HIT Policy Committee
DRAFT
Summary of the September 4, 2013 Meeting

ATTENDANCE

Members present:

- David Bates
- Christine Bechtel
- Neil Calman
- Arthur Davidson
- Paul Egerman
- Judith Faulkner
- Scott Gottlieb
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Farzad Mostashari
- Marc Probst
- Alicia Staley
- Robert Tagalicod
- Paul Tang

Members absent:

- Madhulika Agarwal
- Thomas Greig
- Patrick Conway
- Connie White Delaney
- Aury Nagy
- Joshua Sharfstein

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 52nd meeting of the Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment 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.

Remarks

Chairperson and National Coordinator Farzad Mostashari remarked on the shift in meaningful use to outcomes in Stage 3 and the challenges of new payment systems that place value over volume. The power of HIT can be manifested. The new models require HIT. In talking with providers who are moving to new delivery methods, he found that they recognize the need for meaningful use capabilities. They need them to have the longitudinal information on patients in one place and to be retrievable. They also need the

capabilities for population health management, meaning to be able to identify the patients with care gaps. The providers also talked about the importance of receiving notifications of patients' admissions to EDs and their hospitalizations. Stages 1 and 2 pointed them in the right direction, but it is still too hard to use their EHRs as desired. It is important to continue to establish a common floor across the country and to be able to make common assumptions regarding vendors' offers. This being his final committee meeting, he praised the members for their work. By statute, the committee is a diverse group intended to provide a broad perspective. That diversity was important is finding compromises and consensus.

Review of Agenda

Vice Chairperson Paul Tang thanked Mostashari and the other members. He noted each of the items on the agenda, which was distributed by e-mail prior to the meeting. No additions to the agenda were requested. He asked for a motion to approve the summary of the August meeting. A motion was made and seconded. A voice vote for approval of the summary as circulated with the meeting materials was unanimous.

> **Action item #1: The summary of the August 2013 HITPC meeting was approved as distributed.**

FDASIA Workgroup Update

Chairperson David Bates presented the final report from the workgroup. He showed slides and repeated information on the charge, diversity of membership, division of work, process, examples, research findings, and public comments from the report made at the August meeting at which time the members had directed the workgroup to do additional work. He called attention to the notes to the slides and the summaries from each of the three subgroups. The taxonomy which the workgroup used in making recommendations was described once again as was the framework for risk and innovation, and several use cases. Application of the use cases to the risk framework resulted in several observations. It is easier to classify lower-risk applications (attributes) that are standalone, have narrowly defined functions, and have less variability in context of use. It is harder to classify more complex software precisely that: are more dependent on context of use; have more complex software to develop and assure quality; require greater effort and expertise to implement; require more interfaces to other systems; and have a greater reliance on QMS process and risk controls for known failure rates.

Policy implications of these observations were mentioned by Bates. Clearer criteria for software functions that are not regulated, but might have labeling requirements to promote transparency, could be defined. Clearer criteria for software functions that warrant regulation, or at least greater attention, could be defined. A robust surveillance mechanism to track adverse events and near misses for the majority of software functions that lie in between could be defined.

Bates explained the three classes of current FDA regulation of medical devices and then delineated the pros and cons of that regulation. Positive factors are use of process control that applies consistent manufacturing processes to software and supports innovation in new products. A good manufacturing process has increased the confidence in resulting products and there is a post-marketing surveillance program. Disadvantages are the lack of clarity about who is subject to regulation, being over-prescriptive, and that regulation is geared especiall—but not exclusively—to physical devices. Other factors are the turnaround time, configure and extension, and the "class up" effect on software working with a device. But it can be applied to software with some modifications recognizing differences between physical devices and software. The blood bank use case is commonly presented as a negative use case and requires more in-depth review for lessons learned. Entry impedance is another concern. A way is needed to lower the burden of applying these regulations to new developments and to products that started small without regulation, but then have regulation applied after their development and initial use.

He went on to review the impact on innovation of the ONC certification program. Since the government is funding a capital improvement to health care practice, there is an obligation to promote good products, but innovation may have been adversely affected. The specification of certain software behaviors and certifying specific test behaviors limits innovation and narrows possible solutions to problems to a prescribed solution. It leads to compliance innovation and is justified only when there is an overriding societal benefit (e.g., interoperability, specific patient safety concerns).

