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HIMSS Electronic Health Record Association
Testimony Before
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the National Coordinator for Health Information Technology
HIT Standards Committee Implementation Workgroup Meeting
October 29, 2009

Thank you for the opportunity to submit testimony on behalf of the HIMSS Electronic Health Record (EHR) Association. The EHR Association is comprised of forty-five (45) of the nation's leading EHR companies, currently representing over 90% of all EHRs implemented in America today. Our perspective on standards development and implementation is based on the experience and expertise of a broad range of software companies that are in both the ambulatory and hospital information technology markets.

EHR Association member companies have been focused on advancing standards-based interoperability, standards-based quality measurement, clinical decision support and CPOE, as well as supporting customer implementations of standards-based comprehensive EHRs. In the context of the well functioning standards development process that has included such organizations as HL7, ASTM, Integrating the Healthcare Enterprise (IHE), the Healthcare Information Technology Standards Panel (HITSP) and the HIT Standards Committee, the following key points summarize our collective view of the importance of a single set of standards to support the exchange of clinical documents among healthcare organizations.

Summary Points

The HIMSS Electronic Health Record Association (EHR Association) advocates implementation of a practical set of standards that support movement toward an electronic healthcare environment that will facilitate, inform, measure and sustain improvements in the quality, efficiency, and safety of healthcare. Healthcare professionals will be able to give better care – and the right care – to more patients at lower costs. This enhanced effectiveness and efficiency will lower overall costs and improve their patients' healthcare experience, leading to better health quality and economic outcomes overall.

The EHR Association applauds the Implementation Workgroup's emphasis on practical implementation of HIT standards. We urge you to focus on achieving effective implementation of the standards recommended to date by the HIT

Standards Committee rather than reopening standards decisions already made by the Committee, HITSP and IHE. The Standards Committee Workgroups have done an excellent job in assessing the readiness of specific standards and laying out a multi-year roadmap for ARRA adoption, especially in the areas of interoperability and security/privacy.

We recognize that standards must go through a process from initial development to full implementation. They must pass several hurdles, including weighing cost of implementation against value to the customer, assessing value relative to other potential product features, meeting customer needs and government mandates, and achieving stability and market readiness. Beyond these steps, there is the need for implementation in products in accordance with good software development practices and pilot testing. This process can take three or more years. The Association's Interoperability Roadmap[1] lays out many of these steps in detail. Thus, although we agree that not all adopted HIT standards are ready for 2011 implementation, many are ready, as reflected in the recommendations of the Standards Committee.

In this context, we call out the critical roles of IHE worldwide and HITSP in the US in harmonizing standards and applying standards to priority use cases. The IHE Connectathons have played a critical role in moving standards into effective adoption by vendors and end-users.

A critical question for this Workgroup is what can be done in the next four months to speed and simplify implementation of key standards. Based on internal reviews by our members, extensive customer contacts and customer implementations, the number one priority must be clarity and consistency on what can be expected, leveraging the huge investments to date on key HITSP-harmonized standards.

One central implication of this need for clarity is to avoid reopening well-settled standards decisions. A second priority is to ensure that vendors have a clear understanding of how to implement the ARRA-designated standards.

We suggest the following to meet this latter urgent need: Focus on the January 2010 IHE Connectathon as a major supporting action for ARRA interoperability. Connectathons have played a major role in helping vendors actually implement standards in a collaborative process. More specifically, we propose that, coordinated by the HIT Standards Committee, IHE works with NIST, HITSP and the CONNECT team in the following actions:

1. CONNECT should collect the best "set of open source" tools to facilitate implementation of the HIT Standards Committee recommendation.

2. HITSP and IHE should continue to work together and offer extended technical support to answer questions from "new implementers".

3. HITSP should document precisely the exceptions to HITSP Capabilities recommended by the HIT Standards Committee to ensure pragmatic implementation of 2011 ARRA requirements. In particular, this should cover CCD/C32 content, XDR/XDS transport protocols and security requirements.

[1] The HIMSS Electronic Health Record Association Interoperability Roadmap is available at http://www.himssehra.org/docs/EHRA_InteroperabilityRoadmap_20090310_v3.pdf

4. IHE should reopen the January 2010 Connectathon application (closed since end of September) to additional EHR systems, given the needs of ARRA implementation; and organize a second Connectathon in April/May to provide an additional opportunity for other EHR suppliers. Allowing the actual interconnection testing between EHR systems is the most effective way to bring certainty and confidence that products will correctly exchange information when installed.

One of the most critical standards addressed by the HIT Standards Committee is for exchange of clinical summaries. Such a standard is central to the vision of data liquidity and interoperable electronic health records and, fortunately, is fully available and mature. As a result, we focus on this standard in our statement and highlight the following important points.

