

**Health Information Technology Policy Committee
Final Transcript
Summary of the July 21, 2010, Meeting**

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 14th meeting of the Health Information Technology Policy Committee (HITPC), and reminded the group that this was a Federal Advisory Committee meeting, and was being conducted in public.

2. Opening Remarks

National Coordinator for Health Information Technology and HITPC Chair David Blumenthal noted the high level of influence that the HIT Policy Committee had on the recently published Meaningful Use rule. There will be conflicting opinions about whether the right balance was struck between pushing the industry to a new level of performance and making it achievable. The ONC has also announced a standards certification rule, which has attracted much less attention but is also very important. This rulemaking was considerably influenced by the HIT Standards Committee (HITSC), which provided guidance on specific requirements for interoperability.

The ONC now has the major rules in place, along with all the major grant programs. The Office is hard at work on the National Health Information Network (NHIN) Direct and NHIN Exchange, which are now in the implementation mode. Although work has just started on the actual implementation of Meaningful Use Stage 1, consideration is already being given to the next stage. The ONC is not about to change the rules shortly after release of the first set of rules. However, there will be activities associated with the broad directions for the future and identifying gaps over the next several months.

With regard to the temporary certification process, the rule was issued in mid-June. David Blumenthal expressed optimism that there will be a new landscape in the certification realm, where instead of there being a single certification body, there will be more opportunity for a broader pipeline towards certification. It is hoped that there also will be more price competition and shorter waiting times to get to certification, as well as an opportunity for some variation in the certification process and therefore an understanding of which types of processes work best.

This fall, the ONC will release the final rule on the permanent certification process, which will likely require about 1 year to get up and running to replace the temporary process. Privacy and security is the one area in which there is no opportunity to rest and all parties involved, including the grantees, are looking for leadership on this important issue.

3. Review of the Agenda

Before reviewing the meeting's schedule, HITPC Vice Chair Paul Tang congratulated David Blumenthal and the ONC for the pace and comprehensiveness of all programs in the past year. This activity has taken the country in a dramatic step forward, with a workable balance between future, current, and previous efforts.

4. Meaningful Use Rules and Certification Criteria for EHRs

Tony Trenkle summarized the changes between the Notice of Proposed Rulemaking (NPRM) and the final rule. His presentation illustrated the highlights of what changed and what remained the same. For example, the goals that were set originally and recommended by the HITPC stayed the same. The hospital-based eligible provider was changed by legislation. Medicaid included critical access hospitals in its definition of acute care, so now this will change so that critical access hospitals can also be eligible for Medicaid payments as well as Medicare payments. There was some concern about the high bar for Medicaid patient volume, so this area was expanded to enable more providers to be eligible under the Medicaid side.

A discussion followed, including these highlights:

- It was suggested that it would be beneficial to track and understand the criteria that providers are choosing to defer, so that they can more effectively direct education and services to providers well before the end of stage 1. Tony Trenkle indicated that factors to be considered will include what gets reported on attestations and what gets deferred. These and other data will be correlated with geography and other information to look for patterns. Deficiencies will be addressed with additional outreach and possibly future rulemaking.
- One Committee member noted that it is important to be able to separate out critical access and rural hospitals, and to be able to compare their levels of adoption to other hospitals. In this way, additional outreach, if needed, can be implemented sooner rather than later.
- Deven McGraw noted the language in the final rule that seems to suggest that there is little that can be done in the future in terms of setting measures and objectives to meet privacy goals. It seems that one tool for advancing best practices in privacy and security is being removed. Tony Trenkle explained that certification rules require that functionality be built in to carry out risk assessments. Also, they support defining in meaningful use criteria items that are consistent with the privacy rules that exist now. The point is to make sure that what they do is consistent and provides something that can be attained and audited.
- David Blumenthal commented that in his view, privacy and security goals are not “off the table” at all. The ONC is anxious to find ambitious but achievable uses of meaningful use to protect patient information.
- Gayle Harrell noted the importance of having the public's buy-in on privacy and security issues and expressed concern that when people read the final rule, they will get the

impression that the government is not serious about these topics. Every policy and rule lever possible must be asserted to ensure privacy and security.