Bates presented recommendations to ONC. The legislation does mandate a certification process. The issue then is the nature of the certification program. The recommendations are as follows:

- Judicious use of specific functional requirements: The ONC is encouraged to limit specific functional requirements unless there is a specific public health or patient safety issue. The regulatory description of other features should be in higher-level descriptive—not functional design—terms.
- Flexible compliance measures: The ONC is encouraged to show flexibility in the certifying session itself to allow for multiple approaches to the desired feature. The ONC certification process exhibits some of this approach. For instance, the certification standards for user-centered design leave open the specific implementation.
- Avoid requirements that empower a single, external certification body. When there is a single body, the usual issues that occur when a monopoly is present are in effect.
- Increase predictability: Finally, the ONC is encouraged to increase predictability. The staging process of the requirements does give an opportunity to re-adjust the requirements, but it has resulted in less long-term predictability. The re-certification based upon software change really should be better defined and very limited.

Comparing the medical device regulation with the certification approach, Bates said that process control has less negative effects on innovation than product control. Product definition significantly reduces the flexibility. For the certification approach, how the software was developed does not matter; it only matters if it can run the test scripts at the certification point.

The workgroup attempted to answer these questions on regulation:

- Are the three regulatory systems—ONC, FCC and FDA—deficient in any way with regard to how health IT is regulated?
- Are there ambiguities in the three regulatory systems that need to be clarified so that HIT vendors and others can proceed more easily to innovate?
- Do any of the three regulatory systems duplicate one another, or any other legal, regulatory or industry requirement?
- Setting aside existing approaches, is there a better way to assure that innovation is permitted to bloom while assuring safety?

Bates talked about the FDA mechanisms that could enable innovation. He recommended that FDA should actively establish a policy of "Enforcement Discretion" for lowest-risk HIT, where enforcement of regulations is inappropriate. It should assess exemption from GMP for lower-risk HIT and expedite guidance on HIT software, mobile medical apps, and related matters. FDA lacks internal coordination on HIT software, and mobile medical apps policies and regulatory treatment. It should utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA. There may be a need for additional funding to appropriately staff and build FDA expertise in HIT and mobile medical apps.

In addition to pointing to specific issues within FDA, ONC, and FCC, he talked about cross agency issues. There is unclear and incomplete responsibility over ensuring needed interoperability. ONC may

regulate HIT/medical device interface and FDA regulates med device/med device interface. But the same med device (e.g. infusion pump) could be installed in either configuration. Who is responsible for resolution? More generally, which agency will require interoperability when products need to be interoperable to be used safely? FCC and FDA do not coordinate their review processes on converged medical devices that are brought independently before both agencies (FCC's equipment authorization program and FDA's premarket review). Coordination between agencies should be transparent and help ensure consistency, thereby eliminating duplicative, time-consuming, and costly hurdles. Regarding FCC and FCA conformity assessment, incomplete or missing clinically focused wireless conformity assessment tools that would facilitate safety and co-existence analysis are needed. Additional challenges with adverse event reporting were also described.

Finally, he presented specific recommendation as follows:

> HIT should not be subject to FDA premarket requirements, except:
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> - Medical device accessories (to be defined clearly by FDA)
> - Certain forms of high risk clinical decision support, such as Computer Aided Diagnostics (to be defined clearly by FDA)
> - Higher risk software use cases per the Risk WG report, including those where the intended use elevates aggregate risk
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> Vendors should be required to list products which are considered to represent at least some risk if a non-burdensome approach can be identified to doing so.
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> To develop better post-market surveillance of HIT, a collaborative process with stakeholder participation is needed:
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> - Better post-market surveillance of HIT is needed and should include user self-reporting and reporting from vendors and transparency. Post-implementation testing to ensure key safety-related decision support should be in place. Approaches are needed to allow aggregation of safety issues at the national level, including federal support. Which agency should perform the above will need to be determined but cross-agency collaboration will be essential.
> - This approach would be provisional, to be re-examined periodically
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> We recommend the following areas be further developed which may be accomplished through either private and/or public sector efforts: adoption of existing standards and creation and adoption of needed new standards addressing areas such as interoperability; and a public process for customer rating of HIT to enhance transparency.

