Health Information Technology Policy Committee:
Certification and Adoption Workgroup
DRAFT
Summary of the Meeting July 15, 2009
Park Hyatt Hotel, 24th & M Streets, NW, Washington, DC
and by Web Conference
The meeting was a continuation of the July 14 meeting.

Participants:
Adam Clark
Amanda Ervin
Carol Bean
Charles Kennedy
David McCalley
Gayle Harrell
Joe Heyman
Jodi Daniel
John Glazer
Judy Sparrow
Marc Probst
Paul Egerman
Rick Chapman
Scott White
Steve Downs
Teri Takai

KEY TOPICS
1. Welcome and Opening Remarks
John Glaser, Office of the National Coordinator, opened the meeting by saying that the Certification and Adoption Workgroup would present its preliminary recommendations to the HIT Policy Committee for action July 16. He invited interested persons to attend. Additional opportunities for public comment will be announced.

2. Non-Vendor Products Panel
Steve Downs moderated.

Open Source
Edmund Billings, Chief Medical Officer, Medsphere, began by noting the problem of low adoption of HIT. Most of the current products were developed by and for early adopters. The “full-blown” comprehensive EHR consist of much more than most providers can afford, implement, or adopt. His company obtained the Veterans Health Administration (VHA) VistA Clinical Information System through a Freedom of Information Act request and combined it with other open source products. His company markets to small and
medium-sized hospitals. He described the installation and use of open source in the Midland Memorial Hospital system, which achieved HIMSS stage 6 at a total cost of ownership of approximately $7 million in conjunction with a $20 million update completed before the installation. Midland’s cost was much less than the 10 other hospitals with comparable HIT. Since the software was obtained at no cost to Midland, the total cost over a 5-year period was primarily consultative services and implementation. Physician adoption of CPOE and other features brought about substantial improvements in central line-associated primary bloodstream infection rate, ventilator associated pneumonia bundle compliance, and reconciliation of medications, all of which were associated with cost savings. Use of open source means savings on software licenses and more money to apply to adoption.

Providers do not have the resources for comprehensive HIT solutions. Instead, they need complete solutions. First of all, they need to be connected to the Internet throughout their facilities, not just at the front desk. They want to spend money on services not on software. They will not adopt in the absence of a business model.

Dr. Billings concluded with the following recommendations:

- Do not require certification on ‘comprehensive’ criteria.
- Certify solutions only to protect the customer: e.g., support for meaningful use, “plug and play” interoperability, patient safety, privacy, etc.
- Certify modular solutions to support incremental adoption, continuous innovation and customer choice.
- Certify sites on demonstrated “meaningful use.”
- Require and incent for electronic communications.
- Shift payment for value, quality, and wellness as soon as possible.
- Support VistA, the Resource and Patient Management System (RPMS), and the National Health Information Network (NHIN) as national assets.

**Modular EHR**

David Kates, Senior Vice President Business and Product Strategy, Prematics, Inc., said that the vast majority of physicians in the United States are located in small practices. HIT adoption is these practices woefully behind. They do not have wireless networks; they do not have a dedicated IT person. There is great opportunity to improve care in these settings but improvements must fit in the work flow and be of immediate benefit to the physicians, office staffs, and patients.

Acknowledging his CCHIT membership, Dr. Kates said that certification is crucial and should focus on a modular approach. Prematics delivers a workflow automation tool that allows a doctor to write a prescription and deliver it safely and efficiently to the pharmacy, but what Prematics is really doing is introducing technology to the doctors, in their hands, in the exam rooms, while with the patients, and providing meaningful information in the context of writing a prescription. The process includes the provision of clinical information related to other medications the patient is on and formulary information that might drive the use of lower cost or generic alternatives. The use of this technology provides opportunity to deliver other clinical information in that setting, such
as lab order entry and results reporting with clinical decision support (CDS), problem list management, and reporting to registries, followed by progressively automating documentation of progress notes to maximize reimbursement. All of this makes a good business case and can be done incrementally.

In conclusion, Dr. Kates emphasized that ONC needs to focus its efforts on overcoming barriers to HIT use. Certification is crucial to the implementation of HITECH. Certification’s benefits include the following:

- Informs buyers regarding significant investment
- Ensures that safety, quality, and cost-effectiveness can be achieved.
- Provides a foundation for sharing of relevant clinical information
- Defines and consistently implements standards necessary for interoperability and to support continuity of care

Home-grown System: CCHIT – Innovation Killer of In-house Developed HIT?

Carl A. Christensen, Chief Technology Officer, Marshfield Clinic, reported that Marshfield Clinic has been practicing informatics since 1967. The Clinic’s EHR is shared with other organizations. It is the official legal medical record. Marshfield was the first in-house developed system to receive CCHIT certification. Certification requires a huge outlay of resources, which, according to Dr. Christensen, does not result in comparable value. To obtain CCHIT certification in 2008, Marshfield expended approximately 65,000 hours over and above the time expended for the 2006 certification. An estimated 20% of the work yielded little or no value and the remaining portions were not immediately useful. In fact, the overall effort diverted attention from what was considered high value enhancements to CCHIT compliance tasks, undertaken solely for the purpose of compliance.