- The EHR Association continues to support the adoption of a single content standard for the exchange of clinical summaries among healthcare providers.

- The extra costs associated with supporting multiple content standards run directly counter to principles of healthcare reform and to the ARRA stimulus funding objectives to improve quality and access as well as reduce costs. Proposals to maintain multiple clinical summary exchange standards (e.g., CCR as well as CDA/CCD) are a step backward from the progress that has been made to date.

- CDA/CCD has been demonstrated to be applicable to both ambulatory and acute care settings and personal health records (PHRs). As detailed below, CDA/CCD has been widely implemented by many HIT vendors (including the 75 EHRs that received CCHIT 2008 certification), and deployed by numerous customers.

- The careful process of development and harmonization of the CCD as a single standard reflects its power, maturity and industry acceptance.

- CDA/CCD has been developed using a roadmap approach to allow for incremental implementation as EHRs are more broadly adopted and as the demand for specific functionality, such as structured data elements and data exchange, grows.

- CDA/CCD has been vetted and recommended by HITSP as a harmonized standard, is included in past and current CCHIT requirements for EHR certification, has been formally endorsed by the Secretary of HHS, and is being successfully used in the NHIN and by many federal agencies.

- CDA/CCD supports ARRA objectives for meaningful use, which include the exchange of clinical summaries among disparate EHRs and with patients.

- CDA/CCD is expandable, vendor neutral and is a widely adopted healthcare IT standard worldwide.

Ongoing Collaboration

Please see the following appendix which provides a detailed discussion of the EHR Association's position on CDA/CCD and standards in general. We appreciate the opportunity to provide this input to the Standards Committee and its Implementation Workgroup. We and our member companies stand ready to assist you in any way that we can.

Sincerely,

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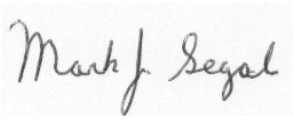

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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR 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 US. The association, comprised of more than 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.himssehra.org.

Appendix: Detailed Discussion of a Clinical Summary Standard

Since its inception, the EHR Association has worked toward a single standard for exchange of clinical documents, and strongly advocated and supported HL7 and ASTM in their harmonization of the Continuity of Care Record (CCR) and the Clinical Document Architecture (CDA), a process that led to the Continuity of Care Document (CCD). The HL7 CCD (which uses the CDA XML schema) emerged as the standard for communicating patient information, based on its adoption by the Health Information Technology Standards Panel (HITSP), subsequent acceptance by the Secretary of HHS, its use in the NHIN pilots, and the incorporation of the CCD in the 75 EHRs that received CCHIT 2008 certification.

The introduction to the CCD implementation guide specifies the relationship between CCR, CDA and CCD, emphasizing that the Continuity of Care Document (CCD) was developed as a collaborative effort between ASTM and HL7 that the HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, and standardized data sets. From the perspective of CDA, the CCR is a standardized data set that can be used to constrain CDA specifically for summary documents, as described in the introduction to the HL7 CDA Implementation Guide. [2]

Recently, renewed efforts have been made to question HITSP's guidance regarding CDA/CCD as the harmonized standard for clinical summary exchange, focusing on two key points.

- First, it has long been suggested that CDA/CCD is too hard for small practices to implement and support. This argument is not at all compelling or valid. Both CCR and CCD are data interchange formats handled by software, not by end users. It is vendors, not physicians or providers, who must be concerned about implementing one XML approach or another. We have seen that EHR vendors using disparate technology platforms and serving a range of physician practice sizes have successfully implemented CCD. PHR vendors, like Microsoft HealthVault, have also successfully implemented CCD. The functionality of CCD is by definition at least as robust as CCR (CCD is an implementation of CCR), and customer implementation costs for either CCD or CCR are similar. Clinicians care about functionality, and are not concerned about XML schema differences.

- The second major criticism of CDA/CCD as the harmonized standard is that multiple standards in this area would be acceptable to the market and even desirable. Some argue that the industry should not

[2] *"The purpose of this document is to describe constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR).*

The CCR is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, and standardized data sets. From the perspective of CDA, the CCR is a standardized data set that can be used to constrain CDA specifically for summary documents.

The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture." Health Level Seven (HL7) Implementation Guide: CDA Release 2 Continuity of Care Document (CCD), April 01, 2007

designate a single standard for clinical summaries, and that both CCD and CCR should be permitted, at a minimum. This argument is also not supported by the facts. Maintaining two (or more) standards would increase support costs, since consumers' systems (i.e., EHRs and PHRs) would require the capability to at least read both, and potentially write both. Vendors would similarly incur additional costs in supporting two standards that are on different development paths, especially in terms of ensuring data interoperability between the standards.

