# HIT Standards Committee
# DRAFT
# Summary of the February 18, 2014 Virtual Meeting

## ATTENDANCE

**The following members attended the meeting:**

- Dixie Baker
- Steve Brown
- Anne Castro
- Jeremy Delinsky
- John Derr
- Lorraine Doo
- Floyd Eisenberg
- Jamie Ferguson
- Lisa Gallagher
- John Halamka
- Leslie Kelly Hall
- Stanley Huff
- Elizabeth Johnson
- Rebecca Kush
- Arien Malec
- David McCallie, Jr.
- Kim Nolen
- Jonathan Perlin
- Wes Rishel
- Kamie Roberts for Charles Romine
- Eric Rose
- Christopher Ross
- Sharon Terry
- Andrew Wiesenthal

**The following members were absent:**

- Keith Figlioli
- C. Martin Harris
- Anne LeMaistre
- Nancy Orvis

## KEY TOPICS

### Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 54th meeting of the Health Information Technology Standards Committee (HITSC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting with an opportunity for public comment (three-minute limit), and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking. She announced that applications for several seats on the HITSC will be accepted until March 3, 2014. Applications may be

made via HealthIT.gov website. ONC is seeking an amendment to the charter to establish a two-year term limit with a maximum tenure of six years. One-year extensions are being sought to retain several members, who have been so informed.

**Remarks**

Chairperson Jonathan Perlin introduced National Coordinator Karen DeSalvo, saying that he had worked with her post-Hurricane Katrina. He praised her work highly, especially in interfacing public health and health services. DeSalvo thanked the members for their work. Much progress toward widespread adoption has been made over the past decade. Many opportunities to advance standards remain. The HITPC has been directed to take a multiyear approach to policy objectives. She said that she wants the HITSC to look further into the future to ensure that the HITPC policy recommendations are realistic. Over the next few weeks, ONC managers will attempt to harmonize the work of committees, workgroups and staff. In order to deliver on the promise to the public, a longer horizon is required. The HITSC can inform the work of the HITPC.

**Review of Agenda**

Chairperson Jonathan Perlin asked for corrections of, additions to, or approval of the summary of the December meeting as circulated. Hearing none, he declared the summary approved.

**Action item #1: The summary of the December 2013 HITSC meeting was approved.**

**Comments**

Vice Chairperson John Halamka declared that balance is important. He noted support for the one-year extension of terms. He commented on each of the items on the published agenda.

**HITSC Workplan**

Noting that, given DeSalvo's remarks, the workplan is in a state of flux, Perlin gave members the opportunity to comment on her remarks. Arien Malec repeated observations made at previous meetings that the FACAs should work with alternative payment models beyond meaningful use. The micro details of meaningful use should be deemphasized in favor of more focus on interoperability for value-based and patient-centered care. Perlin interrupted and asked Malec to comment on only one topic at a time. However, Malec continued and said that the timing for Stage 3 is not realistic and must be re-examined.

Leslie Kelly Hall announced that she is looking forward to hearing DeSalvo's vision for patient engagement. Stan Huff spoke in support of strategic thinking as opposed to filling gaps in known problems. He suggested considering the ideas delineated in the PCAST report for a more open services strategy. Perlin suggested working offline to exchange ideas. He, too, supported the idea of pausing to think about the future. Floyd Eisenberg appeared to agree with Huff's comment about rethinking. He referred to a meeting last week about measure development and CDS, sponsored by ONC and CMS, at which a recommendation was made for review, coordination, and alignment of standards across components. The learnings from measurement can be applied to CDS. He also suggested more consideration of exceptions in measures.

Dixie Baker reported that she and several other committee members are involved with the Patient-Centered Outcomes Research Institute (PCORI). She is on a data standards task force. Since there is an overlap of topics, she requested a closer working relationship between HITSC and PCORI, specifically a facilitated transfer of information. Perlin mentioned an upcoming PCORI-IOM conference on health systems leadership. DeSalvo assured them that ONC staff is working within HHS to maximize opportunities through these efforts.

Eric Ross informed DeSalvo that he represents the interests of small practice physicians, who are the backbone of service in their communities. He asked that ONC investigate what in meaningful use is making things more difficult for this group. DeSalvo said that coming from Louisiana, she is well aware of the constraints experienced in small practices.

John Derr spoke on behalf of non-eligible providers and asked for more recognition of the pharmacists' role as members of the health care team.

Halamka declared that in the next 30 to 60 days, he expects to see a set of intended policy outcomes and goals. He referred members to his blog for information on what should be solved tomorrow and what must be considered in the next few years. He expects to discuss a list of ONC goals at the March meeting. Once goals are agreed on, mapping to standards can commence. Perlin agreed.