- Gayle Harrell also acknowledged the writers of the final rule for hearing the public outcry regarding flexibility for specialists. Even so, it will be extremely difficult for some specialists to qualify for meaningful use. Some core measures, such as height, weight, body mass index (BMI), and smoking cessation do not apply to some specialists and will place extra burdens on them. Tony Trenkle explained that in the NPRM, measures were divided up by specialty. A number of subspecialists indicated that those measures were not relevant to them, and others reported that dividing the measures by subspecialty was not appropriate. The specialty group divisions were not included in the final rule, but a broad range of measures from which to choose were included. He recognized that in Stage 2, more complete and overall better sets of measures will be needed for all specialties, but given the current retooling process, only 44 were available for Stage 1.
- Tony Trenkle reminded the group not to get overly preoccupied with what appears in the meaningful use matrix without recognizing that it is just one of many quality programs that are out there. All of these programs need to be integrated and coordinated as much as possible.
- In response to a question about outreach and communication to the consumer, Tony Trenkle explained that some changes in the final rule were made to reflect consumer issues, and that this is an area that will require greater attention in the future. Linking with other consumer resources and educational efforts will be considered over the next stages. Care must be taken with regard to how this material is communicated so that public perception does not move ahead of reality. This is a work in progress; there are great advantages to EHRs, but the message needs to match the reality.
- Tony Trenkle indicated that a decision has not yet been made as to whether clinical quality information will be made public. The intent to include administrative transactions has in future stages has been announced, and they are not included in the Stage 1 requirements. He explained that quality measurement is a journey—the first time quality is measured within a system, the measurements will be wrong for one reason or another. The process of looking at the data, figuring out where the reporting mistakes and the process mistakes are, is part of the early phase of this journey.
- Paul Egerman commented that standards and certification could be used for improving interoperability, which was called out in the legislation. He asked if Stage 2 could include items like lab results interfacing and more content standards, which would help to improve interoperability and reduce barriers for adoption. Although this may not be included in meaningful use, it is very important. ONC's Farzad Mostashari explained that this comment touches on the Office's strategy for interoperability. The recommendation from the Adoption and Certification Workgroup was not to make a laundry list of everything that the EHR should be, but instead to focus on meaningful use. As a principle, the certification criteria were limited almost entirely to issues that were directly connected to a meaningful

use requirement. Lab results and many other areas do tie directly to meaningful use, which must be considered by ONC.

- Judy Faulkner urged the group to keep creativity and initiative in mind—the HITPC should not write the definition for EHRs for the future, because it will not do as good a job as industry and the open marketplace.

5. ONC Reports

Before the ONC presentation, Paul Tang asked for and received unanimous approval of the minutes from the last HITPC meeting, held on June 25, 2010.

Action Item #1: The Committee approved the minutes from the June 25, 2010, HITPC meeting by consensus.

ONC's Doug Fridsma then provided updates on a number of ONC projects. One of the biggest pieces of feedback the ONC received from this Committee was to increase the specificity of certification criteria so that it is testable, it represents a constrained set of standards, and so that everybody is using the same protocol. That has been the biggest change within the standards and certification rule.

ONC removed one of the transport rules around REST and SOAP.

Within the smoking regulation, more specificity was provided. With regard to privacy and security, a more specific set of standards was adopted. These were recommended by the National Institute of Standards and Technology, and represent best practices. A more detailed report will be provided at the upcoming HITSC meeting.

There is now a final rule for the temporary certification process, a final rule for certification criteria, and meaningful use. Much of the current work within ONC office is focused on operationalizing these initiatives. Also, the Office is in the final stages of awarding contracts. Within the next 2-3, ONC should be standing up the interoperability framework. This is an effort to move through the lifecycle of standards and certification development. Additional information will be provided at a future HITPC meeting.

ONC has received three part one applications from potential Authorized Testing and Certification Bodies (ATCBs), and application that includes parts one and two. The Office is in the process of reviewing these applications at present.

