HIT Policy Committee
FINAL
Summary of the August 7, 2013 Meeting

ATTENDANCE

Members present:

- Madhulika Agarwal
- David Bates
- Christine Bechtel
- Paul Egerman
- Judith Faulkner
- Scott Gottlieb
- Thomas Greig
- Gayle Harrell
- Charles Kennedy
- Deven McGraw
- Farzad Mostashari
- Aury Nagy
- Marc Probst
- Joshua Sharfstein
- Alicia Staley
- Paul Tang

Members absent:

- Neil Calman
- Patrick Conway
- Arthur Davidson
- Connie White Delaney
- David Lansky
- Latanya Sweeney
- Robert Tagalicod

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 51st 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 Farzad Mostashari, National Coordinator, noted that yesterday his resignation was announced by the HHS Secretary. He told the members that he was humbled by the response. The progress made in HIT may symbolize the U.S. capacity to do big things that matter. The progress is due

to the partnership of smart government and the private sector. Government has a critical but limited role. Openness is important. His future plans have yet to be determined. He believes that this period between rule makings is a good time for his departure. He said his heart told him that it was time to leave.

Review of Agenda

Vice Chairperson Paul Tang thanked Mostashari for his leadership and praised him highly. He referred to the packed agenda, calling out each item on the previously distributed agenda. The FDASIA Workgroup will submit final recommendation to the HITPC in September. He asked for a motion to approve the summary of the July 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 July 2013 HITPC meeting was approved as distributed.**

New members Alicia Staley, appointed by GAO as a patient representative, and Aury Nagy, a neurosurgeon in Las Vegas representing providers, were introduced.

FDASIA Workgroup Update

Chairperson David Bates reviewed the charge to the workgroup. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 calls for the HHS Secretary to "post a report—within 18 months (or by January 2014)—that contains a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication". The workgroup is not expected to develop the framework itself—that will be done by FDA, ONC, and FCC—but has been asked to make recommendations to guide the development of the framework. Bates acknowledged that the members frequently disagreed. The workgroup formed three subgroups, conducted one in-person meeting, deliberated for 3 months, and had dozens of conference calls both in subgroups and the larger group. They considered much of the prior work done in this area, including IOM committee recommendations, and had input from representatives of the three agencies. They also reviewed public commentary on the FDASIA process. Bates related results of several studies pertaining to HIT and safety.

He continued. The Taxonomy Subgroup assigned HIT to one of two categories—requires risk-based regulation or risk-based regulation not needed. He gave examples of in-scope as hospital information systems-of-systems and decision-support algorithms. Out-of-scope examples are claims processing and health benefit eligibility. Another subgroup devised a risk framework. The patient-risk framework enumerates various important factors influencing the risk of software systems. It does not weight or "calculate" any specific risk score for a given software product. Rather, it serves as a framework to assess the factors to consider when evaluating the potential risk of patient harm arising out of the use of the software system. While the matrix characterizes the relative risk of certain conditions of each risk factor, these serve as directional guidance only. Exceptions for each relative risk condition exist. He referred to several slides that defined the many terms used in his report. He showed slides that described the risk framework matrix, which uses three risk categories—lower, medium and high. He worked through the application of the framework to three examples—an e-nutrition app, an insulin pump, and an EHR. He reported that the application indicated that it was easier to classify lower risk applications (attributes) that are standalone with narrowly defined functions and less variability in context of use. It was more difficult to classify more complex software precisely because of the several other variables that must be considered, such as context of use, effort and expertise required to implement, interfaces to other systems, and greater reliance on QMS process and risk controls for known failure rates. He talked about the policy implications: define clearer criteria for software functions that are not regulated, but may have transparency labeling requirements; define clearer criteria for software functions that warrant regulation,

or at least greater attention; and create a robust surveillance mechanism to track adverse events and near misses for the majority of software functions that lie in between.

Bates continued. He described the current FDA medical device regulation based on three classes plus a zero class to which regulation is not applied. He said the workgroup concluded that the benefits of this system are: process control, not product definition; consistent manufacturing process that can be applied to software; support for innovation in new products; increase in the confidence in resulting products; and a post-marketing surveillance program. The disadvantages are: lack of clarify on who and what is subject to regulation, being overly prescriptive, geared to physical devices, turnaround time, and the "class up" effect on software working with a device.

