

# Meeting Summary

## Health Information Technology Standards Committee

May 15, 2009

### Call to Order and Introduction of Committee Members

Dr. Blumenthal, National Coordinator for Health Information Technology, opened the first meeting of the Health Information Technology (HIT) Standards Committee meeting by thanking Committee members and others in attendance. A roll call was taken of those in attendance and those participating via teleconference as follows:

**David Blumenthal**, National Coordinator for Health Information Technology, HHS

**Jonathan Perlin (Committee Chair)**, Hospital Corporation of America

**John Halamka (Committee Vice Chair)**, Harvard Medical School

**Dixie Baker**, Science Applications International

**Anne Castro**, BlueCross BlueShield of South Carolina

**Christopher Chute**, Mayo Clinic

**Janet Corrigan**, National Quality Forum

**John Derr**, Golden Living, LLC

**Linda Dillman**, Wal-Mart Stores, Inc.

**James Ferguson**, Kaiser Permanente

**Steven Findlay**, Consumers Union

**Douglas Fridsma**, Arizona State University

**C. Martin Harris**, Cleveland Clinic Foundation

**Stanley Huff**, Intermountain Healthcare

**Kevin Hutchinson**, Prematics, Inc.

**Elizabeth Johnson**, Tenet Healthcare Corporation

**John Klimek**, National Council for Prescription Drug Programs

**David McCallie, Jr.**, Cerner Corporation

**Judy Murphy**, Aurora Health Care

**J. Marc Overhage**, Regenstrief Institute

**Gina Perez**, Delaware Health Information Network

**Wes Rishel**, Gartner, Inc.

**Richard Stephens**, The Boeing Company

**James Walker**, Geisinger Health System

### Opening Remarks

Dr. Blumenthal reminded Committee members that many new activities have been created by Congress and the administration, particularly through the American Reinvestment and Recovery Act and its HITECH provisions. Media outlets across the country have been reporting on the future of the U.S. health care system. Organizing this health care system to most effectively deliver on the promise of providing Americans with high-quality, efficient health care represents a tremendously important challenge. Utilizing technology to manage information and improve the quality and efficiency of health care is at the core of these efforts; there are a series of statutory deadlines moving this work towards a 2011 deadline for providers of care who wish to take advantage of Congressional incentives.

Dr. Blumenthal introduced Drs. Perlin and Halamka and thanked them for serving as Chair and Vice Chair, respectively, of the HIT Standards Committee. He urged Committee members to consider how their decisions relative to standards and technologies will lead to meaningful use and how meaningful use will contribute to the management of a chronic illness or other medical condition. The application of meaningful use with regard to doctors, hospitals, long-term facilities, and every other outlet for patient care should be at the forefront of Committee discussions. Dr. Blumenthal asked the Committee to generate results that are usable and leave space for innovation.

## **Response to Dr. Blumenthal's Remarks**

Dr. Perlin acknowledged that the HITECH act compels the HIT Standards Committee to carry out a large amount of work in a rapid manner. He noted that this first Committee meeting would be the most complex, because it will set the agenda for future HIT Standards Committee meetings. He described the Committee's membership as bringing together many of the moving parts that are part of the U.S. health care system. Dr. Halamka emphasized that the current alignment of policy, regulations, and incentives represents a tremendous opportunity. He added that the HIT Standards Committee is well-situated to use this foundation to assist in determining standards that will be used to produce true data exchange by 2011. Although there is not yet a clear-cut description or definition of the term "meaningful use," the HIT Policy Committee is tackling this issue and will be providing guidance to the HIT Standards Committee in this regard. Dr. Halamka suggested that the HIT Standards Committee consider medications, laboratory reports, quality, and care coordination in their initial discussions related to meaningful use.

## **Committee Charge: Mission and Process**

Jodi Daniel, Office of the National Coordinator (ONC), presented an overview of the Congressional statute and outlined the HIT Standards Committee's mission and process. The recommendations that come out of this Committee will have a significant impact with regard to certification process, incentive payments, etc. She explained that the HIT Standards Committee is a Federal Advisory Committee and that ONC will be relying heavily on its recommendations and guidance. The HIT Policy Committee will set the policy priorities, while this Standards Committee will look to the standards and certification criteria that established by that HIT Policy Committee. Ms. Daniel explained that the ONC supports both committees, and will work to ensure that there are collaborative, rather than overlapping, efforts.