Doug Fridsma reported on activities related to the NHIN. With regard to NHIN Exchange, there is support for the virtual lifetime record and pilots are being set up involving the Veterans Administration (VA) and the Department of Defense (DoD). This effort was characterized as a type of federal Beacon Community focused on the difficult challenges associated with interoperability. It is hoped that these pilots will provide lessons to inform Stages 2 and 3.

NHIN Direct Project continues to collaborate with the Tiger Team to address the policy issues that arise. Pilot testing is to be the next phase.

The Committee's discussion included these points:

- Deven McGraw noted that the accounting of disclosures standard in the NPRM changed in the final rule into a standard that is voluntary. Doug Fridsma reiterated that privacy, security, and accountability are critical issues that must be included. They remain a priority, but there are still some policy issues needing to be addressed before a strategy is fully developed. The issue will be revisited in Stages 2 and 3.
- Farzad Mostashari updated the Committee on the progress of regional extension centers. Sixty centers have been selected to cover about 95% of the U.S. population. To address gap areas, another solicitation has been released. ONC is working to bring the extension centers online, recognizing that all knowledge is local, and that the best source of information for these extension centers is probably each other.
- Regarding the workforce program, Farzad Mostashari explained that in the long term, if there are good jobs in a sector, people are going to get trained and fill those jobs. But this is a transitional period, and they are aware that there are people who cannot get into community college courses right now because all of the courses are full. Programs have been developed to train those with IT backgrounds on the health IT issues, and vice versa. He hopes that as early as this fall, community colleges will begin offering these courses. Proficiency exams and other tools aimed at accelerating the transition also are in development.

6. Enrollment Workgroup Update

Enrollment Workgroup Co-Chair Sam Karp reported that the group is making progress in conceptualizing a minimal set of standards that will work across a variety of use cases and architectures. A set of very preliminary proposals came forward at a Workgroup meeting 2 days prior to this meeting and will be vetted and refined in the next few months.

The key principles guiding the Workgroup's activities are:

- Keep it simple—think big, but start small
- Don't let "perfect" be the enemy of "good enough"
- Keep the implementation cost as low as possible
- Do not try to create a one-size-fits-all standard

The group has activated four tiger teams in the areas of: (1) verification interfaces, (2) business rules, (3) plan/benefit handoffs, and (4) privacy and security. Each tiger team has developed a series of recommendations that was presented to the group.

Doug Fridsma gave an overview of eligibility enrollment data elements, and the harmonization process that has been developed. He discussed the data analysis approach, and outlined assumptions and constraints. He then discussed the 41 responses that have been received on the Federal Advisory Committee Act (FACA) blog.

A discussion followed the presentation, and included these highlights:

- In response to one Committee member's question about what the Workgroup is planning to do with regard to citizenship and legal status, Doug Fridsma explained that some of the programs have a binary construct, for example, are you a citizen or not? Others ask, what kind of relationship do you have? Are you a legal resident? Do you hold a green card? The business rules to determine a person's residency status need to be developed.
- Paul Tang asked about authentication; Paul Egerman indicated that both the Enrollment and the Privacy and Security Workgroups will be working on this issue. The basic concept is, if a numeric identifier cannot be used, what other data can be used and matched up? What are the criteria, and the levels at which one establishes that type of matching criteria? Paul Tang asked, if someone is applying for eligibility, how do they prove that they are who they say they are? Paul Egerman explained that the approach with the NHIN Exchange is to require that an applicant physically appear and get some sort of certificate. He noted that there would be a number of choices in this regard. This is a question of identity-proofing, which has not been addressed within this group. The Workgroup hopes to leverage how this is being done in other places, and this is an issue that must be addressed in order to move forward with any of the exchange programs.