Next, Bates introduced a slide entitled lessons learned—recommendations for a new regulatory framework:

> Certification regimens should be used judiciously. When specifying specific implementations, they can narrow creativity and innovation to a specific or narrowed list of solutions.
>
> There are some instances where narrowing choice is desirable: e.g., interoperability standards. Instead of a certification process to differentiate the market, use transparency because transparency in the marketplace is more efficient and richer in content. Certification just reveals that the system passed the certification test and all vendors will, At that point, there is no differentiation. National goals, like JCAHO and Meaningful Use, should be encouraged because they are flexible and set a problem agenda rather than a product agenda. They do change and, if well set, correct the market and create markets. Where the market goes, vendors will follow

He presented a summary of recommendations for a new regulatory framework:

National accountability based on:

- Outcomes assessment rather than product definitions
- International/national standards for quality process – measureable and transparent
- International/national interoperability standards to lower the entry cost
- Encourage configuration and extension to support process and solve problems
- Transparency of product and results
- Support ability to experiment or iteratively develop
- Aggregation of safety issues at a national level

Local control, local accountability for the following:

- Design, document, and prove a local control system
- Accreditation of the software implementation process, e.g., through an entity such as JCAHO
- Local configuration of software
- Local extensions of software
- Ability to iteratively develop, implement, and measure changes
- Integration with medical processes
- Training of end users
- Sharing of lessons learned
- Surveillance by the organization
- Post-implementation testing

Bates went on. He presented three slides of overall recommendations:

- Definition of what is included in HIT should be broad but have also described exclusions
- Patient-safety risk framework and examples should be used as building blocks to develop a more robust and transparent framework which would allow application of oversight by level of risk
- The agencies should address the deficiencies, ambiguities and duplication the FDASIA group has identified
- New framework(s) with some of the characteristics aimed at stimulating innovation may be helpful
- Substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful (should be Class 0), except for: medical device data systems (MDDS); medical device accessories; certain forms of high risk clinical decision support; and higher risk software use cases. For the regulated software, it will be important for the FDA to improve the regulatory system to accommodate the characteristics that make software development, distribution and use different from physical devices
- New risk framework(s) should support reevaluation of what is currently regulated as well as new HIT
- Vendors should be required to list products which are considered to represent at least some risk and a non-burdensome approach should be developed for this
- Better post-market surveillance of HIT is needed and it should include standard formatting of involved reports, transparency of results, and also post-implementation testing
- Approaches are needed to allow aggregation of safety issues at the national level, including federal support to enable this
- FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices that discourage or limit the free flow of safety-related information
- How to organize the governance of this should be addressed by a cross-agency group, which should include key stakeholders

Discussion

David Lansky asked how the framework might apply to the HIT policy process. Bates said that initially EHR certification was necessary, but now the policy solution may be different and minimally prescriptive. Mostashari said that exceptions may be around interoperability. More stringency may increase innovation. Standardization of the user interface would be a bad idea. Requirement for CDS is a good idea, but not how to do it. Bates responded that the United Kingdom established best principles for user interface although he would not agree with the need for standardized user interfaces. But transparency is needed. The HITPC has struggled with CDS. Post-implementation testing would be helpful.

Judy Faulkner expressed support for innovation and agile development and the recognition that software is constantly changing. By international standards, did the workgroup mean working together in international groups or importing standards? She described difficulties with implementation testing: Would the setup, the report, or something else be tested? What about the high-risk software use cases? CDS is not one thing; it is a combination of things threaded throughout. Mostashari asked about systems-related adverse events, such as how an organization implements HIT, which would include staff training and many other variables. Did the workgroup consider safety issues in health care more generally? How does regulation of health care safety interact with device safety? Regarding international standards, Bates said that some are good and others need work. Post-implementation testing will help get to some part of the problem. Responding to Mostashari, he said that some mechanisms are OK but are not great. HIT will create new safety issues; many are preventable. The federal agencies have a special responsibility to deal with them. The existing approaches for safety are not terrific. When information on safety issues has been aggregated, perhaps the Joint Commission can become involved. Regarding high-risk software, Tang said that the matrix includes implementation to allow the regulatory agency and provider to examine risk.