The EHR Association strongly supports the efforts to date of the 600 members of HITSP, hundreds of HIT experts, computer scientists, informaticists and clinicians to vet these essential standards and ultimately recommend CDA/CCD. This single, harmonized vendor-neutral, expandable standard will meet future needs as healthcare becomes more connected across communities and geographies; supports meaningful use goals to enable mobility and reuse patient information to directly align with ARRA objectives; and has been broadly accepted and implemented by both vendors and their customers in the US and internationally. To accept multiple standards for the exchange of clinical documents at this juncture would represent a costly and unnecessary step backward for the entire HIT industry. Key elements of this rationale are as follows:

- **Single, harmonized, vendor-neutral standard.** The Association's member companies share a commitment to the exchange of clinical summary data among disparate EHRs and other systems. The CCD is a result of the harmonization of the CDA with the CCR, and has the benefit that code written to support CDA can be used for other documents, such as discharge summaries and quality reporting. Whatever the standard – which must support content, codes and transport – there must be consistency, predictability as the standard evolves and, critically, vendor neutrality.

  CCR, which originated in the ambulatory environment, was an excellent start toward achieving effective, consistent exchange of clinical data among provider organizations; and served to move the market forward in the development of this essential standard. CCD, based on both CDA and CCR, became the means to extend the same standard to the broader patient care environment, thus positioning provider organizations of all types to participate in local health information exchange initiatives as well as, eventually, the nationwide health information network. This standard also provides a solid level of patient information transparency to the consumer, who expects information exchange without the risk of defective translations through the IT continuum of ambulatory care, inpatient care, long-term care, PHRs and more.

  For example, one of our members has observed that using CCR to display a medication entry can raise clinical safety issues if one system cannot produce all of the discrete data elements required, but the consuming style sheet attempts to recreate the medication text from the details, resulting in missing information. This mapping inaccuracy can create a potentially dangerous situation by presenting incomplete medications lists to patients and their care providers. CDA specifies exactly what should be shown to the human whereas CCR has no such specification. Alignment through the common framework of CDA and templates means that a medication entry represented in a CCD looks like a medication entry in a history and physical, and also looks the same as a medication entry in a quality report.

- **Expandable to meet current and future requirements.** The CCD is a CDA document type that addresses all the CCR data requirements. There are, however, several other CDA implementation guides that have been defined, so CDA aligns CCD with other known and future needs. Current examples of such CDA extensions include quality reporting to CMS, histories and physicals, ED notes, discharge summaries, syndromic surveillance, consultation notes, operative notes, antepartum summaries, personal healthcare monitoring reports, healthcare-acquired infection reports and more. The CDA infrastructure is now being extended to accommodate even more document types. To do the same with CCR would require a similar effort that would be duplicative of the CDA development effort, and would slow progress toward interoperability because of the need for users to decide which standard to use for what purpose. It would also impose costs on vendors to support two different data exchange formats – costs and delays that would ultimately impact the entire HIT market.

- **Supportive of meaningful use goals to enable mobility and reuse of patient information.** Both meaningful use and the approach to CCD that has been used to date in EHR certification are based upon a roadmap approach, moving over time to more capabilities through the CCD and other CDA document types, more use of structured data elements, and a shift from allowing PDF/free text with a CDA header to structured and codified CCD. This roadmap enables migration to semantic interoperability, thus allowing immediate data reuse, and accommodates various levels of data sharing concurrently. As a result, care providers and healthcare consumers will be able to increasingly exchange and use patient data, leading to more coordinated, effective and efficient care delivery.

- **Alignment with and need to focus on achievement of ARRA objectives.** We must maintain clarity and consistency regarding standards for 2011 and beyond to enable providers and vendors to move forward to achieve the central ARRA objective of increasing adoption of interoperable EHRs that can exchange clinical summaries among disparate systems and other HIT. Confirming CDA/CCD as the standard for clinical summary exchange will allow all HIT stakeholders to remain focused on achieving meaningful use through the exchange of clinical summaries across inpatient and ambulatory settings using the CDA standard. It would be counter to the progress we are making and confusing to the market (both vendors and provider organizations) to change course and support multiple standards, or to support a different standard than CDA/CCD. In addition to the costs and disruption of parallel development efforts to support more than one standard (i.e., millions of dollars in software development, standards development and standards harmonization), most importantly, supporting multiple standards would be a step backwards in achieving true health data reuse and interoperability.