**ONC Updates**

Doug Fridsma showed a slide depicting the concept of a learning health care system and spoke about all of the links among its several elements. He described how data moving from PHRs to EHRs to HIEs can be analyzed and eventually used to develop clinical guidelines, policy and CDS, and how standards are related to these efforts. He moved on to HITPC recommendations and letters of transmittal. He summarized the HITPC recommendations on query for a patient record, provider directories, provider data migration, and patient portability and showed the status of work on standards to support the recommendations. The NwHIN Workgroup will work on standards for those topics. Fridsma then referred to the recommendations on authentication, standalone certification, and patient authorization. Patient authorization will be assigned to the Privacy and Security Workgroup with the other items going to the Implementation Workgroup.

Jodi Daniel told them that the Meaningful Use Workgroup is scheduled to present its Stage 3 recommendations for HITPC action on March 11. Although several HITSC members have commented on various Stage 3 draft recommendations, staff wishes to obtain more comprehensive feedback. She proposed forming a group of five or six volunteers to consolidate and give rapid feedback for presentation at the March 26 HITSC meeting. The group may want to recommend items for assignment to one of the workgroups.

Daniel continued. The 2015 Edition will launch a new approach to certification, which will allow for certification criteria to be updated more frequently. It will incorporate learnings from the 2014 Edition and reference updated standards and implementation guides. Participants in the EHR incentive programs will not need to upgrade and EHR technology certified to the 2014 Edition will not need to be recertified. The HITSC workgroups will be asked to respond to the forthcoming NPRM, expected to be published this month.

**Q&A**

Halamka clarified with Daniel that the task is to take the Meaningful Use Workgroup's objectives grid and to refine it in consideration of standards maturity, difficulty of implementation and workflow. He gave UDI implementation and CDS as use case examples. Halamka volunteered for the task force.

Wes Rishel inquired about and commented on certification. Will mandatory certification be expected in the next stage? Certification has certain limitations; for instance, certified vendors may not be able to interoperate. He recommended having opportunity for voluntary certification for interoperability. Daniel replied that proposals for Stage 3 are not yet known. Staff will try to keep pace if standards are ready. Mandatory certification is possible. The goal is to put things forward earlier. Rishel opined that mandatory certification can help bring vendors in line. Daniel reminded them that meaningful use certification is voluntary, although it is required for the incentives.

Jeremy Delinsky asked whether, since CCHIT will no longer participate in certification, staff is monitoring the implementation of migration. Halamka interjected that CCHIT will continue until May. Based on his employer's experience, the CCHIT staff is working on achieving a smooth transition.

Eric Rose volunteered for the task force and asked where to find the grid to which feedback is solicited. Consolazio explained that although the Meaningful Use Workgroup has not completed the grid, she will make the most recent version available.

Cris Ross reported that he and Liz Johnson, co-chairs of the Implementation Workgroup, wish to work on the task force. But, in addition, they recommend that all of the objectives be reviewed for feasibility by the Implementation Workgroup. Perlin said that anyone interested in volunteering for the task force may communicate with Consolazio. Halamka instructed interested members that the grid is available at the February 11 HITPC meeting link. The Meaningful Use Workgroup is scheduled to meet February 19. Presumably another version of the grid will be generated as a result of that meeting.

Malec commented that fixing the current certification criteria is different from certifying on new criteria. He said that he hopes vendors will be able to certify on the fixed criteria, thus avoiding the 2015 Edition. Daniel responded that modular certification is available.

**Consumer Technology Workgroup Report on Patient Generated Health Data (PGHD)**

Halamka said that patient engagement is one of the most important uses of interoperability. The use cases for certification should be based on mature and tested standards. He recognized the tension between what one wants to do and what one can do. Chairperson Leslie Kelly Hall showed slides and reviewed the backstory of the HITSC members' deliberations on the workgroup's previously submitted recommendations, particularly regarding C-CDA, Continua, and care team rosters and the readiness of standards to support select use cases and patient reported outcome measures. She explained that representatives of the workgroup met with representatives from the Clinical Operations Workgroup and agreed on the following overarching recommendations:

> Concern regarding certification only items, as systems must be engineered to incorporate standards/processes which may not yet be mature
>
> Standards application should be constrained to where they are needed and useful

Specific to PGHD the recommendation is as follows:

> Where there is a need for patient data sharing, the C-CDA is suitable. C-CDA is recommended as a container for certain types of templates that are well understood (e.g. problems, meds, and allergies). C-CDA over existing (Direct, Exchange) and other modes of transport are reasonable ways to get data in and out of EHRs, PHRs, and patient facing applications. C-CDA should not be required as the architecture that organizations (e.g. ACOs) have to use. The outcome goal is for the entire care team (patient/families/providers) to be able to contribute to an integrated medical record. If unable to integrate, systems must have the functionality to receive C-CDA containing specific templates (e.g. to accomplish the same goal of patients participating in problems, med, and allergy reconciliation). Need to allow for innovation and flexibility in this space to not unduly constrain options for individuals to connect with their care teams in the ways they prefer in the future. Suggest using the C-CDA template payloads that are sufficiently mature, but not over-specify how they are to be moved about.

