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

Participants:
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KEY TOPICS

1. Welcome and Opening Remarks
John Glaser, Office of the National Coordinator (ONC), opened the meeting by saying that the American Recovery and Reinvestment Act of 2009 (ARRA) specifies that in order to receive financial incentives, Medicaid and Medicare providers are required to engage in meaningful use of information from certified electronic health records (EHR). The HIT Policy Committee charged the Certification and Adoption Workgroup with examining the certification process and payment system referenced in the HITECH legislation. ONC encouraged the Workgroup and others to consider a wide range of possibilities for certification processes. Dr. Glazer encouraged participants to be analytical and both complementary and critical of the certification process to date.

2. Meeting Objectives and Outcomes
Paul Egerman, Co-Chair, described the purpose of the meeting as information gathering, a continuation of the group's effort to obtain information of widely varying viewpoints. In addition to the invited presenters, he said that public comments will be heard. Viewpoints not yet heard are of particular interest. In the afternoon the Workgroup will met in executive session to review the testimonies and to continue its discussion of recommendations to the HIT Policy Committee. If the members reach consensus, the recommendations will be presented on July 16. Prior to

adoption by ONC and the secretary, the proposal will be published in the Federal Register for public comment. Co-Chair Egerman stated that HHS had given the Workgroup complete autonomy.

3. National Research Council (NRC) Study on Computational Technology for Effective Health Care

William Stead, Vanderbilt University Medical Center, began by reporting on the NRC committee that was formed to examine the gaps between health information technology (HIT) and what was required to support the Institute of Medicine's view of health care. He described the composition of the committee, its data collection methods, and the conclusions presented in its report. The central conclusions were:

- Current efforts aimed at nationwide deployment of HIT will not be sufficient to achieve the vision of 21st century health care, and may even set back the cause.

- Success will require greater emphasis on providing cognitive support, that is, assistance for thinking about and solving problems.

- In the near term, embrace measurable health care quality improvement as the driving rationale for HIT adoption efforts.

He went on to describe his analysis of what the findings implied for certification, focusing first on the mismatch between computational techniques (automation, connectivity, decision support, and data mining) and the scale of the problem. According to Dr. Stead, the use of computers has actually increased fragmentation in health care and reform efforts could aggravate current problems. The patient is being lost in transactional detail. Radical change is needed to architect systems that can accommodate disruptive change.

He said that interoperability needs to be redefined as data that can always be correctly interpreted over time as knowledge advances, and captured as raw signal data, annotated with standard terminology. A system was built for the Memphis RIO to tackle EHR more like a secure Google problem than a data processing problem for a cost of $2 per year per "citizen". Regarding certification, he said that "less is more". Certification should be done only where definitions are precise and at a granular level. Liquidity of data, decision support content, and audit trails should be the foundation of certification. He gave the example of E-prescribing, which consists of nine decision points each of which requires different decision support, different data requirements about the patient, different measures of the completion of that step, and different dependencies. He argued for an approach that certifies a set of the absolute minimum number of functional building blocks and includes post-market surveillance. Software should not be certified without the associated patient data and decision support.

In conclusion, he listed essential areas of measurement and reporting:

- Ease of learning: set of functions a role needs to do, training time, time to peak efficiency

- Ease of use: time to complete and error rate for standard tasks, sensitivity and specificity for standard information-seeking tasks

- Cognitive support: % of users handling new information correctly for a set of standard patients

- Adaptation to change: time from issuance of an urgent drug interaction update to its deployment in 80% of operational systems

- Effectiveness: % of alerts overridden by role, % of ADEs following an alert override, % of ADEs in absence of an alert

Q and A

What is required to change from an emphasis on automation to decision support?
Instead of scaling up an automation system to do everything, one should shrink it down to its components, give it an information foundation that is data mining, and then use decision support and social networking tools on top. This could be done by 2014.

In Memphis, the RIO constructs a EHR-like record. Clinical information such as patient history, discharge information, and lab results from six hospitals, safety networks, key reference labs, and one of the key payers is dumped and aggregated. It is not an exchange; it is an aggregation, data mining, and visualization capability. Data parsers, simply semantic algorithms that recognize structure, break into fragments, construct matching algorithms, use the knowledge of the National Library of Medicine's medical thesaurus to construct something like an electronic health record. Data are exported into a regional data bank with facility-specific vaults, which can control the data. The RIO runs algorithms across it that identify what person it relates to, what type of data it contains, and constructs what looks like an electronic health record from a secure browser. The Robert Wood Johnson Foundation supported its development.

What are the base and the foundational components of such a system and should certification extend to the different applications or functions that run on top of that base?
The certification should be based on the extent to which the data are interpreted equally effectively outside of the system and within the system. The current incentive system has allowed the industry to compete on making the parts of the systems work better together, which by definition means they work less well with other systems. The key is to accept separatability.