7. Privacy and Security Tiger Team Update and Recommendations

Privacy and Security Tiger Team Chair Deven McGraw began this presentation, offering recommendations on fair information practices in health information exchange, focusing in particular on collection, use and disclosure limits (including data reuse and retention). The group examined health information exchange as it applies to Stage 1 meaningful use and articulated a series of overarching principles and expectations with regard to policy-related issues:

- The relationship between the patient and his or her health care provider is the foundation for trust in health information exchange.
- Entities involved in health information exchange—including providers and third-party service providers—should follow the full complement of fair information practices when handling patient information.
- These include transparency, data integrity and quality, purpose specification, collection and use limitations, data minimization, security safeguards, individual access and control, and oversight and accountability (ONC has articulated these in the Nationwide Framework for Electronic Health Information Exchange, which was incorporated by the HITPC into the Strategic Framework document).

- These principles, and particularly those related to purpose specification, collection and use limitation and data minimization, were used to answer some specific exchange questions, which Deven McGraw outlined and discussed.

The Tiger Team also discussed the role that individual choice should play in health information exchange. The fundamental principle is that the relationship between the patient and his or her provider is the foundation for trust in health information exchange. The provider “holds the trust” and is ultimately responsible for maintaining the privacy and security.

Paul Egerman discussed patient expectations. Patients should not be surprised to learn what happens to their data. The team is reviewing consent from the standpoint of a patient’s participation in exchange generally (yes/no), and they are viewing exchange from the standpoint of Stage 1 of meaningful use. They are not discussing more granular consent issues, such as consent by type of information. This discussion is planned for after this meeting.

Paul Egerman reminded the Committee of a previous Workgroup recommendation, that no additional patient choice is needed (beyond what current law requires) in direct exchange from one provider to another for treatment. The provider maintains control of his/her record and makes decisions about disclosure (to whom, what information, etc.). This model maintains the trust of provider-patient relationship.

He then presented the questions that the team was considering with regard to patient choice to participate in exchange:

- What factors trigger the need for patient consent to participate in information exchange?
- What approach should ONC take to a national policy on choice?
- Should providers have a choice as to whether they participate in models of exchange?

Paul Egerman reviewed the team’s recommendations on trigger factors for exchange, and their recommendations for a choice model. He also discussed two different views on approaches the ONC could take towards a national policy on choice. Descriptions of these two views are found in the appendix of the distributed materials. He noted that in the end, whichever model is chosen, it substantially amounts to the same thing—it is a question of finding the most efficient way of doing things, rather than just annoying the patients with too many forms and creating an administrative management issue. The team feels that providers should have a choice about participating in exchange models.

In discussion, the following comments were made:

- Judy Faulkner noted that these efforts extend into areas that are morally and ethically complex decisions. The Workgroup needs to be careful when considering anecdotal information, and focus on being data driven. How does one get the data to make evidence-based decisions? She suggested that the group must look deeper than vocal minorities, because those who are vocal are paying attention to these issues and are the most able to opt

out, if they choose. She suggested paying particular attention to the patients who do not have enough time to opt in (or to opt their children in).

- Neil Calman emphasized the need to pay attention to the administrative burden and commented that he does not think opt in is a reality. There are 100,000 patients in his network, and he asked, how many years will it take to explain to them all the intricacies of exchange? Informed consent is going to be incredibly time-consuming, and suggested that he has not seen the government take on the responsibility of talking to people about these policies for the first time. This has to be a function that takes place at a different level. What is really going to happen, he said, is that millions of people are going to sign a paper with small print explaining their privacy rights, and it will not actually be informed consent. He believes that it has to be an opt-out process; practices that want to participate in exchange will tell their patients, “this is the way our practice works: if you do not want to do business this way, you need to go to a different practice.” It is not realistic to think that a practice can do business in two different ways (on paper and electronically).
- Gayle Harrell reminded the group that citizens have a constitutional right to privacy in this country, and that there is nothing more private than one’s health information. Unlike the case with financial information, there is no way that an individual can be made whole if that information has been divulged. A real choice for patients regarding what happens to their information must be in place. She noted that opt out is not a choice, the only real choice is opt in.
- Christine Bechtel noted that the American Recovery and Reinvestment Act (ARRA) established a consumer education campaign about electronic health information. It would be helpful to have a detailed update at the next HITPC meeting about this activity. She expressed concern about what she characterized as an unhelpful global discussion about opt in/opt out.
- It was noted that if it is possible to get a person’s health information in extreme circumstances with some manner of “break the glass” mechanism, then that means that an individual with bad intentions could obtain that information in other circumstances. Who is going to take on that liability? If the government’s message is that everyone is going to be opted in, is the provider still liable if a breach occurs? Right now providers would indicate that they absolutely feel liable.
- One committee member suggested that when people have more confidence in the privacy and security of their information, it will improve their attitudes towards information sharing. Having said that, she believes there is a core group of people who are not being driven by privacy concerns, but rather an ethical issue. They feel they should be asked. It’s not that they would say “no,” but they want the courtesy of being asked.
- Neil Calman stated that the answer to this issue centers on education. A specified educational process should be required, with details on exactly where and how the education will be provided. Once the education is provided, the individual practitioners might be in a

