



GE Healthcare
Integrated IT Solutions

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Adoption and Implementation of Health IT Standards by the DHHS Office
of the National Coordinator for Health Information Technology**

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Good morning. My name is Hugh Zettel, and I am director of government and industry relations for GE Healthcare Integrated IT solutions. I want to thank the IOM for giving GE this opportunity to provide input into your review of standard-setting activities by the Office of the National Coordinator for Health Information Technology (ONC).

The Need for Interoperability

GE has long been a proponent of and, indeed, a leader in the pursuit of interoperability. As both a vendor of health IT and as one of the country's largest purchasers of healthcare¹, we have taken this position for two fundamental reasons.

First, interoperability saves lives. A clinician needs an accurate, comprehensive, and up-to-the-minute picture of a patient's condition on which to base critical treatment decisions. Being able to access the medical history and medication allergies of patients who find themselves in an emergency room thousands of miles from home is a clear-cut and dramatic example. But a more common, subtle and pressing problem occurs thousands of times every day, when patients cross a healthcare boundary (such as being discharged from a hospital or transferring to a long-term care facility) and their medical information doesn't make the transition with them. The loss of information that occurs on the margins degrades the quality of care providers can deliver, and all too often leads to errors that result in injury or even death.

Second, interoperability also enables transparency, which leads to improved quality, efficiency and consumer/purchaser satisfaction. Transparency gives patients and purchasers access to information about cost and outcomes, so that they can make more informed decisions about care. Pay-for-performance initiatives also require interoperability so that results can be tracked across the entire continuum of care, not just for an individual provider or healthcare organization.

GE's Role in Promoting Interoperability

GE has a long history of successfully driving open, standards-based data exchange with other vendors. The earliest example is the Digital Imaging and Communications in Medicine (DICOM) standard, which has enabled diagnostic imaging devices and software systems to exchange images and related information regardless of vendor. Diagnostic imaging vendors historically created proprietary formats for the CT or MR images created by their systems. While image exchange was interoperable between systems supplied by the same vendor, this was not the case among systems supplied by competing vendors. This lock-in limited the flexibility of hospital radiology departments to utilize imaging technology in an optimum fashion. DICOM allowed images to move from system to system, enabled hospitals to centralize storage of images to reduce costs, and led the radiology department to move towards diagnosing images on a computer screen. Consequently, DICOM enabled the creation of today's \$2 billion picture archiving and communications systems (PACS) market, while also enabling many hospitals to eliminate one of their highest expenses from their operating budgets: film. PACS has transformed the workflow within the radiology department, leading to increased efficiency and higher quality of care. Physicians at different locations can consult while simultaneously examining the same images and comparing them with other clinical results to get a more complete picture of the patient's condition.

GE has also been a long-term leader in Integrating the Healthcare Enterprise (IHE), an industry-led initiative that is creating a standards-based framework for clinical IT. IHE was established in 1998 by the Radiological Society of North America (RSNA) and the Health Information Management and Systems Society (HIMSS). The popularity of DICOM led to the desire to improve imaging information exchange beyond the radiology department to other clinical IT systems in the

¹ GE's direct healthcare costs in the U.S. total approximately \$2.2 billion annually for our nearly 1 million employees and their dependents.

hospital. Early on IHE recognized that solving healthcare interoperability problems sometimes requires multiple standards and established a process that allowed multiple standards to be profiled and specified in a precise manner to resolve workflow challenges while maintaining plug-and-play capabilities.

IHE's interoperability showcases (Connectathons) – held at major industry conferences – encourage competing vendors to build and demonstrate data exchange between their products, via a collaborative and transparent process. This includes laboratory results, radiology images, medical summaries, and cardiology reports – the very information that today is often still faxed, couriered, or mailed between the majority of healthcare organizations in the U.S.

GE has been instrumental in HL7 standards efforts, representing users and vendors in the definition of clinical document sharing and context setting (user and patient) standards. GE's Centricity® EMR was the first major healthcare information system to provide a production-ready CCOW-compliant product. GE also worked with the HL7 board and industry vendors to define strategies for broad vendor adoption of CCOW.

And, GE is one of the founders of the HIMSS EHR Vendor Association (EHRVA), a group of the top 42 EHR vendors committed to making EMRs interoperable and to accelerating EMR adoption in hospital and ambulatory care settings. EHRVA is playing a pivotal role in creating and driving a single set of standards for electronic health records interoperability, similar to the role NEMA played in transforming diagnostic imaging interoperability in the 1990s. Standards for electronic medical records are complex, because they involve multiple types of data and terminologies that are not 100 percent congruent from one specialty to the next – or even from one hospital to the next.