All the power of the Internet has been achieved with three simple standards, for location, display, and transport, without any standardization of content. In order to achieve something similar in health care, it is necessary to back off on some of the more engineered aspects.

What certification standards should be applied to support cognitive decision support?
A central model is not the way to go. The problem can be broken up into pieces; it can be clarified. We need to start measuring the cognitive, the ability of our systems to in fact enhance decision making. The best of today's systems actually get key information to the right point in the work flow. But we need to understand what's going on with the patient, which is going to be necessary for care coordination across the continuum. For example, we need systems that inform

the physician of the top drugs that are the highest priority to treat the conditions of a specific patient.

4. National Institute of Standards and Technology – Standards and Certification Programs and Processes

Cita Furlani, Director, NIST Information Technology Laboratory, described NIST's mission and broad scope of work before explaining its statutory responsibilities for ARRA. ARRA substantiates NIST's current roles in HIT. It provides funding for NIST to expand its activities in HIT standards development, harmonization, and testing. NIST is to have a consultative role in voluntary certification programs and assist with pilot testing of standards and implementation specifications.

Conformity Assessment Overview

Gordon Gillerman, Chief, Standards Services Division, explained the purpose and process of conducting conformity assessments. NIST provides Federal agencies with assistance related to the development of standards and general conformity assessment systems, and administrative infrastructures, and helps to design the programs themselves. Generally, NIST does not operate the programs itself. Conformity assessment is a term defined in international standards. It includes but is not restricted to certification. There are four types of conformity assessment:

- Testing
- Supplier's Declaration
- Certification
- Accreditation

Dr. Gillerman went on to describe the role of three parties in the four types of conformity assessment:

- First party - seller or manufacturer
- Second party - purchaser or user
- Third party -independent organization with no interest in the transaction between the seller and buyer

A supplier's declaration, which is first party conformity assessment, is used when the risk assessment for compliance is reasonable and there are mechanisms in the marketplace for removing non-compliant products. Only third parties can conduct certification activities. Certification is used when the risks associated with nonconformity are moderate or high. It includes several well-defined steps including evaluation of the evidence. A compliance decision is based on an evaluation of that evidence compared to the requirements for certification. Then there is a public attestation of conformity by the third party certification organization, followed by surveillance or follow-up. Accreditation is the conformity assessment of conformity assessment organizations and their programs. Accreditation provides confidence that laboratory certification bodies and other conformity assessment organizations perform according to international standards and with integrity and technical confidence.

He went on to give examples of several business models in which the government has varying levels of involvement, depending to some extent on the level of risk involvement and who bears the cost burden. Typically, the models are run in the private sector.

Q and A

Has NIST worked with government agencies on certification in situations in which reimbursement is also a consideration?
NIST is working with the Departments of Justice and Homeland security on the effective use of grant money for first responders' body armor. An armor testing and certification program was set up.

Is there a risk that certification will cost so much or require so much work that smaller practices will forego certified HIT and as a result create a division between small practices and cancer care centers and other specialty providers?
There is always that risk. Certification requires testing and testing can be costly. The system is geared toward finding the balance between cost and confidence. Certification refers to the product, not the physician.

Will ONC describe what needs to be certified and then NIST will design the process?
NIAST will assist in the design of the process and help ONC make a more informed decision. NIST will also consult with the current certification organization for HIT. It is not likely that NIST will be a certifying agency or an accreditation agency in this situation. ONC would likely contract with other organizations in the private sector to perform those functions. Typically, NIST recommends that new requirements be added into the international norms for certification programs and in this case ISO ICE Guide 65.

Who is responsible for monitoring and surveillance?
The certification body could contract out the tasks associated with surveillance. The decision to maintain the certification or not maintain the certification must be undertaken by the certification body according to the international standards.

How broad is NIST's scope?
There is a difference between a personnel certification and certifying software or an integrated hardware software platform. They are all different applications but there are systems in place and there are international standards that apply to the conformity assessment of each. The technological sophistication is not the issue. There are also examples of the certification of the integration of certified products.

Are there any accreditation organizations that could accredit a certifying organization for HIT?
All accrediting organizations that are operating on a large-scale and are moving to or have adopted ISO ICE guide 65 as their standard of operation and have the requirements could perform this function. But it is essential that the organizations have the requirements and deploy them effectively. Someone must develop the requirements for that particular application.

What about measuring and certifying ease of learning, ease of using, and adaptation to change?

This would entail monitoring the effectiveness of products in place. It is important that data and information are used to enhance the requirements and improve the products over time. Biometrics and voting machines are examples. NIST has been working with ONC on tests that determine whether the systems actually meet the standards.