According to Bates, the workgroup attempted to address these questions:

- Are the three regulatory systems—ONC, FCC and FDA—deficient in any way with regard to how HIT 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 safety is assured?

Bates summarized problems identified by the FDA. The FDA needs to explain how to discern disease related claims from wellness, and needs to deregulate low-risk disease related claims. FDA needs to explain its position on which basic IT elements are regulated when connected to a medical device, and deregulate or down-regulate those that are low risk. FDA needs to explain which forms of CDS software it regulates. FDA needs to specify its rules for deciding the regulatory status of software modules either incorporated into a medical device, or accessed by a medical device. FDA needs to explain how the quality system requirements and facility registration apply to manufacturing of standalone software. FDA needs to adopt a paradigm for reviewing software that is intended to be part of a larger, but unspecified, network. For instance, staff could build on the efforts of a working group of companies, academics, and hospitals that developed and submitted a pre-IDE regulatory submission to help refine the FDA clearance process. Regarding post-market requirements for networks, responsibilities for reporting adverse events and conducting corrective actions can be clarified, but FDA likely needs a new approach that reflects shared responsibility across users, producers, and regulatory agencies.

Bates delineated what FDA should do to enable innovation:

- Actively establish a policy of "enforcement discretion" for lowest-risk HIT, where enforcement of regulations is inappropriate
- Assess exemption from GMP for lower-risk HIT
- Expedite guidance on HIT software, mobile medical apps and related matters
- Incorporate internal coordination on HIT software, and mobile medical apps policies and regulatory treatment
- Utilize external facing resources to proactively educate the public about how policies and regulation impact HIT and MMA

He also noted that funding is required to appropriately staff and build FDA expertise in HIT and MMA. Moving to problems with ONC, he said that the ONC program does not include capability in law enforcement, nor are its programs framed with mandates where necessary. Safety depends on appropriate post-installation configuration. There is no means to educate or require compliance with documented and evolving best practices. ONC should avoid regulatory rules and certification test cases that endorse a

specific solution or implementation to a desired feature. Although ONC does a good job of periodically reviewing its programs and getting rid of those that are no longer necessary, more effort is needed. Regarding FCC, Bates said that planning for deployment of wireless technologies is difficult in spectrum-crowded, interference-prone environments (i.e. most hospitals). Pre-clinical test and evaluation tools and environments could help manufacturers and health care delivery organizations. Spectrum management and identification, diagnosing, and resolving wireless co-existence/Electromagnetic Compatibility (EMC) problems that affect HIT and medical device performance (in health care facilities and mHealth environments) requires attention.

He described several cross-agency issues. ONC may regulate HIT and medical device interface and FDA regulates med device and 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, who 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. Clinically focused wireless conformity assessment tools that would facilitate safety and co-existence analysis are incomplete or missing.

He described many error or adverse event reporting issues. It is difficult to obtain data for system performance analysis. When medical device HIT system-related adverse events occur, it is often difficult or impossible to find the root cause of the failure. Data logs may be incomplete, inaccessible, non-existent, or not in standardized format. Root cause of events may span regulated and non-regulated space. The workgroup considered existing approaches used by NHTSA, CPSC, ASRS, FDA MedSun and ASTERD, NTSB, and PSOs as well as the possibility of a health IT safety administration. Additional analysis is required. The current reporting pathway often does not facilitate timely resolution. Broader access to safety and performance data to enable timely improvements was emphasized.

Specific recommendations to date are:

> HIT should not be subject to FDA premarket requirements, except: medical device accessories (to be defined clearly by FDA); certain forms of high risk CDS, such as Computer Aided Diagnostics (to be defined clearly by FDA); and higher risk software use cases, including those where the intended use elevates aggregate risk
>
> 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
>
> To develop better post-market surveillance of HIT, through a provisional, collaborative process with stakeholder participation, including spontaneous reporting, post-implementation testing to ensure key safety-related decision support is in place, and allowing for aggregation of safety issues at the national level, including federal support.

