensure that all of their work comes down to a harmonized set of standards and implementation specifications. It is essential that ONC and its contractors deliver on this promise, and use an open, transparent, coordinated process to engage the community and leverage their collective efforts in order to maximize industry involvement and "buy in" to the effort.

Going forward, a centralized and coordinated process is needed for engaging SDOs and harmonization organizations, such as IHE, in meeting the needs for interoperability and information security standards for EHRs. While government can be an enabler for this standards coordination process, a neutral and uniform approach is necessary to ensure that the principles of transparency, openness, stakeholder representation, healthcare leadership, industry engagement, impartiality and balance, due process, consensus, relevance, and effectiveness are maintained. A timely evaluation of the optimal process for standards coordination is needed to address this urgent and important need.

In this testimony, we have previously suggested that the open, consensus-based and public domain work products of HITSP and IHE should be leveraged to quickly, efficiently and cost effectively advance standards for health IT. To this end, IHE is a global non-profit entity that has, over the past decade, developed a framework for standards-based interoperability of health IT systems that is being adopted and implemented worldwide. Each IHE integration "profile" describes a clinical requirement for systems integration and outlines a standards-based solution to address it. IHE profiles address critical interoperability issues related to information access for care providers and patients, clinical workflow, security, administration, transport and information infrastructure. IHE profile development includes multiple opportunities for public comment review and feedback. Vendors that implement IHE specifications participate in annual testing events hosted in a structured and supervised environment, to ensure compliance, and publish integration statements for their IHE-compliant products prior to real-world implementation.

A number of IHE transport profiles, such as Cross Community Access (XCA), support the exchange of health information and documents across communities and are being implemented in the Nationwide Health Information Network and various regional health information exchanges in the U.S. and worldwide. Reuse of these profiles in the U.S. standards identification and development process will build on a foundation of proven implementation guides that will accelerate standards adoption and save valuable time and resources.

The second issue that we were asked to address is:

> "What are the strengths and weaknesses of the current health IT standards identification and development process, and what should the top standards-related priorities be for future health IT activities?"

HIMSS was pleased that the Final Rule established standards criteria for supporting Stage 1 of Meaningful Use including:

- Removal of All or Nothing
- General relaxation of the requirements, specifically, implementation of drug-drug and drug-allergy interaction checks
- Maintenance of an active medication list
- Addition of structured lab test results
- Removal of LOINC code requirement
- Removal of requirement to submit electronically in Stage 1
- Change to a core and menu objectives approach
- Addition of a requirement to generate patient lists by specific conditions
- Expanded clinical quality reporting measures
- Moved requirements to check insurance eligibility and submit claims to Stage 2
- Added guidance to expand capability to submit electronic syndromic surveillance data to public health agencies
- Clarified numerous privacy and security criteria
- Moved more aggressive requirements to Stage 2
- Added appropriate implementation guidance

As discussed previously, we were disappointed that HHS did not further leverage HITSP and other harmonization work, such as IHE. Millions in federal taxpayer dollars and thousands of volunteer hours by committed subject matter experts were expended on harmonization efforts. Recognizing this work would have accelerated Meaningful Use adoption. HIMSS urges the

Centers for Medicare and Medicaid Services (CMS), ONC and NIST to ensure that all contractual engagements for standards harmonization and coordination efforts:

- Incorporate HITSP and IHE work products and test tools
- Complement (versus duplicate) each agency's efforts when creating testing procedures, testing tools & services, and reference implementations
- Embrace transparent and open consensus processes with the private sector

The HITECH Act set the vision for transforming the healthcare setting and these final rules are key components in implementing that vision. To achieve HITECH's vision, we recommend that HHS address the following:

- Publish implementation guidance (such as IHE and HITSP interoperability specifications) for all selected standards
- Publish data transport, financial transactions, security and health information exchange standards as soon as possible
- Publish the process and schedule for harmonizing standards and developing implementation specifications
- Set up one repository (such as the National Library of Medicine) for licensure and access to all standards and implementation guides
- Publish, as soon as possible, federal health IT best practices guidelines

Finally, HIMSS urges HHS to publish criteria pertaining to Stage 2 Meaningful Use at least 18 months before the beginning of Stage 2. This will enable sufficient time to develop, test, and deploy software conforming to these standards and implementation guides so that all eligible users can become meaningful users. Beyond the specific concerns associated with the Standards, Implementation Specifications, and Certification Criteria for Meaningful Use Stage 1, HIMSS is concerned that Meaningful Use and interoperability will be hindered without addressing two key areas, a patient identity solution and security of personal health information.

In response to this question, I would also like to highlight an important work product of one of HIMSS' many multi-stakeholder member workgroups – the Patient Identity Integrity

Workgroup. Last year, this workgroup published a landmark white paper describing the challenges and costly efforts healthcare organizations face every day in their efforts to ensure the integrity (accuracy and completeness) of data attached to or associated with an individual patient, including the correct pairing or linking of all existing records for that individual within and across information systems.

Obviously, patient identity integrity is of central importance to achieving quality of care, patient safety, and cost control. In addition, the primary goal for nationwide health information exchange is to allow authorized users to quickly and accurately exchange health information in an effort to enhance patient safety and improve efficiency. Achieving this goal is dependent on the ability to link or match multiple, disparate records relating to a single individual.

This white paper describes nine key influencers for improving data integrity in this area. One key influencer listed is the need for standards for patient identification data and format, and another has to do with the need for a study of the current technical solutions available to uniquely identify a patient. Using the results from the study, we can anticipate the exponential exacerbation of problems and errors with patient data matching in the health information exchange environment and evaluate potential solutions. We can do this by having *current* data on available technical capabilities as we formulate an "informed patient identity solution," a position discussed in the white paper and endorsed by the HIMSS Board of Directors.