What about an evolutionary strategy in which the standards change on a 3-year schedule? Standards are typically set early and remain. When standards change and the bar is raised, interoperability comes into play. As the standards improve, interoperability can be affected. However, raising the bar in product safety has worked.

To what extent will NIST be concerned with security of information and what is the recourse if security of patient information is breached?
NIST has responsibility for setting the standards for the Federal government on cyber security issues. Having the standards and ensuring that the appropriate components are tested prior to deployment is critical. NIST is always looking for ways to augment testing.

What is the typical time frame for coming up with standards?
Standards development can be a lengthy process in the United States compared to other countries. The process is driven by the private sector. The goal is to have a consensus based, voluntary process. It moves more expeditiously when the right people are in the room. It can also be accelerated by providing the right kinds of testing tools and clear standards.

5. Vendor Panel
The moderator stated that the presence of these vendors did not indicate a government endorsement of their products. They had indicated an interest in "giving information" and had been invited to testify. The Workgroup had given them several questions to answer in their presentations.

Ambulatory EHR
Sheldon Razin, CEO, Quality Systems/NextGen, described his company's experience with certification. The EHR was certified in 2006, 2007, 2008, and for the pilot in 2009. Certification has had positive effects for NextGen as well as for its physician group clients. The process enforced standards and reinforced the company's research and development efforts. Certification encourages continuous improvement.

Management believes that CCCHIT should be the sole certifying body. It has 4 years of experience and an established process, which works well. CCHIT has a broad base of stakeholders, physicians, health plans, health systems, hospitals, IT vendors, pharmacists, public health agencies, and medical records personnel. CCHIT is planning to expand into the specialties. Dr. Razin said that having more than one certification body with different criteria would confuse the market. The core system should have a high bar and standards should be raised over time. Specialties can be added on after the core requirements are met. Certification should be both broad based (core) and specific (specialty). Certification criteria should:

- Reflect a high level of IT solutions functionality that will support the plans for meaningful use

- Embody a review of overall system capability, such as clinical decision support and client notification support when and if errors in software are discovered

- Consider a review of company financials to include long term viability

- Focus on interoperability and the ability to submit progressively more complex quality indicators

- Be based on product use and validated at all times.

Dr. Razin said that he believes that vendor systems, in-house systems, and open-source systems should be certified against the same standards, with open-source being site certified. And he went on to outline recommendations for the inclusion of privacy and security in certification. Any release of information or information access should be documented in the EHR. When information is restricted because of privacy concerns, there should be a notice that the record is incomplete. But provisions should be incorporated so that when the patient is in dire need of help, the privacy condition can be broken to provide life-saving information. Privacy issues should be driven by the patient or patient advocate. The system can develop software to exchange information, but the exchange of information should be felt up to the patient and custodian. Breaching privacy should result in severe penalties.

In-patient EHR

David McCallie, Vice President, Medical Informatics, and John Travis, Regulatory and Compliance Strategy, presented the perspective of Cerner Corporation. Dr. McCallie began by admitting that his approach is much smaller and more focused than the one described by Dr. Stead. ARRA demands an aggressive time table. Focus is essential. He recommended three areas of focus, all of which are oriented to achieving meaningful use. Interoperability is the most important focus on in the short run. The second is functional behaviors, which are the things that purchasers expect the systems to do and what they should be certified on. The third area is product integrity. The purchasers expect products to be able to maintain intrinsic security, privacy, and data validity. These features should be part of the certification process; they cannot be verified by end users on their own.

Dr. McCallie said that meaningful use should be the sole goal for the next 4 or 5 years. Certification efforts should be aligned as much as possible with the stimulus-driven funding. Cerner Corporation management agrees that certification should switch from an all or none model to a modular approach. The definition of a module can be based on sub-sets of meaningful use criteria. Users could assemble a system out of existing and piece parts or new parts to put together a package that makes sense to them for meaningful use. Although usability is very important, it may be impossible to build it into certification; many problems with use have to do with the way clients configure the software.

The Cerner Corporation representatives emphasized that certification should be based on objective standards. The ideal would be a machine-driven certification with a harness to hook up a system, run a test suite, and get an answer. If that approach is not possible, then there should be

a multi-person panel involved in decision. The process should be on-going, for example, by making the test harnesses available to the sites themselves, not just to vendors, to perform continuous self-assessment to ensure they are maintaining themselves in a certified state. They cautioned the Workgroup about hidden conflicts of interest, saying that certification should be based on the objective standard itself, not any particular network If the product is hooked up to a network for testing, any network-specific agreement should be separate from the certification process to avoid inadvertently introducing essentially de facto requirements that are not part of the standards process itself.