The workgroup members had many opinions on what a new regulatory system should and should not do. For one, a new framework must establish national accountability and local accountability. The former must include:

- Outcomes assessment rather than product definitions
- National and international standards for quality process—measureable and transparent
- National interoperability standards to lower the entry cost through full participation of affected stakeholders
- 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 and accountability must include:

- Design, document, and prove a local control system
- Accreditation of the software implementation process, e.g., through an entity such as JCAHO
- Scope
- 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

Whatever the current deficiencies, Bates concluded that the current approach is not compatible with a learning system. Finally, he concluded with 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
- The agencies should address the deficiencies, ambiguities, and duplication the FDASIA group has identified
- New frameworks 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 and 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
- As recommended by the IOM Committee, 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 and better post-market surveillance of HIT is needed
- Standard formatting of involved reports
- Post-implementation testing
- Approaches 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

Discussion

Scott Gottlieb commented that in framing FDA authority to regulate "certain IT," the workgroup needs to think about what is and is not a medical device and when a device is used as not intended and, therefore, does not come under regulatory purview. There are challenges. He presented an argument for low-risk use not being a medical device and, therefore, not under FDA authority. He suggested that Bates go back and examine what is and is not a medical device. Someone said that the statute is broad. A scheduling system is not a device. Mostashari said that Gottlieb was referring to what is out-of-scope. Gottlieb and Bates agreed that ambiguity should be reduced. Mostashari instructed Bates to be clear about what is in-scope and then to apply risk assessment.

Jodi Daniels, ONC, recognized the presence of representatives from FDA and FCC. Paul Egerman noted that in comparing FDA and ONC approaches, it should be recognized that certification is voluntary, a fundamental difference. Certification must be completely objective, which requires exact prescription. It is important to differentiate anecdotes and data. Bates observed that ONC certification is not exactly voluntary since it is required for payment. It is important to acknowledge that inferior products can be certified.

Josh Sharfstein emphasized actual harm as when something seriously goes wrong. What about the free flow of information? How does one know this is happening? Bates described the Australian safety data base and its identification of a ventilator problem. The data base is publically accessible with spontaneous reporting. A representative from the FDA described several mechanisms for receiving information on potential problems with medical devices. Among others, there is a hospital system that can be queried and pilots to identify problems via health IT. FDA is going toward a national surveillance signal notification system. The system will link an occurrence signal with a way to address it. The UDI system will link a device with patient experience for rapid identification of problems.

Mostashari stated that he wanted to make sure members understood that ONC works with FDA to coordinate. There are strengths of both approaches. One goal of Congress is to look at what else is there and how can the gray areas be approached. He told Bates that he expected something on gray areas: Did the Taxonomy Subgroup consider that? Bates acknowledged that it had not.

Gayle Harrell was concerned with duplication of reporting. She wants a formal mechanism for coordination across agencies with someone being ultimately responsible. The FAA uses voluntary reporting, which may result in near misses. Concerns with liability may restrict getting a complete story. Perhaps there are ways to protect reporting from liability. Bates said that the workgroup members agreed on the need for coordination, but they said the agencies should work out the mechanisms. Liability limitations have yet to be considered.

Judy Faulkner referred to slide 39 and higher risk software and wondered about a definition. Regarding the reference to computer-aided diagnosis, she declared that computer anonymous diagnosis is a better term. What is dangerous? An incorrect claim may result in harm as can a malfunctioning scheduling system. She continued to raise issues. The incentive program may cause providers to opt-out of providing care to Medicaid and Medicare recipients. Being so busy with meaningful use inhibits vendor innovation. Reports do not necessary indicate serious problems.

Mostashari referred to local flexibility and slide 45. With some HIT, it is difficult to isolate what is imbedded within culture and context: Is that a taxonomy issue? Bates said that many HIT problems are caused by not following good implementation procedures. Mostashari pointed out that hospital safety is regulated.