Bakul Patel, FDA, said that the workgroup considered software and post-implementation. Some things are purely software and some are devices that are currently being regulated. Tang said that transparency and sharing as well as aggregation and analysis of data are important.

Neil Calman asked about users. Are they using the software appropriately? Everyone will soon be a user. Yet this proficiency is not a component of professional licensure or medical school and residency training. He suggested specifying a level of accountability for vendors regarding training of users. Vendors should be responsible for some level of training for users. Critical parts of the software are often bypassed. Bates acknowledged that the workgroup engaged in some discussion of the topic, but it determined that responsibility should be delegated to local groups. Faulkner observed that training is critical. In her experience, a "training of trainers" model has not worked well. Users need a trainer who has had actual experience in the same organizational setting. There is often a breakdown in in-service training, often due to the pressure of too-rapid implementation.

Mostashari commented on the risk framework and the likelihood of a hazardous effect. He said that data on prevalence or frequency should be incorporated. Using life years only normalizes the measure. Bates acknowledged that Mostashari's point was a good one.

Gayle Harrell wondered about transparency when three bureaucracies—with FDA being the most insular—are involved. How can reporting be balanced across different agencies with different philosophies? The private sector must be involved. Bates referred to examples of communities that share experiences with devices and tools. FDA has some approaches along these lines. Harrell said that analysis, not anecdotes, is required. Bates declared that if the public has information, it will use it. Someone pointed out that with de-regulation, there will no longer be liability protection.

Another member mentioned the conversion of HIT and devices. Bates said that the workgroup talked about how to deal with the topic. One can always image risks with a specific device, but it is difficult to assign weights. Such potential risks can periodically be revisited.

Paul Egerman observed that the FDA plays an exceptionally important role in protecting the public. Considering software as a device seems to be the heart of the issue under consideration. At some point the software changes from a device to a business process that cannot be easily regulated. Regarding the recommendation for a consumer evaluation of HIT systems, he pointed out that such evaluations already exist it the private sector. Bates replied that the workgroup members are aware of those systems, but they are proprietary and expensive. The members wanted something more broadly accessible.

Charles Kennedy said that based on his personal experience, the data cannot be separated from the software. He asked whether the workgroup had discussed the quality of underlying data sets. Bates told him that the focus was on standards for interoperability. The problem is a significant one, but over time it will get better. Kennedy said that lab systems do not deal well with variations in data.

Matthew Quinn, FCC, remarked on the pleasure of working with the workgroup, which was a unique interagency approach. What are the most important one or two problems to respond to? Bates responded with better product listing and more robust post market surveillance.

Without exception, those members who commented during the discussion praised the FDASIA Workgroup's report and the work of the members and chairperson. Tang asked for a motion to approve the report and accept the recommendations. A motion was so made and seconded. A voice vote resulted in unanimous approval.

> **Action item #2: The report and recommendations of the FDASIA Workgroup was accepted unanimously as presented.**