GE is a coauthor of the *EHRVA Interoperability Roadmap* – an effort to articulate an achievable path to interoperability. The roadmap sets out a phased timeline for the interoperability needed to implement a nationwide health information infrastructure (NHIN). The first phase of that roadmap was demonstrated at the HIMSS Conference in 2006, with GE joining 37 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, and GE and EHRVA are reaching out to other stakeholders to encourage further implementation and convergence of the roadmap.²

Don Woodlock, GE Healthcare's General Manager of Imaging Solutions, was the only speaker at the *Secretarial Summit on Health Information Technology*, July 21, 2004, to advocate open, standards-based interoperability. And numerous GE employees contribute their time and energy to establishing and staffing bodies, including the Certification Commission for Health IT (CCHIT) and the Health Information Technology Standards Panel (HITSP).

Assessment of ONC's Standards Activities

This committee has been asked to examine and evaluate ONC's activities in developing standards for healthcare information technology (HIT). The balance of my remarks will be broken down into four areas:

1. Supporting the exemplary efforts of HITSP;
2. Providing interoperability solutions that meet the needs of clinicians now;
3. Creating synergies between the certification process and the competitive marketplace, and
4. Enabling market forces to drive adoption of interoperable solutions.

² The EHRVA interoperability roadmap can be found at <http://www.himssehrva.org>.

HITSP is a best practice

In our estimation, HITSP is the most successful of all the ONC initiatives pursuing interoperability. It is supported vigorously by the healthcare IT stakeholders. There are several reasons for this:

- HITSP's process is transparent, increasing confidence in the process and the results.
- HITSP provides a forum for public and private sector collaboration and communication. This collaboration is critical, because neither the public nor the private sector alone can make interoperability happen.
- HITSP has leveraged the work of existing multi-stakeholder processes, such as those developed by IHE, to ensure truly compatible implementations by different vendors, both here in the U.S. and worldwide. IHE's implementation and testing processes have been leveraged by many countries and regions around the world, including the U.S. (through HITSP), France, Canada, Austria, Italy, and Japan. By establishing a larger-scale market for HIT interoperability, this approach helps reduce the cost of achieving interoperability and makes the inherent technology risk more acceptable for vendors.
- HITSP has demonstrated that its consensus-based decision-making process can yield results, for example, the ASTM CCR/HL7 CDA harmonization and efforts to drive semantic interoperability in lab transactions. While there are critics who disagree with some of the results that HITSP has created using its consensus-based approach, this is not an area where we should let the perfect be the enemy of the good. The thoroughness of the HITSP process allows us to have confidence in the standards that are recognized, so that we can keep making progress toward interoperability and give providers confidence to make interoperability investments.

We offer these suggestions for making HITSP even more effective:

- Better synchronization with CCHIT to address market needs. Because CCHIT preceded the formation of HITSP, CCHIT's first certification criteria were based on interoperability requirements that had yet to be finalized by HITSP. Going forward, CCHIT's annual cycle of issuing new criteria does not easily accommodate HITSP requirements that need to be phased in multiple steps.
- AHIC commissioners should "walk the talk" by endorsing and implementing HITSP's work in the constituency groups they are supposed to represent.
- Expedite compliance by 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* to ensure future HIT-related grant requirements utilize 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 with state HIT infrastructures.

Meaningful interoperability solutions based on the clinicians' current needs

Several studies have detailed the potential impact of interoperability in meeting the goals established by the IOM that patient care be safe, timely, effective, equitable, and patient-

centered. In the process, HIT could save more than \$77 billion a year in the U.S. alone, from increased efficiency and productivity, as well as avoided costs of preventable medical errors.³

In order to achieve these results, however, we must lay a foundation by encouraging the adoption of EHRs throughout the continuum of care. When fax machines were new – and rare – their utility as a means of exchanging information was limited. Similarly, until we reach a critical mass of EHR adoption, the question of whether the systems are interoperable is virtually meaningless. At the 3rd NHIN Public Forum, in January of this year, all of the consortia prototype demonstrations had sustainability models that relied on a substantial EHR footprint.