Niche Vendors

Donald A. Deieso, Chairman and CEO, Perigen, began by saying he preferred the term specialty rather than niche. He pointed out that to date CCHIT has not recognized specialty products such as Perigen's clinical support system for hospital-based perinatal services. This lack of recognition has several consequences. The most powerful transformative advances occur in the specialty firms and without certification they are disincentivized. Setting certification requirements based on the most common denominator of what is available from the largest firms institutionalizes an average and discourages innovation. The most exciting opportunities for driving improvements in health care reside at the intersection of clinical information and advancements in technology. The proposals for defining meaningful use do not recognize issues of women's and infants' health, areas in which disparities are quite pronounced. He recommended that certification do the following:

- Promote "modularity" of certification requirements
- Establish clear mechanisms for disbursement of incentives – specialty solutions v. enterprise EMR
- Address vulnerable and protected populations with early specificity of meaningful use measures, specifically women's health and pregnancy
- Create a national forum to promote innovative solutions at the intersection of clinical and technological advances

Dow R. Wilson, Executive Vice President, Varian Corporation, spoke about the need for certification from an oncology perspective. He said that the goals of general ambulatory and specialty certification are the same, but the criteria for implementation differ. He presented three recommendations and then described how each should be supplemented to include the specialty of oncology:

- An electronic health record must contain comprehensive information relevant to a patient's condition, the treatment plan, and its outcomes. Oncology requires specific terminology and data collection to support physicians in the selection, planning, and management of chemotherapy and radiation treatment. Therefore, test cases for oncology EHR should include oncology specific elements.
- EHR should have the capability to integrate evidence-based practice guidelines and research results into information systems. Oncology-focused EHR products include information for the treatment of cancer and meet these criteria. Oncology-specific EHR vendors would have to adjust their software to comply with certification procedures designed for a general ambulatory system.

- Compliance with general ambulatory criteria will delay oncology-specific developments by vendors, and offer little value to the oncology-specialist. All EHR should allow clinicians to not only manage their own patients and highlight problems specific to the individual, but also recognize when the problem moves beyond one patient and is impacting a larger population. Cancer measures within the Physician Quality Reporting Initiative (PQRI) identify oncology specific data for the promotion and monitoring of quality care.

He concluded by saying that without specialty certification it will be difficult to determine whether the EHR is capturing the appropriate information to support values relevant to oncology.

Q and A

What about a situation in which a community with six certified EHR and a connectivity vendor has been working on HIT for 5 years and the systems cannot talk to each other?
The NextGen representative said that his company has a product, Community Health Systems that will enable the six vendor products to communicate; the only requirement is that they are using standards. Another presenter responded that the current certification effort focuses on just a tiny part of the interoperability equation. Until health information exchange standards are settled, it is difficult for the vendors to know exactly what they plug into. The circuit that is plugged into must be certified as well. E prescribing is much further along and there is greater success with disparate systems.

What about having two types of certification, one specific to meaningful use by CMS and the second similar to what CCHIT is currently doing?
Several of the presenters said that this was a good idea.

What is the impact of certification on vendor organizations?
It has driven the embrace of interoperability and has reinforced security and privacy standards. Organizations should evaluate the benefits of certification. There is concern about the relationship between certification requirements under the Stark safe harbor requirement and under meaningful use. It would be helpful if the certification periods could be synchronized.

What can be done about interoperability?
There are standards that could be used fairly quickly based on the documents sharing model called XDS. Whether those are the right standards or not should be debated and decided quickly. The model described by Dr. Stead is based on sharing textual documents and finding smart ways to search them. It is difficult for vendors to commit substantial resources toward the development of products until the standards have been determined. Actually, many products are currently interoperable.

What level of effort will be required of your clients to make these meaningful use modifications? What kind of time frame do you see and what is the impact?
Probably one of the first demands will be to exchange data on referrals. Some communities have RIOs to facilitate this exchange but many do not; yet all are being held to the same requirement. Software is usually updated with a new version every 2 years. It takes about 6 months for a client

to update. Another question is have the clients implemented CPOE, which typically takes a while. Clients will expect the vendors to have the meaningful use reporting capability.

How would the harness testing work?
The current CCHIT process requires the vendors to test the software before the formal certification. This could be extended to implementation; the providers that are implementing systems could use the test harnesses to certify that not only the software out of the box was capable of working, but the implemented version that they are running also passes the test. The test harnesses could be designed to be easily used—something like Skype. Perhaps NIST could be responsible for the harness design.

6. EHR Purchaser Panel
Physician from a Small Practice
Keith Michl, solo practitioner, Manchester Center, Vermont, described the evolution of the use of EHR in his practice. He reported that he had used separate practice management and EHR systems over the years until he purchased a CCHIT system. He has had four different management practice systems. He once spent $7000 for a new EHR system but found that the features seen in the demonstration were not easy to use. He said that he has been using electronic-backed servers through a Web based service over the past few years, but has not been able to import lab data. He went on to say that he has been using a patient counseling and tracking program for his chronic disease patients. His also participates in an experimental freestanding immunization registry that interfaces with the EHR.