A reporting component was one example of uselessness. Although Marshfield arguably has one of the most comprehensive ambulatory clinical data warehouses in the country with capabilities that far exceed the basic reporting capabilities required by CCHIT, the logistics imposed by the CCHIT testing process forced Marshfield to write and maintain a parallel reporting system which provided no additional value. In contrast, a CMS demonstration project added considerable positive value to the organization’s HIT and also improved quality of care.

One of the biggest benefits of CCHIT certification is the reduction of buying risk for purchasers of HIT, but this does not apply to in-house developed systems. 2008 CCHIT certification had minimal impact on the quality of Marshfield’s HIT, had a negative impact on quality of care, and increased overall health care costs. The quality of the implementation process is far more important than the feature list.

Q and A

With a modular approach, how do we ensure we are creating a data foundation that will be supportive of decision algorithms?
Both from the interoperability standpoint and the overriding data model, the modular component must be able to access the information to be shared and to support quality measures. There needs to be a common framework with definitions and architecture. The modular certification process needs to enforce how information will be exchanged and how the data will live.

**How many of your clients use VistA?**
The Indian Health Service’s 200-facility network, West Virginia public health hospitals, and seven commercial hospitals are clients. The stimulus package has increased interest in VistA. The VHA demonstrated that the way to build the best practice is to build it into the content. Meaningful use criteria will help to reduce the variance across sites and systems. Certifying a system protects the customer, but does not guarantee results. The deployment, implementation, and focus lead to results.

**What would be the effects of certification on changes in self-developed and VistA systems, which occur in a very rapid cycle, compared to a typical vendor cycle of every 6 months?**
The VistA community is large and development is continuous. Service packs come out every 3 months. The code itself is advancing much more frequently, but customers have limits to the frequency with which they can make changes.

**What about certification of multiple versions of VistA?**
Medsphere has two versions, open VistA and commercialized VistA and RPMS. Both are certified. It would be better to have a single certified version. The modular approach to certification is the modular approach to adoption. Adoption is incremental. The modular approach allows for a focus on meaningful use. A site-specific, implementation-specific validation is required. The site has to prove its meaningful use to be certified, not just submit a code saying the product is certified.

**What about the view that the open-source community needs to compete with the commercial products on an open playing field?**
Vendor products should not compete on comprehensive feature functions. With only 1.5% adoption, competing for service and results is the goal, not competing on product and code. The open source community generated a list of improvements to the process that would make it work for open-source. The open source community is not looking for a separate certification process.

Whether an organization is a large monolithic enterprise system, fully certified, or an in-house integrator, bringing in multiple systems, once a certain size of enterprise is attained, the organization is doing in-house development. It is not to say that having some good housekeeping seal of approval or something for buyers of modules or systems is a bad thing, but it should not be driving the incentives and focus.

**What would a site certification entail?**
Site inspection would be based on meaningful use criteria and examine accomplishment. Rather than the increasing focus on the granular level, there should be consideration of flexibility and ability to innovate.

CCHIT introduced the term modular, but capabilities may be a better term. CMS will also do inspections. The site inspection is the opportunity to examine how the purchaser or provider is using the product.

Regarding the EHR-M approach for providers that prefer to integrate technology from open sources, how is interoperability ensured?

CCHIT puts the burden on an organization to create its EHR. The modular approach has merit for a large organization with the ability to integrate the tools into the workflow and practice. But in the smaller physician practice, adoption needs to focus on small steps to support meaningful use. A foundation platform with the interoperability data model and liquidity is needed to allow data to flow across modules. All products need to be validated in the field. Over time, this will stimulate the service industry and contribute to adoption.

3. Public Comment

Members of the public were asked to submit their comments in writing.

Jim McDonald, College of American Pathologists, asked if a technology platform had been approved. Although the public comment period was not designed to entertain questions, he was referred to the HIT Standards Committee, which will release its recommendations on July 21.

Anthony [unknown name] commented that in the description of site visits to evaluate use, the Workgroup is creeping close to the line of what CMS will be doing. He suggested that the Workgroup is guessing at where that line is, and either it should be ramped up with the site visit type approach, or scaled back, which goes against the trend of adding on more levels of functionality.

[unknown name], American Physical Therapy Association, asked that certification be inclusive of all health care providers. Although E-prescribing capabilities are an important component of care, physical therapists and other health care professionals are currently limited in their ability to prescribe medication and order tests. She urged the Workgroup to recommend that EHR be used to coordinate care across a wide array of providers.

Brian Ahier reminded the Workgroup to consider ADA requirements. He asked that the Workgroup explore the accessibility of Web-based Personal Health Records (PHR) for persons with disabilities.
Richard Thorson, HMHSA, commented that CCHIT has not been constrained in the past to use only ANSI-approved standards. Some of the CCHIT standards have no source other than the volunteer committees, which are not open to the public. Quite unlike HL-7 and X 12, this is a non-HITSP, non-open process leading to a set of certification criteria not constrained by having gone through standards processes. For an industry that commands $2.6 trillion this is a shaky approach.

Andrea Pennington, Logical Images, said that she strongly agrees that HIT can address many of the problems with cost and quality. The modularization of EHR is a step in the right direction. She suggested that CDS software be included and made eligible for modular certification and that reimbursement incentives be used to encourage adoption.

Rochelle Spiro, a consultant pharmacist, said that she works in long-term health care. She is working with a group of pharmacists’ associations to provide an electronic health record, which they expect to take through certification.