To paraphrase Mickey Tripathi, president and CEO of the Massachusetts eHealth Collaborative, speaking as part of the sustainability panel at the 3rd NHIN Public Forum, without EHR adoption, there is no hope for sustainable health information exchange.

And we cannot achieve sufficient EHR adoption without aligning the market forces that govern healthcare. Our healthcare system is designed to reward quantity, not quality, of care. What clinicians are interested in *today* is technology that will help them with billing and with capturing and exchanging information accurately. That is what they are asking vendors for, and that is what they will buy. We cannot achieve quality transformation by leapfrogging over the basics.

In this case, the market is behaving rationally. The basics – getting information entered electronically and accurately, for example – are a prerequisite to accomplishing more sophisticated functions such as decision support. Brent James, Executive Director of the Institute for Health Care Delivery Research at Intermountain Healthcare, has proposed a six-step process for transitioning from paper to electronic records “where each step pays its own way and lays the foundation for the next steps.”⁴ The process starts with automation of billing and scheduling, then lab and pharmacy, and so on, and only in the latter half moves toward encoding data in order to achieve interoperability.

Unfortunately, current efforts to drive adoption, such as Stark relaxation, are being carried out absent any coordination with ONC’s interoperability initiatives. One would expect use-case priorities to be synergistic with department policy initiatives such as Stark; yet none of the first three use-cases comes close to helping donating entities meet the definition of interoperability set forth in the regulation. How does syndromic biosurveillance or consumer empowerment use cases address the more pressing issue of coordinating care for the average Medicare patient who sees six different providers – care that accounts for millions of transactions every year? The answer is, they do not.

Industry has recognized and is acting on these needs. In its Interoperability Roadmap, EHRVA proposed using a series of use cases that parallel the incremental phases of achieving interoperability. This sequence starts with sharing care status information and arrives at health surveillance only at the very end. Yet it is only now, in its third year, that AHIC is even beginning to address basic bread and butter interoperability needs, such as sharing medical summaries or ensuring that medical information seamlessly follows a patient in the transition from inpatient to outpatient care. Given that more than 90 percent of patient encounters occur in the outpatient setting, this should have been one of the first use cases developed.⁵

We respectfully suggest that if AHIC truly wants to support breakthroughs, defined as having an impact in healthcare quality and productivity within 12 to 18 months, these are the areas on which we should focus our time and attention, rather than responding to the narrow political interests that are compromising AHIC’s effectiveness:

³ See, e.g., Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, And Costs, Hillestad et al., *Health Affairs*, 24, no. 5 (2005): 1103-1117; The Value Of Health Care Information Exchange And Interoperability, Walker et al., *Health Affairs* Web exclusive (January 19, 2005): <http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.10v1>

⁴ E-Health: Steps on the Road to Interoperability, James B, *Health Affairs* Web exclusive (January 19, 2005): <http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.26v1>

⁵ See EHRVA letter to the Office of the National Coordinator, July 20, 2007 at <http://www.himssehrva.org>

- Going forward, ONC should work with AHIC to provide use cases that will have the desired impact – use cases that will be relevant to, say, family practice physicians and caregivers, and give them a reason to invest time and expense in EHR systems. To accomplish this, we need to de-politicize the process of setting priorities. As former Speaker Newt Gingrich put it in the introduction to David Merritt’s book *Paper Kills*⁶, “AHIC must focus on the real-world data exchange needs of physicians and other providers.”
- ONC should adopt EHRVA recommendations that it focus on interoperability solutions between the inpatient and outpatient settings that do not require a health information exchange, and leverage the HITSP standards in a manner that allows them to scale to a HIE and NHIN when their community or state is ready.⁷ We are encouraged that several of our customers already see the benefits of using the HITSP specifications to build out their existing IDN network infrastructures, making these investments with the certainty that the HITSP specifications are being adopted in the EHR vendor community, as well as being required in federal HIT efforts.
- ONC should leverage IHE’s work in creating Patient Care Coordination Domain, which is based on several foundational use cases, including ambulatory referral to an inpatient setting, inpatient discharge summary, and emergency department referral from an ambulatory setting. These use cases were championed by leading provider organizations 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 in the context of the entire interaction that occurs in clinician-patient workflow.

Creating synergies between the certification process and the competitive EHR market

As described above, the current process for setting certification priorities for interoperability is disconnected from the real-world needs of providers who will be using (or not using) the technology. There is no good way to collect feedback from the stakeholders who will be most affected.