He described the Vermont statewide chronic disease management program that was established 4 years ago. It is a paid for performance system using a separate Web based electronic registry, which has required duplicate data entry for his practice. In 2007 the local hospital started to give grants to primary care practices to establish EHR. Requirements for receipt of the grant included interfacing with state agencies and registries. Without the grant his practice would not have been able to afford the system. The training and transition to the new system required extensive time and effort. Even though CCHIT standards call for a two-way system, exchange does not happen unless the partners are willing to negotiate with all of the vendors. Expensive interfaces were required.

Problems remain. His Web portal cannot directly interchange data, which requires copy-and-paste into the electronic record. The vendor that promised electronic prescribing is not certified for E-prescribing bonuses. However, he is able to integrate practice management, scheduling, and EHR to great benefit. The database is very robust. The CCHIT-required electronic order registry is very challenging for10 or 15-minute visits with complicated internal medicine patients. (A recent visit with a diabetic patient required 20 mouse clicks.)

Dr. Michl said that to date he is not sure how the new system will actually help in his practice; so far, there has been significant loss in productivity. He believes that unless a small practice has a physician who is strongly committed to the concept of EHR, adoption will be difficult. He said that he is skeptical about adoption without strong financial incentives upfront. Early adopters should be rewarded. Given the concerns about the primary care workforce, many of Dr. Michl's

colleagues are concerned about EHR being one of the factors that if overly promoted and underfunded will push primary care to the brink.

Medium-sized Health System

Paula Anthony, CIO, East Texas Regional Medical Center, described her experience with the introduction of HIT in a system of small, rural hospitals. She said that HIT is a key driver of growth in the East Texas system because small providers cannot afford to install HIT on their own. As hospitals were brought into the system, they had to discard their old systems and start over because of the lack of interoperability. It was necessary for management to take a slow and expensive approach to HIT. Although East Texas is organized as an integrated delivery network, it is really a collection of rural community providers, which are important to the economies of their small towns. The patient population is static with a high prevalence of chronic disease. Patients move in and out of the referral centers and continuity of care is vital.

Small rural hospitals are slow to adopt HIT. They lack capital and also the human resources. Employees must play several roles and there is no dedicated IT support. Many of the vendors serving the market are not certified. She said that she was concerned that as vendors scramble to update products and meet new certification cycles, release cycles may become more frequent, thereby increasing the cost for small institutions. She also expressed concern about the possible inadvertent focus on features and function, rather than on meaningful use per se.

She cautioned the Workgroup about complexity and scalability. She has found that the ability to operationalize products is far less than the opportunities they offer. Some systems are simply too complex and too expensive to be of benefit. The environment must be considered. A product may be successful in one environment and not in another. Leadership, motivation, and focus on the part of the clinic manager, office staff, and nurses are critical.

With regard to certification, Dr. Anthony said that she hoped the standards allow the leveraging of existing technology. Until recently, the value of certification was in vendor accountability; it was not a major determination as to whether or not a certain system would be selected. She said that she recognizes it is now a powerful market force. Meaningful use will be based on adoption, which will be dependent on factors that are difficult to certify. Before the market comes to bear on poorly architected solutions, hospitals could spend a lot of time and money on poor choices.

Timing is also a major concern. Some of her vendors do not intend to bring to release certified products until mid-2010, which will make it difficult to meet the time requirements for the demonstration of meaningful use. She said that she supports the notion of modularization of a certification process. Clear requirements for true interoperability are essential. Beyond that, a considerable amount of work must be done to build consensus that the adoption of technology, which is disruptive to productivity, will result in the betterment of care.

Large Health System

Stephanie Reel, Vice President of Information Services, Johns Hopkins Medicine, advised the Workgroup that HIT is but one piece of a continuous, coordinated approach to the improvement of care. Equally important are quality improvement methods of problem definition, measurement, team facilitation and goal setting, as well as practitioner and patient involvement.

After new systems are deployed, a long process of iterative assessment, improvement, and innovation must follow. She noted that what is important to patient outcomes is not always what is being measured.

Dr. Reel said that she expects that standards adoption can make a difference in interoperability. Certification may help to weed out vendors that cannot meet the needs of an evolving health care system. But on the other hand, certification could introduce some further building on top of mediocrity in an immature industry. Vendors may focus on certification to the neglect of innovation. She said she is in favor of making incremental progress, beginning with a focus on the basics, for example, sharing problems lists and information on allergies and immunizations. She continued by saying that HIT is more than adoption; it is changing the care delivery system and the development of the workforce. HIT should foster sharing, learning, and leveraging of best practices.