Finally, I would like to highlight an annual HIMSS Security Survey that examines in-depth information from healthcare organizations regarding security implementation practices and technology uses. The HIMSS Security Survey, now in its third year, analyzes the responses of IT and security professionals from healthcare provider organizations across the U.S. regarding the policies, processes and tools in place at healthcare organizations to secure electronic patient data. The study covers a multitude of topics regarding organizations' general security environment, including access to patient data, access tracking, and audit logs, use of security in a networked environment and medical identity theft.

Last year, we probed our respondents with regard to their preparedness and approach for meeting new privacy and security requirements contained in ARRA, and we were privileged to provide testimony to the HIT Standards Committee as to the results and trends uncovered in this study.[ii] This year, we have partnered with the Medical Group Management Association (MGMA) to include an even larger population of ambulatory and medical group practices. The results of this year's study will be available in early November, and we would be happy to provide those results to the Subcommittee.

Closing

HIMSS is pleased to see these final federal rules and the ONC Standards and Interoperability Framework and related contracts being implemented in order to put into action legislative and executive branch intent to transform healthcare using IT. Through our robust member structure, we will continue to evolve our positions to reflect the current needs of health IT professionals to improve healthcare quality, safety, efficiency, and access for all. HIMSS believes that by linking credible health IT principles emanating from our members' needs and experiences, we will help our nation successfully transform healthcare using effective IT.

Celebrating our 50-year history of serving the healthcare community, HIMSS remains deeply committed to working with federal and state leaders in a bipartisan manner to improve the quality, safety, and efficiency of healthcare for all through the appropriate use of IT and management systems. HIMSS members appreciate and understand the cultural and technical challenges that healthcare providers face in meeting the requirements for Meaningful Use.

In closing, I'd like to highlight a few health IT initiatives within HIMSS that aim to recognize best practices in the use of health IT and measure the level of EHR adoption throughout the U.S. These initiatives will be critical reference points in evaluating the success of the HITECH Act in transforming the way we do healthcare. To recognize healthcare's excellence in using IT to improve access, safety, quality and efficiency, the HIMSS Nicholas E. Davies Awards of Excellence[iii] recognizes management, functionality, technology and value – the pillars of health IT success. Objectives of the Davies program include promoting the vision of EHR systems

through concrete examples; understanding and sharing documented value of EHR systems; providing visibility and recognition for high-impact EHR systems; and sharing successful EHR implementation strategies.

The awards focus on four healthcare settings: organizations, ambulatory sites, public health, and community health organizations. Since 1994, the Davies program has honored 71 healthcare organizations, private practices, public health systems, and community health organizations that have implemented health IT, specifically EHRs, in their respective locations. I invite members of the Subcommittee to visit HIMSS' State HIT Dashboard[iv] to locate Davies winners in or near your Districts. Mr. Chairman, I'm pleased to report that there are two Davies winners in your home state of Oregon: Kaiser Permanente Northwest in Portland,[v] and the Indian Health Service in Warm Springs.[vi]

Next, I would like to highlight the HIMSS Analytics' EMR Adoption Model[SM] (EMRAM)[vii]. Knowing the baseline of current adoption of health IT is critical to understanding the realities at U.S. hospitals and the federal government's EHR adoption goals. According to quarterly health IT implementation census data from HIMSS Analytics, the use of health IT among healthcare providers has steadily increased over the past four years.

Using a census survey, HIMSS Analytics' EMRAM tracks adoption of EMR applications within all 5,217 U.S. civilian hospitals and health systems and scores hospitals based on their progress towards meeting the criteria for various stages within the Model. There are eight stages for hospitals, ranging from 0 to 7, as they move to a completely electronic environment (Stage 7); at the pinnacle of the model, paper charts are no longer used in the delivery of patient care.

As of June 2010[viii]:

- 16.3 percent of U.S. hospitals (850 of 5,217) have achieved "Stage 4" or higher of the Adoption Model. This is up from 3.7 percent in December 2006.
- Another 50.2 percent of U.S. hospitals (2,621 of 5,217) have achieved "Stage 3."

As it has for the past six years, HIMSS Analytics will continue to gather data and release quarterly updates of its census-based survey, shedding light on EHR adoption levels.

Driving the appropriate use of health IT will improve patient safety and the quality, accessibility, and cost-effectiveness of healthcare. Thanks to our informed and committed member volunteers, HIMSS will be a leader in the transformation. HIMSS looks forward to working with the legislative and executive branches in helping to ensure that the components of the HITECH Act are appropriately implemented. HIMSS actively equips its members with the knowledge and tools they need to successfully navigate these regulations, including FAQs, white papers, and educational webinars.[ix]

Again, it was a pleasure to be with you today before this Subcommittee and alongside these distinguished panelists. I would be happy to answer questions that members of the Subcommittee may have and look forward to providing our members' expertise to help you transform healthcare in the U.S. Thank you for this opportunity.

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[i] *CIS Purchase Decisions: Riding the ARRA Wave. Klas. August 2010. Available at: http://www.klasresearch.com/Store/ReportDetail.aspx?ProductID=589*
[ii] http://www.himss.org/content/files/HIMSS2009SecuritySurveyReport.pdf
[iii] http://www.himss.org/davies
[iv] http://www.himss.org/statedashboard
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[vii] http://www.himssanalytics.org/hc_providers/emr_adoption.asp
[viii] http://www.himssanalytics.org/stagesGraph.html
[ix] http://www.himss.org/economicstimulus