Stark relaxation provides an example of how this has gotten out of sync. The interoperability deeming provision of the regulation limits participation by specialty ambulatory EHR vendors. In addition, the current specialty areas being addressed by CCHIT leave many of these niche vendors on the sidelines in the EHR donation game, hampering what was until now a robust, competitive market. The annual certification process resulting from 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. Lastly, requirements that eligible systems be certified as interoperable are out of sync with HITSP’s process for providing interoperability specifications that meet the expectations of the regulation.

We offer these suggestions to make the certification process more effective:

- As we noted in our recommendations above, closer collaboration between HITSP and CCHIT in establishing interoperability specification deployment should be strengthened.

⁶ *Paper Kills: Transforming Health and Healthcare with Information Technology*, Merritt, ed., CHT Press 2007.

⁷ See EHRVA letter to Certification Commission for HIT Chairperson, August 20, 2007 at <http://www.himssehrva.org>

- CCHIT should clarify its process for determining how requirements are set based on objective criteria already outlined in several studies regarding EHR capabilities and associated impact.
- 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 continue its vigilance in ensuring certification is not a cost burden to vendors. CCHIT has done a poor job in reporting the total cost vendors bear. For example, 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 is limited not just to standards but to the entire set of tools used to develop and maintain them.

Enabling market forces to drive adoption of interoperable solutions

ONC's strategic planning should include looking for opportunities to enable market forces to drive adoption of interoperable solutions.

Exchange of information should be the standard of care *today*. As previously mentioned, the average Medicare patient sees six different providers. We need to support the emerging Medical Home concept; this could be done by prioritizing interoperability specifications for managing transition of care.

There is a use case for consumer empowerment using PHRs, but we don't have the back office infrastructure in place yet to utilize PHRs to exchange information in an efficient and useful manner that meets consumer expectations. In the late 1990s and early 2000s, Internet development focused on building an efficient and transparent back-office in virtually every industry sector except for healthcare. Once this web-enabled intranet was in place, consumer-facing applications were developed that enabled an explosion in Internet consumerism. We need to follow that same sequence with respect to medical information in order to get the same results: that is, get provider-to-provider interoperability working first.

Nor are we doing anything to motivate providers to exchange information.⁸ While there is no net cost to providers for maintaining the status quo, the cost of acquiring and implementing EHRs can be significant.⁹ Furthermore, as Blackford Middleton, Chairman of the Center for Information Technology Leadership (CITL) at Partners HealthCare System, points out, vendors are responding rationally to the marketplace. Since providers are not requesting data exchange or interoperability, vendors do not prioritize those features. Proprietary EHR solutions, on the other hand, help lock in customers. As long as these two factors continue to reinforce each other, there is no reason for providers to change their behaviors.

Therefore, we need to realign the market in the direction of transparency, enabled through interoperability. There are several (non-exclusive) ways of doing this:

- *Mandate interoperability.* HIPAA created a mandate for efficient electronic payment systems. A similar mandate could be imposed for clinical information exchange.
- *Direct financial incentives for interoperability.* Another approach is to make interoperability financially desirable, by rewarding providers for sharing information electronically, where HIT is used as part of an overall strategy to increase the quality of care.

⁸ Accelerating U.S. EHR Adoption: How to Get There From Here, Middleton B and Brennan PF, *JAMIA* 12:1 (Jan/Feb 2005)

⁹ The Value Of Electronic Health Records In Solo Or Small Group Practices, Miller et al, *Health Affairs*, 24, no. 5 (Sept/Oct 2005), 1127-1137.

- *Incentives based on quality outcomes.* We need to expand the number of pay-for-performance programs that reimburse at higher rates for improvements in operational efficiencies or for increased quality outcomes resulting from interoperability.

Summary

GE has long supported investment in interoperability and will continue to do so as a means to meet the IOM's goal of improving the quality and safety of healthcare. In the past few years, we have seen awareness and understanding of the importance of health information exchange grow exponentially in both the public and private sectors. We have seen the EHR vendor community step up to make standards-based interoperability a reality. Such rapid change does not mean, however, that we can overlook the necessary work that must be done to build a solid foundation and infrastructure for interoperability.

The most important element of that is to increase EHR adoption, and that cannot be accomplished without recognizing and responding to the current realities of the market. We need to refocus current efforts relative to providing interoperability solutions that impact the market today, including more fully supporting the excellent work by HITSP on meeting these real-world needs.