Q and A

If certification were an assurance that meaningful use could be met with the systems that were purchased, deployed, or infused, would certification be of value?
Certification would be valuable if it were narrowly defined by the meaningful use objectives. There should be tight rules about how products are referenced as being certified. The software vendor should tell the purchaser upfront that the product is CCHIT certified and what will be required to actually make it operable. The certification process should certify to the purchaser what the implementation costs are going to be. Using the example of the Joint Commission accreditation process, there is value in certification as long as it is understood that the important factor is has the provider uses the system to improve care.

From a purchaser's perspective, what could it mean to have a two-tiered certification, one narrow and based on meaningful use and the other on more market-based criteria?
A purchaser would do its own due diligence on the second level. The first level could be beneficial by focusing on fundamental certification at the Federal level. For independent hospitals or physician practices, the second level might be a differentiator among those serving the markets. The first tier is the most important immediately given the focus of the stimulus package.

To what extent is liquidity, the separation of data from applications, valuable?
Liquidity would resolve a number of concerns in moving data between systems. Otherwise, it is very expensive to design interfaces for interoperability across and within organizations. Both data standards and data exchange standards are needed. Application need to be flexible.

What about the statement that flexibility is probably more important than functionality?
It may not be certifiable. However, science is driving care delivery; for example, diabetes is now 24 different diseases. HIT systems are capable of providing good functionality, but the science is driving different delivery.

Would it be helpful to have a qualitative evaluation in addition to certification?

In addition to the class ratings, qualitative comments would be informative. However, the comments would have to be objective. The qualitative comments could focus on data structure, architecture, and usability.

7. CCHIT – Certification and Standards

CCHIT Overview and Plans

Mark Leavitt, CCHIT Chairman, described the history, purpose, and process used by CCHIT. Since its formation in 2005, more than 260 volunteers have been involved in its workgroups. The inspection process is firewalled from the criteria development process. Staff members are not allowed to have conflicts of interest with any vendor, including stock ownership. The process includes three juror panels, a robust appeals process, and a retest process. The organization is, according to Dr. Leavitt, accepted by vendors and endorsed by the major physician associations. He believes that certification has encouraged new and small companies because it levels the playing field.

He went on to describe how ARRA has changed the environment. Certification has moved from being voluntary to mandatory for Medicare and Medicaid providers. The providers served by certification will expand from providers wanting extra assurance when investing in new EHR to Medicaid and Medicare providers at all stages of adoption. The array of EHR products will expand as well. The goals have changed from assurance of interoperability, functionality, and security to meaningful use to improve care and support health care reform. In response to changes mandated by ARRA, CCHIT designed three paths to certification:

- EHR-C - Rigorous certification of comprehensive EHR systems that significantly exceed minimum Federal standards requirements
- EHR-M - Flexible certification of Federal standards compliance for EHR, HIE, eRx, PHR, Registry and other EHR-related technologies for providers who prefer to integrate technologies from multiple certified sources
- EHR-S - Simplified, low cost certification of EHR technologies in use at a specific site for providers who self-develop or assemble EHR from noncertified sources.

Dr. Leavitt's PowerPoint presentation described each path in great detail. He pointed out that CCHIT can certify the technology but not its meaningful use. That is the role of CMS. In order to meet the recommended 2011 criteria, products need to be available for purchase this fall. CCHIT will launch its program this fall for implementation in January after HHS announces the interim final rule. A certified product would be valid for 2012.

CCHIT Strengths and Weaknesses

Brian Klepper, a health care analyst and consultant, presented an analysis and critique of CCHIT. He pointed out that CCHIT was organized by and continues to be dominated by the interests that it purports to objectively certify, namely HIT vendors and their trade association Healthcare Information and Management Systems Society (HIMSS). He said that both the executive director and the chairman of the board have close ties to HIMSS. The relationship between CCHIT and HIMSS is, according to Dr. Klepper, an example of how power and money operate to control the marketplace. That interoperability has not yet been achieved "says something about who is

controlling the process". He noted that the testimonies and the discussion at the meeting offered evidence of the inadequacy of CCHIT's work.

HIT policy should support the larger reform goals, the rapid distribution of technology, usability of technology, and lower cost through innovation. But CCHIT has focused on features and functions, rather than on standards and security. Because of the high cost, only a very small minority of physician practices have deployed HIT. And a very large percentage of physician practices that have deployed HIT have turned off many of the features and functions because they are not useful or usable.

