



## **Standards Insight**

### **An Analysis of Health Information Standards Development Initiatives**

*August 2005*

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### **The New Federal Interoperability Initiatives**

Much like last summer's Secretary's Summit, the June 2005 HIMSS Summit: Achieving National Healthcare Transformation, featured a series of announcements of key initiatives from the Secretary of the Department of Health and Human Services (HHS), Michael Leavitt, and the National Coordinator for Health Information Technology, David Brailer MD, PhD. The Office of the National Coordinator for Health Information Technology (ONCHIT) has led a review within the Federal healthcare community of all the responses to last November's request for information (RFI) regarding a national health information network and infrastructure. This effort resulted in a 500 plus page summary, a proposed new standards and policy commission, and four requests for proposals, all of which seek to move forward on the President's call for universal electronic health records (EHR). This month we will briefly review these announced initiatives and examine some remaining issues.

### **The American Health Information Community (AHIC)**

Secretary Leavitt announced the formation of the American Health Information Community, a 17 member board that he will chair, to set national HIT policies, standards and priorities. AHIC, which begins as a public-private body, is to become a private organization in five years. The need for a new central standards and policy authority was a key message at both last year's Secretary's Summit and in the RFI responses. Now we have what we asked for in terms of a central standards and policy body that will pre-empt other forums – which is probably a plus. But AHIC will centralize and inevitably focus

special interest politics. And for the public-private partnership, we are looking at “guided collaboration,” which Dr. Brailer maintains is the best alternative to Federal HIT mandates.

## **The Requests for Proposals (RFPs)**

The RFPs, although cloaked in government procurement terms, are well reasoned and coordinated. Each of the four RFPs envisions a three-year project with an optional fourth year. All are to be driven from the same set of common use cases, collectively developed among the contractors with coordination by the ONCHIT project manager. All look for both demonstrations as well as economic models to deploy and sustain their activities. By now, responses have been submitted and winning proposals could be announced shortly. These are the highlights.

### *Evaluation of Standards Harmonization Process for Health Information Technology*

This RFP requests a harmonization process that will produce a widely used set of standards supporting interoperable health applications and systems, particularly electronic health records. It envisions activities to develop key use cases, identify gaps in existing standards, develop a change management process to align standards and fill gaps, recommend standards, develop implementation guidelines and create a sustaining organization.

Like the other RFPs, harmonization starts from the common use cases. These will be extremely important since they will set the business objectives, priorities and phasing for the standards work. In their absence, standards identification and gap analysis would drive applications and ultimately the clinical and business processes, another case of technology trying to define end user requirements. A key challenge is how this new initiative can enroll the various standards development organizations (SDOs), which have been unable to agree to voluntary harmonization in the past. While no existing organizations are precluded from this contract, the overall pattern appears to reduce the influence of the old world leaders, such as the American National Standards Institute Healthcare Informatics Standards Board (ANSI HISB), Health Level Seven and other SDOs, as well as the National Committee on Vital and Health Statistics (NCVHS), all of whom might collectively be viewed as not delivering necessary interoperability standards in the past.

### *Evaluation of a Compliance Certification Process for Health Information Technology*

This RFP seeks proposals for creating and evaluating criteria and inspection processes for interoperable health applications, specifically electronic health record systems. The RFP expects the winning contractor to produce the certification process, an economic model, a feedback process from stakeholders and demonstrate change in the adoption of EHR systems based on certification.

The RFP, in many respects, mirrors the activities of the Certification Commission for Healthcare Information Technology (CCHIT), including their prioritization of ambulatory EHR systems before inpatient systems, and their representation of many stakeholders. It would have been impossible for the Federal government to anoint CCHIT in an “exclusive” role without an open process. We have already seen evidence of vendor dissatisfaction with CCHIT, and this RFP gives other organizations an opportunity to propose an alternative.

The certification project runs in parallel to both standards harmonization, upon which certification would depend, and the National Health Information Network (NHIN) which must anticipate certification as part of its business case. Certification is viewed as a critical component for both widespread market acceptance and for establishing payment incentives, reasons enough for vendors’ concerns.