Ms. Daniel noted that Congress has set eight specific areas of focus for the HIT Standards Committee, as follows:

1. Privacy and security
2. Nationwide health information technology infrastructure
3. The utilization of certified electronic health records (EHRs) for each person in the United States by 2014
4. Technologies that allow for accounting of disclosures made by a covered entity
5. The use of certified EHRs to improve the quality of health care
6. Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals

7. The use of electronic systems to insure a comprehensive collection of patient demographic data including race, ethnicity, primarily language, and gender information
8. Technologies that address the needs of children and other vulnerable populations.

Ms. Daniel explained that the responsibilities of the HIT Standards Committee are to: (1) make recommendations to the ONC, (2) recognize harmonized or updated standards, and (3) provide for the testing for such standards by the National Institute for Standards and Technology (NIST). Congress has requested that this group develop standards for the recommendations from the HIT Policy Committee. A schedule will be published regarding how this work will be carried out, and an annual publication will be generated to provide the public with a sense of the timeline and the work that has been done, is currently underway, and is planned for the future.

With regard to standards adoption, statute sets forth both regular and expedited processes. For the expedited items, interim final rules must be published by December 31, 2009. These criteria must be regularly updated as standards develop, so the Department of Health and Human Services (HHS) will be engaged in these efforts on an ongoing basis. Also with regard to the expedited process, the HIT Standards Committee can rely on earlier HHS work from the American Health Information Community (AHIC), the Healthcare Information Technology Standards Panel (HITSP), and other groups. Through the regular standards-adoption process, the HIT Standards Committee will make recommendations that will be submitted for public comment, then to the ONC, and then to the Secretary, HHS.

## **Discussion**

Dr. Corrigan asked about the process for developing certification criteria for meaningful use, given that the definition of “meaningful use” has yet to be established. Dr. Perlin indicated that ONC, the HIT Policy Committee, and others are hard at work on reviewing the certification process—recommendations and guidance will be brought to the HIT Standards Committee as soon as possible. He noted that the same holds true for the definition of “meaningful use.” This committee may have to proceed in parallel for a certain amount of time until the work of ONC and the HIT Policy Committee become better defined.

Ms. Daniel reminded the group that the HIT Standards Committee can draw upon information, guidance, and suggestions from any group they feel would benefit their efforts. For example, a representative of the Certification Commission for Healthcare Information Technology (CCHIT) could testify before the Committee. Similarly, members of the HIT Policy Committee, which will also be working on these issues, could provide an update to the HIT Standards Committee.

Mr. Findlay asked how HITSP’s work fits into that of the HIT Standards Committee. Dr. Halamka explained that HITSP is a group of 600 volunteer organizations that come together and harmonize standards. If a use case requires the exchange of a certain type of data, HITSP has tried to develop standards to meet the needs of the particular use case. A different construct is now called for, however, and HITSP is reformatting to be data element and functionality based rather than based on use cases. For example, if e-prescribing is important for meaningful use, then rather than burying this in a standards document, the group could make the standards available in an electronic, available index. HITSP could theoretically receive instruction from the HIT Standards Committee. Dr. Blumenthal commented that HITSP is adopting a goal-oriented view rather than one that is process oriented. The focus is on the uses and what doctors have to get done in their daily work. He added that Dr. Halamka’s work to reconfigure HITSP’s output so that it is more usable in the real world has been valuable.

Mr. Hutchinson encouraged the group to identify where standards have been implemented in the private sector and look to them for guidance and lessons learned.

Dr. Blumenthal commented that there is some concern that the federal government may inadvertently complicate standards and certification, suppressing innovation in the marketplace and freezing into place what will become antiquated technologies. ONC staff consistently keep this in mind and work to prevent adopting processes that will inherently slow the innovative processes in this field.

Mr. Rishel expressed concern regarding the “waterfall” approach of producing a standard and then rolling it out to the industry without a large feedback process. He explained that there is a specific change-off of responsibility from producing the specification and having it recognized, and then having it implemented. He is hopeful that there will be a chance within the bounds of the legislation to create an effective feedback loop.

Dr. Baker noted that the HIT Standards Committee is to review the recommendations of the HIT Policy Committee and asked about the timeline for submission of HIT Policy Committee recommendations to the group. Ms. Daniel responded that no specific date has been set, although it is hoped that recommendations from the HIT Policy Committee are generated and submitted quickly. In some areas, this group can make some assumptions; it also can tackle issues outside of those recommendations from the HIT Policy Committee.

Dr. Halamka suggested that the group begin considering meaningful use and exchange, in anticipation of some of the HIT Policy Committee recommendations. Ms. Castro suggested that it would be helpful to create a roadmap of all of the Committee’s activities up to the 2014 goal.