HIT policy should look forward, not back. HIT is exploding and this should be the focus. Practice management, identification of risk, management of risk and chronic disease, and other areas are of immediate use to clinicians in different settings. Interoperability is a priority for coordination of care, data aggregation, pricing, performance transparency, comparative effectiveness research, decision support, and patient engagement. He said that CCHIT has dragged its feet and many organizations are ignoring CCHIT certification. Organizations such as Beth Israel and New York Presbyterian are exchanging data outside of CCHIT.

Dr. Klepper argued that as it is currently constituted, CCHIT gives HIT legacy vendors inappropriate advantage. Whether or not there are actual conflicts of interest in CCHIT, it gives the *appearance* of being conflicted in a way that would not be tolerated throughout most of the private sector. It should be disbanded or at the very least the CCHIT executive team should be replaced to avoid further conflict of interest. He referenced an article in The Washington Post on undo influence.
http://www.washingtonpost.com/wp-dyn/content/article/2009/05/20/AR2009052003600.html

Aligning HITSP and CCHIT

John Halamka, Chair, Health Information Technology Standards Panel (HITSP), described the purpose of HITSP and its relationship with CCHIT. After the passage of ARRA, ONC asked HITSP to assist it in meeting its requirements for designating standards that support ARRA's notion of "meaningful use". HITSP is working to determine which of the available standards are appropriate for ONC to use. Standards must have been developed through an open, transparent process and be permanent. They must be well described and tested. Sometimes HITSP is asked to harmonize standards where standards barely exist. He listed the interoperability specifications, some of which are still in the process of being accepted.

Dr. Halamka referred to the use cases developed under the auspices of the American Health Information Community (AHIC). They were not transactions or examples of meaningful use. The use case approach did not allow one to take pieces or parts of standards and mix them in an innovative way. Quality measures were not created with EHR in mind, and they have data elements that might be manual paper processes or chart abstractions.

HITSP formed tiger teams to response to ONC's request. The areas of focus are:

- A new EHR centric interoperability specification to meet ARRA requirements
- Security, privacy and infrastructure

- Quality measures
- Data architecture (element, template, and value set)
- Exchange architecture and harmonization framework
- Clinical research

Based on HITSP's past work, a list of 31 capabilities was developed. They define how various transactions should occur. The work was submitted to the HIT Standards Committee, which consists of three workgroups—clinical operations, clinical quality, and privacy and security. Next week, the HIT Standards Committee will submit to the HIT Policy Committee a complete matrix that lists all of the meaningful use and the eight desired statutory criteria along with a corresponding standard. For each, the level of maturity, grade, and 2011, 2013, and 2015 capabilities will be noted.

The Clinical Quality Workgroup will submit its deliverable which will have the data types necessary for measuring quality. Over 38 data types and categories will be described with the same nomenclature. Dr. Halamka concluded his presentation with a number of examples.

Viewpoint on Current Program

David Kibbe, American Academy Family Physicians, commented on certification from the perspective of a practitioner in a small practice. He began by saying that the HIT being deployed today is not meeting the needs of physicians. Decisions around certification must limit the unintended consequences, embrace innovation, and ensure the achievement of meaningful use. Certification should be simple, flexible, and focused on interoperability standards and safety issues. Having interoperability standards is necessary but not sufficient. Business models must be aligned. AHIC was formed 6 years ago, but little has changed. Dr. Kibbe suggested that a distinction be made among validation, evaluation, and certification. Validation is the testing of the appropriate use of a system for meaningful use. And that is not CCHIT's role. Evaluation of testing or the performance of a system is concerned with how well something works in a particular environment. Certification is the testing of the required attributes of a system. HIT certification should focus on safety and interoperability.

According to Dr. Kibbe, competition can help drive down the cost of certification and allow for further innovation. Certification must allow and encourage modular platforms and applications that integrate a combination of applications. Certification should support incremental adoption.

Q and A

What can be done to ensure that CCHIT-certified products are able to interact?
One would have to have a standard model and throw out the existing investment and start over. Assurance should be provided that data are exportable and importable in standard format.

What does HIE certification consist of?
CCHIT has yet to certify HIE but criteria have been developed. The work will continue pending HITSP's report.

How does the purchaser of a certified product know that it is exactly the same product that was certified?

There is a customer complaint process and subpoena authority to deal with fraudulent applications. In the past, testers checked the current version of the product and verified that it worked at at least one site. There is a process for provisional certification without verification at a live site. To data, no certification has been revoked.

In what categories can we expect to see costs drop?
Lab reporting has been standardized. Lab interfacing is less of a problem. E-prescribing is mature and widely deployable. In terms of clinical summaries, problems lists and medication lists can be available soon. Some quality measures may be easy to report but others may require a granularity that doctors do not have.

What about incentives?
A HIE can fall apart if providers do not want to share their data. Competition may make it difficult to share. Incentives for exchanging data to obtain better outcomes must be established. Providers have found a way to submit claims in standard format because they get paid.