Meaningful Use Stage 3 Update

Meaningful Use Workgroup Chairperson Paul Tang reminded the committee members that during the discussion of his presentation at the August meeting of the HITPC members directed the workgroup to explain how the functional objective recommendations link to outcomes and how proposed Stage 3 recommendations link to HHS initiatives (e.g. NQS, Million Hearts) and future payment models (e.g., ACO, MSSP). Furthermore, the HITPC members agreed that although the deeming pathway is a good direction, appropriate eCQMs are needed. Additionally, the reduction of disparities must be addressed. Tang attempted to describe how the workgroup had responded to the directives by showing slides in which Stage 3 functional objectives contributed to functional goals then to priorities to improve outcomes and finally to health outcome measures. He then applied the scheme to the example of the Million Hearts C ampaign. Heart attacks and strokes are the leading cause of deaths of persons less than 65 years of age and are the greatest contributors to racial disparities in life expectancy. Starting with population management, he described how the proposed Stage 3 functions and software could affect outcomes such as morbidity and mortality. Software contains tools to review the patient population to identify patients at risk for stroke or heart attack (e.g., uncontrolled BP, beta blockers, ASA) and to reach patients with uncontrolled BP or who are not taking their medication (e.g., medication adherence). At the pre-visit, providers could use real time dashboards before the patient visit to identify needed interventions. Reminders and other health-reinforcing messages can be shared with patients via their preferred means of communication (e.g., secure messaging). At check-in, information on race, ethnicity, language, and preferred means of communication can be collected. In the exam room, someone uses software to review medication history and to assess medication adherence, uses CDS, avoids unnecessary tests (e.g., duplicate, choosing wisely); and prescribes appropriate medications based upon the patient's demographic information (e.g., age, sex, race) and uses a formulary which identifies generics. After the visit, software: facilitates patient-specific education provided in the preferred language by care team; shares visit information with other members of the health care team; and uploads visit data to the PHR. At home, the patient uploads BP data to her PHR and shares the information with the care team. Proactive care management by the health care team is provided between visits.

Tang moved to other slides showing the similarity of the 2011 National Quality Strategy priorities and Stage 3 proposed priorities to improve outcomes. He gave examples to support the claim. Then he turned to slides that depicted the movement from Stages 1 and 2 functional objectives to Stage 3 functional objectives to achievement of a meaningful use outcome goal. For instance, in Stages 1 and 2 EHRs are used to capture information on patient race, ethnicity, gender, and preferred language. In Stage 3, patient conditions can be treated appropriately using, in combination with other functions, data on race, ethnicity, gender, and language. This may eventually contribute to the elimination of gaps in quality of health and health care across racial, ethnic, sexual orientation and socioeconomic groups.

He repeated the explanation of deeming from the August meeting. Deeming is proposed as an optional pathway that promotes innovation, reduces burden, and rewards good performance. Deeming allows high performers (or significant improvers) that have already met all functional objectives in Stages 1 and 2 to attest for meaningful use by satisfying a subset of objectives. He emphasized that not qualifying for deeming (by performance) does NOT affect susceptibility to penalties (i.e., no downside risk). Potential elements of a deeming framework that have yet to be specified include the following:

- Eligibility: High performer or high improver (based on 12 months reporting)
- Achieve high performance on two eCQMs in each of two high priority categories (total of four measures)
- Reduce disparity gap in one area

He announced the formation of the Accountable Care Quality Measures Subgroup of the Quality Measures Workgroup charged to develop recommendations for HIT-sensitive, outcomes-oriented eCQM concepts and specific measures that could be used for Stage 3 and for the deeming pathway.

Discussion

Harrell wondered how a small provider not in an ACO would do deeming. Tang said that while ACO membership is not necessary, taking into account community health status is necessary. Mostashari suggested that the quality measures be selected to be appropriate for both ACOs and others. According to Tang, this requirement would drive development of measures for specialists.

Devin McGraw referred to slide 21 and registries that can be used for population health analytics. Registries may contribute to a learning system in addition to public health reporting. George Hripcsak said that that was the intent of registries. He offered to clarify the slide to include more than public health agencies. Art Davidson suggested rewording.

Lansky observed that everything depends on the quality measures, which may not yet be ready; there most certainly are no data on which to deem them. He suggested that someone make recommendations on the characteristics of appropriate outcome measures. He advised against deeming on old measures that predate the meaningful use program and do not indicate quality. There are many contributors to outcomes; linking and attributing meaningful use functions to outcome measures will be impossible. He also expressed concern about the lack of infrastructure (certification) to capture outcomes, particularly with regard to registries and intermediaries. This is a structural flaw on which the committee should work. Tang replied that the Quality Measures Workgroup had delineated characteristics, which the subgroup will use to enumerate characteristics and exemplars. He agreed that quality measures are not yet ready; however, there is time for their development prior to the onset of Stage 3. Meaningful use does not control or affect many environmental factors. Mostashari said that deeming should be allowed only for those measures that accomplish the full intent of the program. The measures should align with and be accelerant of other payment systems. He suggested to Lansky that data for the measures may not need to be collected within the EHR. For instance, perhaps a claims-based adjustment used for measuring coordination of care might be an appropriate measure for deeming.