Ms. Johnson suggested that this group align itself similarly to the manner in which the HIT Policy Committee did when it established its three workgroups. Dr. Baker noted that the HIT Policy Committee did not form a workgroup for privacy and security issues, which will be paramount. Ms. Johnson indicated that HIT Standards Committee members could decide whether they need to focus uniquely on privacy and security issues or instead make sure that they are an overarching concern. Dr. Halamka commented that from statute and from many discussions he has had with others, recurring themes appear to be e-prescribing, electronic transmission of laboratory information, clinical summaries, and quality measurement. Dr. McCallie suggested that data exchange be added to this list—it is important to establish a common standard for secure messaging, and Web-based tools are the likely leading contender. Dr. Halamka noted that HITSP worked on this issue in 2008, so there is an existing body of work available to the Committee. In addition to e-prescribing, medication ordering was suggested, so as to include the inpatient component. It would be helpful if there was some capability within the system to know the health issues, problems, and diagnoses of the patient, so that correlations can start to be made between these and the laboratory data, pharmacy data, and all of the text reports that physicians use. Dr. Halamka noted that the clinical summary could include all of these. One interesting aspect of this Committee’s work would be to define “clinical summary,” because it would likely contain much of what has been discussed.

Dr. Chute cautioned the group about promoting the equivalent of an “electronic fax.” He commented that the system must effectively convey meaning—what is ultimately exchanged must be understandable not only by humans, but also by systems, so that something interoperable is being built.

Ms. Castro noted that information can be conveyed in many different ways, and that vendors do not synthesize information in a single way. Some manner of “fast path” to medical data is needed in a standard format. She also suggested that the Committee address images such as x-rays and CT scans.

Mr. Rishel noted that the limitations relative to timing as discussed earlier in the meeting suggest the need to set the bar low to ensure that a significant number of physicians can qualify for payment in 2011. He added that it would be disappointing to leave the bar there, however, so there needs to be an

understanding of how to raise the bar over time. He suggested that the following must be considered in the Committee's approach and assessment: (1) the asynchronous life cycle of IT systems (i.e., whatever is put in place has to be accessible as a retrofit to systems that are already in use as well as to newly designed systems); and (2) asynchronous knowledge of physicians and others using system (i.e., if the standards requirements move too far ahead of users, there is a risk of the continuation of what Dr. Rishel described as "health IT rage" occurring among physicians).

Dr. Blumenthal noted for clarification that the law does anticipate a changing definition of meaningful use over time. This group could create a set of standards that are independent of time, and could then consider what will be appropriate in 2011.

## **Develop a Schedule for Assessment of Policy Recommendations From the HIT Policy Committee**

Dr. Perlin suggested that the HIT Standards Committee address the areas of e-prescribing, laboratory exchange, quality, privacy, and security in within three workgroups focused on the following general areas: (1) clinical, (2) quality, and (3) privacy/security.

Dr. Corrigan explained that the role of National Quality Forum (NQF) is to set standards that are used by many different groups. The NQF convenes the Health Information Technology Expert Panel (HITEP), which examines performance measures. HITEP has found that there is a large amount of ongoing work that is very specific to quality measurement—Dr. Corrigan indicated that it may not be possible to capture all of these activities within a single workgroup. She added that the quality measurement component is closely related to clinical decision support. It is important that a schedule be established, and that the group consider when certain activities are going to occur (e.g., quality measurement is being retooled to keep up with SNOMED).

It was suggested that Ms. Sparrow query each Committee member as to which of the three areas proposed by Dr. Perlin they feel they could best contribute. Committee members can also identify others to serve on workgroups.

Mr. Hutchinson noted that the HIT Standards Committee likely will not take on administrative standards, but these need to be considered from the standpoint that there should not be a significant gap between the administrative and the clinical standards (i.e., efforts should be taken to prevent creating a disconnect between the clinical side and the billing side).

Dr. Harris suggested that the Committee add a fourth workgroup to consider how best to communicate effectively to all of audiences. Dr. Halamka noted that HITSP established its Education, Communication, and Outreach Committee to address these same issues, and that this area may eventually warrant the formation of an additional HIT Standards Committee workgroup.

Dr. Perlin asked Committee members if they could agree to a general working principle of a 90-day turnaround for each of the standards for which they are asked to make recommendations. There was general consensus on this point among Committee members, with the understanding that there would be approximately 60 days for the Committee to do its work, followed by an ONC review that would concluded within the 90-day timeframe.