Are there any embedded assumptions that the Workgroup should revisit?
Data ownership may be an issue as well as the liability involved when one provider has access to data about the service provided by another physician, for instance, when the cardiologist sees that the patient missed her Pap test.

Dr. Leavitt asked for the opportunity to respond to Dr. Klepper's comments about the conflicts of interest within CCHIT. He said that CCHIT was founded by two groups in addition to HIMSS, one of which was the American Hospital Association. The founding contract required CCHIT to be independent by the end of the contract and, according to Dr. Leavitt that has been achieved. He explained that it would be difficult if not impossible to conduct certification activities without the participation of representatives from vendors on the workgroups because these are the people with the required technical skills. He referred to his personal track record and the record of CCHIT.

Dr. Klepper responded that his charges were not personal. He said that his point is there is $119 million of Federal money on the table and that the eligibility criteria will be used in some way to steer that money. The appearance of conflict is not acceptable. It would not be allowed in other environments. He referred to the severe crisis in the U.S. economy and said that transparency is of great importance for good public policy.

8. Public Comment
Several members of the public responded to the opportunity to comment, either in person or by telephone.

Katherine O'Connor, Microsoft, said that her company supports the HITSP standards and CCHIT.

FNAME LNAME introduced himself as someone who spent his professional life in digital technology in the medical field. He made extensive comments, which the Co-Chair asked him to submit in writing. He said that his comments were based on common sense and he believed that

the concept of meaningful use was in fact meaningless. The Workgroup should recognize that digital technology has been applied in medicine for many years. Digital communication should not be that difficult.

FNAME LNAME, American Society of Anesthesiologists, pointed out that in order for comparative effectiveness research to proceed, providers must report to databases and registries. Certification should include the interoperability standards to ensure that these data are transferable from EHR to registries and across databases.

Sarah Cortly, American College of Physicians, spoke about the slow expansion of HIE. The funding for physicians in the stimulus package will supplement the purchase of EHR, but it is not sufficient to change the practice of medicine. Currently, the business model is based on volume.

Debra Peals spoke about patients' rights to control the flow of information about them through electronic systems. The Privacy Rights Coalition represents 10 million patients. The HIT Policy Committee does not have consumer representation and is not discussing the issues that are most important to consumers. Patients are less interested in technology than in access to affordable care and good treatment. Patients want to control their participation in research. The Coalition is very concerned about the security of patient data as well. Many people refuse screening and mental health services because they do not trust the system.

9. Closed Session Workgroup Members Only: Recap of first day testimonies; frame the "sub-topics"; begin discussion on Certification and Adoption Workgroup recommendations

Following the public comments, the Workgroup met in a closed session to discuss the draft recommendations for presentation to the HIT Policy Committee on July 16. The presentation was discussed at the July 8 meeting and subsequently revised. The members went through each slide of the PowerPoint presentation and discussed the extent to which the testimony heard in the first part of the meeting consisted of new information that should be incorporated into the presentation and recommendations. The slide describing the CCHIT was changed to reflect the information presented by CCHIT representatives, in particular information on the plans for going forward with modular certification and other changes.

One of the members summed up the major points of the testimonies as follows:

- Certification should focus exclusively on meaningful use.
- The lack of progress on interoperability is the major problem. There is little evidence that, to date, certification has improved information exchange. Certification should address testing and foundational requirements
- The delineation of criteria for certification is the responsibility of the Federal government. Placing responsibility there may offer some protection from vested interests.
- Certification should address the full range of products – open source, self-developed, modular, and other vendor. CCHIT has made some good initial steps in this direction.

The members also noted the need to address privacy issues in the basic infrastructure criteria. They agreed that their presentation should focus on their recommendations and be consistent with the language of the legislation. They discussed the restructuring of the recommendations under the four points listed above.

Other points made during the discussion included (but were not limited to) the following:

- The minimal data to be exchanged will be determined by the definition of meaningful use.
- Providers that are currently using a CCHIP-certified product should not have to obtain additional certification. Some members suggested that additional gap certification should be required.
- Existing products and certification do not take the public health reporting measures and objectives into account, as well as some of the quality measures. Vendors will need time to close these gaps.
- The vendors could be requested to come back to testify how they propose to deal with gaps.
- A process for monitoring will be proposed.
- A description of the interoperability barriers should be included.
- The recommendations will specify that CCHIT be used as the certification organization in the interim only.

Action Item #1: The Co-Chairs will revise the recommendation for further discussion at the July 15 meeting of the Workgroup.

The HIT Policy Committee is expected to discuss the recommendation but not to insist upon major changes.

SUMMARY OF DECISIONS AND ACTION ITEMS:

Action Item #1: The Co-Chairs will revise the recommendation for further discussion at the July 15 meeting of the Workgroup.