And for devices, the workgroups recommended:

> Need to allow for innovation, as the marketplace is still rapidly evolving. Continua standards are directionally appropriate, but need to align with FDA guidance and other regulatory or sub-

regulatory policy without constraining the marketplace. Due to the immaturity of the market, need to allow for the flexible adoption of device data and other remote data source.

**Discussion**

Andy Wiesenthal revealed that he is skeptical about patient adoption and prevalence of PHR or use of repositories for their data. Therefore, it would be better to focus on transmission to other providers. He supports use of the C-CDA. David McCallie reiterated caution about over-engineering. He indicated that he is relatively comfortable with use of the C-CDA to send data, but not for capture. He is opposed to its use as a questionnaire, which would be overly complicated and burdensome with only a small gain. Halamka said that the workgroups took that limitation into account and assumed that other avenues would constitute the primary uses.

Halamka asked what members thought about the Continua device work. Malec called it a "classic ecosystem problem." EHRs will have to accept device data, and vice-versa. He suggested defining the interface so that intermediaries can take on the function. Halamka responded that the burden of development would have to be examined. Kelly Hall said that a narrow specification can sometimes help innovation. Halamka referred to the IEEE 1173 construct that is more device specific. If the EHR were capable of receiving a C-CDA via Direct, it may come from middleware or a hub and would not add significant additional burden. Malec indicated that that would look like lab data. Halamka reported that Johnson had volunteered on behalf of the Implementation Workgroup to conduct an informal market survey on the topic.

Rishel talked about opportunity to synthesize by recognizing two distinct submarkets for patient devices. One is the traditional device market, typically requiring FDA approval. The other category is marketed directly via consumer channels. When providers develop more structured ways to integrate data, there will be more attention to rigor in content. Standards that are difficult to deal with are not a good idea. Halamka emphasized that FDA guidance must be considered. Jamie Ferguson said that many of the Continua specifications have yet to be considered by FDA. Fridsma said that there are several avenues for coordination with FDA. One is around clinical research with PCORI. Daniel responded that she has a close relationship with FDA staff on devices. The FDA wishes to be supportive of ONC's efforts. Halamka told her to check with FDA prior to formulating regulations.

Baker pointed out that since the consumer market is evolving rapidly, it may be futile to anticipate new products. The types of information that patients can provide should not be constrained. Therefore, she agreed that the better approach is to focus on accepting data from patients.

Rebecca Kush mentioned the FDA eSource guidance on the use of EHRs in research. She suggested that Dr. Fitzmartin be invited to update the committee. Halamka proposed a more general presentation by FDA representatives to include the status of the FDASIA report. Daniel asked members to e-mail topics of interest to Consolazio so that she (Daniel) can arrange a presentation by FDA representatives at an upcoming meeting. Halamka said that the focus of PGHD should be on accept rather than send. Compliance with FDA rules should be confirmed.

Halamka announced that the Privacy and Security Workgroup will sponsor on March 12 a virtual public hearing on NSTIC.

**Public Comment**

Chris Millet, National Quality Forum, referred to last week's meeting between ONC and the Centers for Medicare and Medicaid Services. One of the themes was the need for more coordinated governance across different bodies. He recommended that the HITSC play a strong role in coordination and incorporate into its workplan regular touch points with groups engaged in similar functions, such as the S&I Framework and HL7, to name a few.

David Tao, ICSA Labs, agreed that the C-CDA has the flexibility with its header and body templates to handle new use cases such as an exchange format, not a forms definition language, to send patient questionnaire responses, in addition to established use cases like transitions of care. However, he cautioned against saying that an EHR capable for any C-CDA is capable for all. That seems overstated or might be misinterpreted. Most, and hopefully all, certified EHRs will be able to successfully display any C-CDA, but there will be variability of capability ranging from zero to a lot, regarding EHRs importing and consuming structured data from C-CDA.

**Next Meeting**

Staff will inform the members about plans for the next meeting as soon as possible.

# SUMMARY OF ACTION ITEMS:

**Action item #1: The summary of the December 2013 HITSC meeting was approved.**

# Meeting Materials

Agenda
Summary of December 2013 meeting
Meeting presentation slides and reports
December meeting materials (draft workplan)