Dr. Corrigan asked if each workgroup could be provided with a list of initial standards relevant to their respective area. Dr. Halamka agreed to take on this task. Ms. Sparrow agreed to start working on an initial e-mail to each Committee member that will ask them which workgroup they would like to join. Ms.

Daniel reminded the group that it can suggest individuals to serve on workgroups who are not members of the Committee. She also suggested that ONC try to draft a roadmap document for the benefit of the HIT Standards Committee.

Ms. Castro volunteered to share a copy of a roadmap that has been helpful for her. She also recommended that each workgroup create a “task list” or a roadmap for themselves.

## Public Comment

The following was noted during the public comment session:

- Richard Eaton of the Medical Imaging and Technology Alliance (MITA), provided the Committee with some information about MITA’s experience in the area of systems interoperability. The Alliance is the leader in terms of development, deployment, testing, and protecting the integrity of a digital communication standard. The group is also involved in the HL7 standard and in integrating the health care enterprise in many of the areas under consideration by the Committee. He emphasized the time-related pressures facing the Committee and offered the MITA as a resource. The MITA has been involved in standards development activities for more than 80 years. He also noted that diagnostic imaging is a key part of the EHR, and that the MITA has developed standards for almost all imaging modalities.
- Michael McGrath of Gemalto, a digital security company, noted that the public is generally in favor of EHRs but is registering serious concerns about the privacy and security of their health information. If the bar is set too low as it pertains to authentication, it will not address the public’s concerns. Authentication typically is done by username and password, which is not secure. He urged the group to demand stronger authentication approaches for accessing medical information.
- Philip Barr from Thompson Reuters noted that the roadmap that was discussed earlier in the meeting is very important to the Committee’s future work. He offered to share some structures that he has been working on and has vetted with the National Library of Medicine and with representatives of standards-setting organizations. He also asked about the first step and highest priority of the HIT Standards Committee. Dr. Perlin thanked him for the question but indicated he did not want to presuppose the process; these types of questions would have to be deferred to ONC at a later time.
- Ross Martin of Deloitte Consulting asked whether or not the purview of this Committee will include how reporting will be carried out for stimulus funding. There are a number of competing standards and many unanswered questions. Ms. Daniel noted that the Committee will be focusing on HIT standards, and that these broader types of questions are, for the most part, outside the expected scope of the Committee. She offered to discuss his questions offline.
- Allen Zuckerman, a practicing pediatrician on the Council on Clinical Information Technology, a representative of the American Academy of Pediatrics, and Co-Chair of the CCHIT Interoperability Workgroup, asked that the Committee not to leave children out of the initial standards being considered. He explained that children are a vulnerable population not just because of their health and social vulnerabilities, but because they are in danger of getting left out of HIT in general. He used the automobile industry to illustrate lessons that can be learned relative to products that are out on the market and do not get used. For example, he asked Committee members to imagine if they moved but could not take their cars with them; furthermore, what if they got ready to purchase a car but could not select the type of car they wanted to buy? He commented that two certified EHRs

should be able to exchange patient data, and that in the future, physicians should have a choice in their purchasing.

- Fred Buhr, a former employee of the State of Wisconsin, worked 10 years ago on the Health Insurance Portability and Accountability Act (HIPAA) implementation as a member of the HIPAA Metadata Registry Correlation. He discussed the importance of interoperability on both the human and machine levels. He also offered to serve as a volunteer for any feedback as a live use case.

## **Adjournment**

Dr. Blumenthal asked that Committee members inform Ms. Sparrow regarding which workgroup they would like to join. Before adjourning the meeting, he thanked Committee members and others present for their participation and comments.

## **Action Items:**

The following action items were identified during the meeting:

- The Committee agreed to create three workgroups, comprised of Standards Committee members and outside experts as needed. The three workgroups will be Clinical Operations, Clinical Quality, and Privacy and Security.
- The Committee agreed to a general working principle of a 90-day turnaround for each of the items for which they are asked to provide recommendations. In some cases, their work will not be complete in 90 days, but the group will provide some kind of appropriate feedback within this time frame. Jodi Daniel agreed to come up with the final language for this working guideline.
- Ms. Castro offered to share a copy of a roadmap document that she has found helpful in her organization. The group agreed that the Standards Committee should create a roadmap to guide its work, and that each of the workgroups should also create a task list and roadmap to guide its activities.
- Ms. Sparrow will contact all Committee members to discuss which workgroup they would like to join.