- **Supporting Infrastructure**. A powerful and mature set of standards organized around CCD for data transport and security have emerged and been well tested and accepted by standards bodies, vendors and customers. These include XDS, XDR and ATNA. To truly achieve easy implementation of interoperability ("plug and play"), there must be development and agreement on not just the data interchange format (CDA/CCD), but also the technical protocols for patient identification, data exchange, authentication, encryption, and logging. These protocols are already available for CDA/CCD, have been widely tested (including in the IHE Connectathons), are already available or in late stage development from many software vendors, and are already included in the upcoming CCHIT certifications.

- **Breadth of Acceptance of CCD.** There are now at least 75 CCHIT-certified and tested EHR products that support CDA/CCD, based on CCHIT 2008 requirements. Although some have criticized the 2008 criteria for CCD as too "text-based," this more "relaxed" approach to CCD is the first step in a logical progression in which CCHIT had already published 2009 (now 2011) certification criteria to require structured medications, allergies and problems in CCD, with industry-standard coding of medications and allergies; and a roadmap to SNOMED-CT problems, along with standardized HITSP-endorsed infrastructure (IHE XDS). Many vendors were developing along that progression even before ARRA.

- Moreover, a growing number of EHR and other HIT vendors have demonstrated their ability to implement and support CCD and other CDA-based documents, as seen in the IHE Showcase at HIMSS09 with 70 participating companies. These include, but are certainly not limited to the following companies. See the many vendors and products that have achieved CCHIT 2008 certification at http://www.cchit.org. IHE participants providing EHRs include:

  - ALERT Life Sciences Computing
  - Allscripts**
  - CPSI*
  - eMDs**
  - Epic*
  - GE Healthcare**
  - Greenway Medical Technologies**
  - McKesson**
  - Medical Informatics Engineering
  - NextGen**
  - Sage**
  - Siemens*
  - Tiani Spirit

**EHR Association member, **EHR Association member that supports small practices*

These and other HIT vendors are working with their customers, healthcare provider organizations of all types and sizes, in operational environments to demonstrate the utility of CDA/CCD. Included among those organizations are:

- Boston Medical Center, Massachusetts
- CentraCare, Minnesota
- Exempla Healthcare, Colorado
- Froedtert & Community Health, Wisconsin
- Froedtert St. Joseph's/West Bend Clinic, Wisconsin
- Hennepin County Medical Center, Minnesota
- Kaiser Permanente, California
- Kaiser Permanente of Colorado
- Mayo Clinic, Minnesota
- Mid Rouge Independent Physicians Association (IPA), Oregon
- Memorial Care, California
- North Memorial Healthcare, Minnesota
- Providence Health and Services, Oregon
- Sanford Health, South Dakota
- Talbert Medical Group, California
- The Children's Hospital, Colorado
- Vermont Information Technology Leaders (Vermont HIE)

- In addition, a number of federal and state agencies have adopted CDA/CCD, including the Veterans' Administration, the Department of Defense, the Indian Health Service, the Federal Hospital Association, the Centers for Disease Control, the Social Security Administration, the Center for Medicare/Medicaid Services, the National Institutes of Health, the Health Resources and Services Administrations, and the Food and Drug Administration. Additionally, the CCD was used in the NHIN pilot projects and its requirement for human readability was described as a significant advantage as described in the NHIN Core Content Specification for Exchange of the Summary Patient Record.[3]

- Finally, many PHR vendors support CCD either alone or with CCR. For example, Microsoft has indicated that it supports CCD along with CCR. Although CCD is a bit more complex than CCR, it is still an XML format and well within the scope of what can be reasonably adopted by PHR vendors and "Health 2.0" developers and vendors. The choice of CDA, with approaches similar to CCD, has already been confirmed by many other countries in their national and regional programs including England, Canada, the Netherlands, Italy, Japan, France, China, Germany, Switzerland and Finland. This movement toward CDA-based clinical data exchange synchronizes with global standards initiatives and promotes consistency across the international clinical community. With more people traveling across borders for care, such global standards coordination will be increasingly important for continuity and cost effectiveness of care.

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[3] *"This single specification addresses the requirements for a semantically processable summary record and viewable summary record that could be used for look-up and retrieval. It is possible to use a single specification for both purposes because CDA-based documents can be used to generate human-readable documents. As stated in Section 1.2.3 of HL7 CDA R2 document…"The CDA requirement for human readability guarantees that the receiver of a CDA document can algorithmically display the clinical content of a note on a standard web browser."* For the full NHIN document, go to http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848155_0_0_18/FINAL%202008%20NHIN%20Coop%20Specification%20for%20Exchange%20of%20the%20Summary%20Patient%20Record%20%20Final.pdf