position to make the decision about opt-in vs. opt-out, or provider choice vs. opt-in. This Committee may never reach consensus about opt-in or opt-out.

Action Item #2: The Committee unanimously accepted the recommendations of the Privacy and Security Tiger Team.

8. Adoption-Certification Workgroup Update

Adoption-Certification Workgroup Chair Paul Egerman updated the Committee on the workgroup's recent activities, which include continued focus on certification efforts, discussions with ONC staff on the most appropriate areas to support, presentations from Melinda Buntin (on data collection and analysis and modeling and performance measurement) and Ned Ellington (on provider support, research, and resources), identification and prioritization of areas of focus, and definition of a proposed hearing to focus on barriers to EHR adoption.

The Adoption-Certification Workgroup can support ONC teams by participating in an expert panel looking at initial models, offering individual discussion and support to ONC teams, and aggregating ideas from the vendor and user communities. Recent workgroup focus areas and discussions have addressed the following: adoption challenges faced by specific market segments, coordination with the HITSC Implementation Workgroup, monitoring the certification process for effectiveness, REC best practices, EHR best practices, training and education, success stories on adoption, patient access to data issues, EHR safety, health information exchange adoption, workforce issues, and specific physician issues.

The Workgroup will also help support an upcoming ONC hearing to explore the barriers to EHR adoption, and look at tools for the small- and medium-sized end users.

9. Information Exchange Workgroup Update

Information Exchange Workgroup Chair Micky Tripathi announced that David Lansky has replaced Deven McGraw as Workgroup Co-Chair. The group has a new focus on the areas of Medicaid and public health. It is examining the market in an effort to identify and help facilitate areas that need policy work. This includes specific transactions relating to meaningful use, cross-state issues, and the intersection with the health information network as it starts to develop. On the agenda going forward is a second phase of investigating health information exchange policy issues and examining provider directories.

10. Public Comment

Robin Raiford, a concerned citizen, urged the Committee to address consumer concerns about data sharing in this way: "share your data, and maybe they (doctors) won't kill you. Don't share your data, and they'll kill you." Her suggestion was to offer to patients a bracelet or band, similar to the yellow Lance Armstrong band, to indicate a data sharing preference. "Don't make it so safe that people keep dying," she commented.

Allison Viola of the American Health Information Management Association commented that as the HITPC examines barriers to EHR adoption, it should look one step beyond adoption, at the actual implementation efforts. An examination of meaningful use and the use of the EHR as it relates to workflow analysis and resources would help to make this a more robust discussion.

Lorraine Fernanz, Initiate, commented that the public, when educated, does understand and wants to be included in information exchange. He offered the example of one organization that strives to keep it simple when talking with patients. They ask, “would you like to have your information shared electronically with your other providers?” She noted that the assumption that in the paper world, health records were secure is not valid. She also noted that the value over the last decade of the social security number has decreased, while the value of the phone number has increased dramatically.

SUMMARY OF ACTION ITEMS:

Action Item #1: The Committee approved the minutes from the June 25, 2010, HITPC meeting by consensus.

Action Item #2: The Committee unanimously accepted the recommendations of the Privacy and Security Tiger Team.