Marc Probst expressed his hope that over time some of the measurement requirement would diminish. The question is how to minimize measurement and move to outcomes.

Faulkner wondered whether deeming would be a substitution for everything. What about functions that have nothing to do with quality measures? How does an organization know if it is a high performer? Should not deeming be available for all? Will vendors have to have functions for deeming specifically? What about the availability of standards? Some things are not in EHRs. When she mentioned a problem with lab data, Mostashari instructed her to take the labs out of the discussion. Tang talked about looking for proxies for good quality in the absence of good measures. Deeming is not for all functional requirements. Hripcsak recommended deeming for a subset of the functional measures. Mostashari said that is a part of what must be worked out. He told the members to submit their suggestions to the Meaning Use Workgroup. At this time, approval was being sought for the concept of deeming, not the specific procedures. Tang assured Faulkner that deeming would require no further effort for vendors.

Christine Bechtel talked about her support for Tang's statement that the workgroup will examine criteria for robustness of measures. She referred to letters of support for PGHD from consumer advocacy groups

and reported that the HITSC Consumer Technology Workgroup is reviewing the availability of standards for PGHD. Tang assured her that he was seeking endorsement of the goals, not the objectives. Bechtel went on to say that she had concerns with the operationalization of deeming and was hesitant about the use of legacy measures. Deeming is voluntary and providers are expected to select variables on which they can have an effect. She referred to a letter from 17 consumer groups concerned about deeming patient safety.

Harrell talked about what analytics will be available and asked whether vendors would have to provide additional functions. Or will there be independent deemer services? The tools and cost throughout the entire system must be considered. Tang talked about linkages to a near real time dashboard, acknowledging that the tool is currently missing. It may be a new Stage 3 functionality. Mostashari talked about CMS moving to a one-report system.

Lansky requested clarification on what the members were to vote on. Are the bullet point examples of measures included in endorsement? Mostashari said that they were to vote on the framework of the meaningful use Stage 3 functional goals and priority to improve outcomes. A motion for approval of the framework was made and seconded. A voice vote resulted in approval with one abstention by Judy Faulkner.

> **Action item #3: The framework (functional goals and priority to improve outcomes) for stage 3 as presented by the Meaningful Use Workgroup was approved.**

Public Comment

Janet Marchibroda, Bipartisan Policy Center, said that her organization concurred with the FDASIA recommendation to explore a new framework. She encouraged policy makers to take her organization's report on the topic under consideration.

Linsey Hoggle, Academy of Nutrition and Dietetics, reported that her organization has developed HL 7 standards for nutrition messaging. It is under a one-year draft standard for trial use and will be ready for Stage 3. The organization is working on standards for allergies. She asked that the importance of nutrition in health care be recognized in Stage 3.

Wes Rishel, Gartner, was excited about deeming. However, he pointed out that small specialty practices cannot control many of the factors that affect patients. They work in isolated practices and lack information. Since deeming would be optional, it would be a shame to deny it to those that have the capability. To have it as an option may increase demand for data.

Data Update

Robert Anthony, CMS, reviewed the registration and payment data. Medicaid participation is gradually increasing. As of July, there were nearly 410,000 active EP registrants. Ninety percent of EHs have registered and 81 percent have been paid. Fifty-two percent of EPs have registered for Medicare and 25 percent for Medicaid. Sixty-three percent of Medicare EPs that are meaningful users are non-primary care clinicians. There are more than 220,000 meaningful users. More information is available at the CMS website.

Jennifer King, ONC, reported that 67 percent of EHs, which constitute 74 percent of U.S. beds and account for 77 percent of Medicare discharges, have attested for meaningful use. Small urban hospitals continue to lag; 55 percent have attested, compared to 75 percent of large hospitals and small rural hospitals. Forty-five percent of EPs have attested with an additional 15 percent of AIU only participants. Fifty-one percent of Medicare EPs attested to Stage 1 by the end of the program year 2012.