Charles Kennedy referred to slide 11 and product types. He talked about the use of claim data in clinical settings. The agreement of claims and clinical data varies by diagnosis. FDA indications for use of drugs affect malpractice cases: Did the workgroup consider malpractice? Bates agreed with Kennedy's first point. He responded that the workgroup did not discuss malpractice. Perhaps they can consider the topic during future meetings.

Paul Egerman pointed out that not all HIT comes from vendors. There is open source and self-developed HIT. Patent policy should be considered. Some argue that software should not be patented because it is essentially based on business processes. Bates acknowledged that not all software comes from vendors although most HIT software today comes from vendors. Gottlieb said that legislation may be required to resolve ambiguities. Going back to the regulatory agency with adaptations should also be considered.

Devin McGraw complimented Bates on his leadership and that of the members. It is important to have guidance on innovation. Bates said that the workgroup's next steps will be to review the HITPC comments and members' feedback on today's slides. Final recommendations will be submitted at the September meeting.

Mostashari told Bates to have the Taxonomy Subgroup do more work on characteristics, to consider reporting to patient safety groups, and to focus on areas that increase both safety and innovation, such as interoperability. More depth is needed. He also wanted consideration of small scale testing in protected, tested environments.

Privacy & Security Tiger Team Query/Response and MU Stage 3 Security Risk Assessment Update

Co-chairperson Paul Egerman began the presentation of the final recommendation on non-targeted query. He went over the backstory. In April, the HIT Policy Committee approved recommendations from the Tiger Team on targeted queries for treatment, aimed at creating an environment where providers can have reasonable assurance for responding to external queries, consistent with their professional, ethical and legal obligations. Those recommendations also included additional recommendations for non-targeted queries, including providing individuals with meaningful choice on listing with an aggregator. In May, the tigers followed up those recommendations with a preliminary conclusion that the overall query recommendations were sufficient to address non-targeted queries as well. The HITPC responded stating that it would like further deliberation, recommending that the Tiger Team hear from practitioners in the field on the state of non-targeted query for treatment, and then reconsider the recommendations. The recommendation today re-affirms previous conclusions. Following up on the HITPC's direction to collect more information from practitioners, the tigers organized a virtual hearing with eight persons identified as having organizational experience with non-directed query. After deliberating on key themes from the hearing, the tigers reaffirmed that the previous recommendations, initially considered in the context of targeted query, also apply to non-targeted query. The testimonies indicated the great care and effort the HIEs took in crafting policies and operations that worked for their particular communities. Should conditions change in the future, the recommendations can be revisited.

Chairperson Deven McGraw methodically reviewed the relevant HIPAA requirements and the previously accepted recommendations, which, in summary, said that data holders may be reasonably assured of a requester's identity through, for example, the use of DIRECT certificates, or membership in a trusted network or a pre-existing relationship. In addition, the data holder may be reasonably assured of a requester's treatment relationship with a patient if, for example, there is prior knowledge of the relationship, the relationship can be confirmed within a network, or if the requester provides some communication of consent. She emphasized that they determined that additional policies were not needed for non-targeted queries. The existing recommendations on meaningful choice and targeted query are sufficient in addressing non-targeted queries. McGraw also talked about key themes from the hearing. Access to each of the eight networks is controlled to members who have executed some sort of participation agreement. Each network provides patients with some choice; most are opt-out but some are opt-in. For sensitive data, most depend on the data partner to withhold data requiring additional consent, or other types of sensitive data. One network made Part 2 (substance abuse treatment data) available in the HIE (but only to providers who specifically request it, subject to a second consent from the patient, and subject to a second attestation of a treatment relationship, with a reminder about re-disclosure limits). In many networks, patients who have concerns about access to sensitive data in the HIE are counseled to opt-out (or not to opt-in). Many of the networks have role-based access levels for participants. All networks do audits of access and disclosures, but only some make the information directly available to patients. None do an override of patient consent. All networks limit access to certain purposes—treatment is common to all; many others also allow for operations and public health reporting purposes; a couple

allow for payer and payment access. Most have some either inherent or express geographic limits. Testifiers expressed some concern about having federal policy potentially disrupting the arrangements they had carefully implemented; however, most expressed a desire for some guidance or common agreement terms that would help facilitate network-to-network (or HIE-to-HIE) exchange, and additional guidance on how to handle sensitive data.