### *Privacy and Security Solutions for Interoperable Health Information Exchange*

This RFP seeks recommendations to “standardize” business rules and state regulations that apply to the privacy and security of patient information as well as to analyze other government impediments to interoperable health applications that share individual health data.

It is in essence a HIPAA “do-over” to standardize all the policies, procedures and technology solutions that each provider organization and other covered entities painstakingly developed based on their own individual risk assessments and mitigation plans. Different policies and security mechanisms defeat interoperability. While the NHIN projects can hardwire their few required participants to agree on sharing rules, this would not scale to other organizations and states, a prerequisite for an NHIN.

### *Developing a Prototype for a Nationwide Health Information Network Architecture*

This is the key RFP seeking six demonstrations projects that could scale to the national health information network. Winning contractors must demonstrate two or more providers, four or more organizations and two or more different (vendor) applications interoperating in a useful way. Each contractor must also create a business plan for sustaining the NHIN.

This RFP caused the most questions and concerns, particularly in regards to the use of proprietary software. The RFP requires free license to all work products concerning the architecture but not the implementation. Clearly this may not be compatible with some vendor models for Regional Health Information Organizations (RHIO). On the other hand, the NHIN architecture does not define the RHIO. The presumption is that RHIOs will not develop standards but implement those designated by AHIC using recommendations from the new standards harmonization bodies as certified by the new certification body, subject to standard privacy and security rules. The NHIN contractors are expected to make their best guesses as to how all these initiatives will play out in designing their projects. But completing the circle, the chosen architecture will drive the

requirements for specific standards and transactions, as well as underlying policies, procedures and processes.

## **The Unresolved Issues**

As can be seen even in this brief review, there is much coordination of efforts necessary not only in managing, staging and sequencing the winning contractors but fitting these efforts into other initiatives, such as the Medicare e-prescribing roll-out, the growing number of proprietary enterprise clinical systems, and the many independently evolving RHIOs.

Narrowing the definition of interoperability within the NHIN contracts to “systems communicating and exchanging information in an accurate, effective, useful and consistent manner” excludes addressing the clinical and business requirements. Why are we doing all this in the first place? Both Secretary Leavitt and Dr. Brailer were clear that AHIC and the RFPs did not and would not address economic issues, aligning incentives, reimbursement changes and infrastructure funding. They indicated that further announcements in these areas would come within a month. However, without the business case and financial incentives, NHIN, RHIOs, widespread EHR systems, certification bodies and AHIC are speculative. Mark McClellan, head of the Centers for Medicare and Medicaid Services (CMS), recently told Congress that “pay for performance” proceeds in two steps: first inducing providers to provide quality data (using less than 1 percent incentives) and second to use incentives to improve quality (using public reporting and 1 to 2 percent incentives).

Meanwhile we have half a dozen Congressional proposals, each with a somewhat different slant on the role of the Federal government and on funding, but all still restricted to demonstration projects, not to reimbursement transformation or infrastructure funding.

While the overall strategic framework-driven process is one of multiple phases, beginning with these demonstration projects, is the intent of ONCHIT to produce an all or none “interoperability”? Much of the economic benefits of interoperability are outlined by the Center for Information Technology leadership’s Level 4 seamless exchange. Dr. Brailer himself has indicated a preference for establishing interoperability before addressing the EHR adoption gap. The danger is that many other initiatives might freeze their activity waiting for what comes from ONCHIT. Whatever architecture and standards come out of this process, we will be in a messy transition phase for a long time.

What is the message? Interoperability, i.e., standards harmonization, certification, new security/privacy rules and NHIN, will not be “finished” in one year or two years or even three years. When will be a good time to invest in EHR systems? When will CMS be comfortable with aligning financial incentives? When will Congress fund infrastructure? In the meantime we need to encourage adoption of EHR systems within the context of saving lives and saving dollars.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier, HIMSS vice president of informatics, at [jsensmeier@himss.org](mailto:jsensmeier@himss.org) or to its author Ed Larsen at [erlarsen@erlinc.com](mailto:erlarsen@erlinc.com).