Steve Posnack introduced a review of certification. Many products were certified that have never been used in attestation. King continued. 991 vendors have a certified 2011 Edition product. Six percent (56 vendors) also have a certified 2014 Edition product. Of the 991 vendors, 469 served as the primary 2011 Edition vendor for EPs attesting to Stage 1 MU. Four percent (21 vendors) also have a certified 2014 Edition product. Sixty-six percent of EPs that have attested to Stage 1 used a primary vendor that had any 2014 Edition product as of August 2013. With hospitals, Of the 991 vendors, 56 served as the primary 2011 Edition vendor for EHs attesting to stage 1. Twenty-seven percent (15 vendors) also have a certified 2014 Edition product. Sixty-four percent of EHs that have attested to Stage 1 used a primary vendor that had any 2014 Edition product as of August 2013.

Q&A

Mostashari noted that the time of going to Stage 2 is predicated on the provider's time of entry into the program. The more advanced half of the users has a financial advantage, but they must move to Stage 2 more rapidly. These schedules may affect concerns about the more difficult measures.

Harrell said that last month she had asked for more information to explain the lower participation rates of small urban hospitals. She requested a response. King referred her to slides in the appendix of the presentation, saying that the majority of CAHs that have not attested are enrolled in RECs. Forty-eight percent of small urban hospitals are for-profit. They may be more concentrated in the south and may be disproportionately specialty hospitals. Harrell requested a breakout.

Responding to a question from Davidson, King explained that of the 991 registered vendors, only 60 percent were used in attestation, including those certified for modules. There is no way to predict at this time whether they will drop out. Some may have been modular certifiers. Davidson inquired about the risk for providers that have a low penetration vendor. Someone pointed out that the largest penetrators will most likely continue in the program. But some customers will have to find another vendor.

Bechtel asked King about hold-ups with certification. A vendor told her that his company will not try to certify until the quality measures have been determined. Mostashari declared that there are no structural barriers; certification is dependent on the resources applied by the vendor and the agility of its development process. Although some associations have said that they cannot meet the timelines, other vendors have requested moving forward with the timelines. Posnack pointed out that after certification, much more must be done for roll-out and implementation. Bechtel said that in order to advise on the timing of Stage 3, the committee needs hard data on cycles.

Probst asked Faulkner about the extent to which worker availability is a concern of venders that continue to be involved in the program. She replied that workforce availability is a huge issue. She wondered about the issues with vendors dropping out of the market. Is it because the barrier to entry is too high? She said that she wants an analysis. Posnack indicated that it may be possible to look at mergers in the industry. Some vendors may get certified and use the products for other purposes. Mostashari observed that prior to HITECH, there were not 900 EHR vendors. HITECH created an influx. Some are successful new companies, but many are not. In all industries, there are periods of concentration. He told them that he expects to see many more 2014 certifications. 2014 will be much more difficult than 2011.

Lansky noted a political issue in that certain vendors that are having problems will exert pressure to slow down the schedule. What can the HITPC do to ensure more market segmentation? He had heard reports of rural hospitals not being able to get vendors. Posnack indicated that he will explore the issue.

Faulkner talked about all of the different things vendors have to do. Her employer uses criticality and available time to prioritize. Mostashari said that her concern was similar to what Bechtel was asking about. The time required varies across vendors and is influenced by variables such as being cloud based. He suggested that the committee consider the roll out requirement for a new stage and what is appropriate

timing. Should the schedule be attuned to the slowest, the fastest, or the mean? Tang asked whether the EHR Association could provide relevant data on time requirements for development and implementation. Faulkner agreed to inquire.

Referring to consolidation, Davidson asked how many purchasers have had to go to a new product. What happens when one company buys out another? Mostashari talked about using multiple policy levers and working with the EHR Association to make it easier when a provider has to switch vendors. Data portability is a related issue. There are guidelines for what to consider in a contract. Although some survey data on the number of providers that expect to change vendors have been published, the quality of the data is questionable. Nevertheless, it is likely a significant number. Davidson said that ONC should give guidance on what providers should look for.

Harrell said that providers may have made huge investments. The available workforce and consolidation must be considered in setting timelines. Mostashari asked King to provide some information on moving to the next stage based upon time of entry into the program.

ONC Policy Updates

Seth Pazinski reminded the members of the September 16 Consumer HIT Conference. The *HHS Strategies to Accelerate HIT* was recently released (http://www.healthit.gov/policy-researchers-implementers/accelerating-health-information-exchange-hie). The *Federal Health IT Strategic Plan Progress Report* is available at: http://www.healthit.gov/policy-researchers-implementers/federal-health-it-strategic-plan-progress-report. A cross-vendor exchange demonstration with NIST was initiated in August with results expected in October 2013. Visit: http://www.healthit.gov/policy-researchers-implementers/federal-health-it-strategic-plan-progress-report. Solutions, success stories, and case studies are available: http://www.healthit.gov/providers-professionals/case-studies-data. Westat prepared a guide for EHR contracts; visit: http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety-tools-and-resources.

ONC Standards Update

Lauren Thompson used the usual format to report on the S&I Framework activities. There are 2,612 Wiki registrants. Regarding structured data capture, two implementation guides are targeted for development based on REST/OAuth and SOAP/SAML. Development has begun on SOAP/SAML IG, targeted for completion the end of September. The forms SWG kickoff was June 5, led by AHRQ and NLM. Recommendations on form structure have been presented to the All Hands Workgroup. The standards SWG kickoff was July 11. EHR interaction and auto-population has been discussed and was finalized the end of August. The next steps include continuing implementation guide development with a consensus-approved standards solution plan. The C-CDA was revised to support transitions of care and care plan exchange for the HL7 fall ballot cycle. Recommendations were developed and submitted to align care plan exchange efforts with various HL7 workgroups. Care plan standard development activities are being coordinated with other SDOs and federal care plan activities. Potential pilot sites are being identified.

Public health reporting artifacts created to date include: the Public Health Reporting Initiative Reference Implementation Framework, a reference document on interoperability standards for several public health programs; and the PHRI CDA Guide, which specifies the CDA structure for public health report for *Communicable Diseases* and *Adverse Events.* A PHRI Web page with documentation on testing or pilot projects demonstrating the use of interoperability standards is referenced in the PHRI Reference Implementation Framework. In September 2013, PHRI will begin Phase 2 with a *Call for New User Stories* and analysis of phase 1 user stories for inclusion of additional reports into the PHRI Reference Implementation Framework. The meeting materials include Thompson's full report.

Q&A

Lansky asked about cataloging the apps for Blue Button Plus. Mostashari agreed that there should be a place to go to find out whether one's plan and provider have apps. ONC is working with someone to create a hub. Awareness of the availability is a primary issue. It is a private sector responsibility according to Mostashari. Lansky said that public agencies should give some information as well.

Announcements

A hearing on advanced directives will convene September 23. A hearing on accounting for disclosures will take place September 30. Reports of the hearings will be made to the committee. The Certification and Adoption Workgroup has been charged with proposing recommendations on a voluntary certification program for ineligibles.

Public Comment

Marcy LNAME, AMA, reiterated that her organization and the AHA sent a letter to the secretary last month asking that stage 2 be postponed. Small and rural providers as well as vendors are not ready. Patients may be in danger. They recommended: Allow providers to meet stage 1 meaningful use requirements using either a 2011-certified or 2014-certified EHR; establish a 90-day reporting period for the first year of each new stage of the program for all providers; offer increased flexibility to providers in meeting Stage 2 requirements; and extend each stage of the meaningful use program to no less than three years for all providers. She asked committee members to review the letter, which is posted on the associations' websites.

David Powell suggested that CMS and ONC staff work together to collapse and analyze their data to answer the questions posed during the Q&A. New information rather than repetitive and conflicting data would be helpful.

Tang thanked Mostashari for his many accomplishments.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the August 2013 HITPC meeting was approved as distributed.

Action item #2: The report and recommendations of the FDASIA Workgroup was accepted unanimously as presented.

Action item #3: The framework (functional goals and priority to improve outcomes) for stage 3 as presented by the Meaningful Use Workgroup was approved.

Meeting Materials

- Agenda
- Summary of August 2013 meeting
- Presentations and reports slides