McGraw went on to report on another topic—the question: What, if any, security risk issues (HIPAA Security Rule provisions) should be subject to meaningful use attestation in Stage 3? Instead of selecting additional HIPAA Security Rule provisions for emphasis in Stage 3, she explained that the tigers want to improve accountability for complying with the existing meaningful use security measures – in particular, the requirement to perform a security risk analysis and correct identified deficiencies. The following recommendations were presented to strengthen security risk analysis:

> For Stage 3, CMS should emphasize that when an entity attests to having conducted or reviewed a security risk analysis with respect to its certified EHR technology, the entity is attesting to compliance with the HIPAA Security Rule with respect to such analysis.
>
> To achieve compliance with this objective, entities must: conduct a security risk analysis or review an existing risk analysis and document the results of the risk analysis or review, including the actions taken (or the schedule for actions planned to be taken) to correct any deficiencies identified during the analysis or review.
>
> Add an accountability measure, requiring entities to identify the individual(s) who is/are responsible for conducting and documenting the risk assessment.
>
> Link attestation to specific meaningful use objectives, rather than present as a single, standalone measure. Specifically, require attestation that a risk analysis has been performed on any new functionality provided as a result of deploying the 2014 or subsequent meaningful use criteria. (Those for 2014 focus on exchange and interoperability between organizations, and consumer engagement.) Such an attestation would indicate that the entity had complied with the HIPAA Security Rule by performing the required analysis and documenting the results, including correction of identified deficiencies.
>
> CMS should provide additional education, such as FAQs, to the meaningful user community on the expectations and importance of conducting and documenting security risk analyses and correcting deficiencies. For example:
>
> - Expand FAQs to discuss the availability/use/benefits of third-party assessment tools and services, and of risk analysis checklists, particularly those developed by the regulators.
> - Expand FAQs to clarify that a component of the risk analysis process includes the requirement to correct any deficiencies that impact compliance with the HIPAA Security Rule
> - Highlight also (for larger entities with the requisite resources) the option and value of having internal auditors leverage OCR's audit program protocol to conduct substantive pre-audits.

Discussion

Regarding non-targeted query, Tang asked what happens with queries outside of trust arrangements and crossing between opt-in and opt-out organizations. Advising patients with privacy concerns not to opt-in indicates there is a concern. How does the recommendation reconcile with the report that the panelists wanted guidance? McGraw responded that a mechanism for nationwide query does not currently exist. Some sort of a network is a prerequisite to query. Recommendations should not be made in the absence of

a defined problem. She acknowledged that Tang's questions may be relevant at some future time. Egerman reminded them of the recommendation for meaningful choice per being in an aggregator. Once the choice is made, the recommendations do work. Mostashari remarked that the conversation is similar to the one about standards. People implement in different ways. Once outside the local environment, one must be more specific in order to exchange. One can start with a broad framework and over time, become more specific.

Harrell talked about trust among organizations and the governance structure of HIE. She noted the importance of governance although there is no longer a workgroup on that subject. Mostashari referred to other ONC activities on governance. Harrell said that the data holder has lots of responsibility and governance establishes that trust.

Staley referred to opt-in and opt-out: What about a standardization of one or the other over time? Egerman and McGraw informed her that subject had been addressed in August 2010. Meaningful choice requires that patients understand the choices. Staley asked whether meaningful choice follows the patient. McGraw replied that the recommendations are very specific on where choice applies. They apply in those circumstances in which the provider no longer exercises control, such as when an aggregator is used. Staley wondered about a patient seeing who has requested her data. Egerman responded that that is the next issue to be addressed by the tigers.

Mostashari asked about data holders not having control over data: What was the use case? Egerman said that before EHRs, record holders had policies on release of information. With aggregators, providers may not have control. Mostashari said that he could imagine contractual or business relationships that eliminate providers' control over release policies. He acknowledged that he agreed with the spirit, but sometimes providers themselves do not have meaningful choice. The principle extends beyond the architecture to when the provider does not have a choice about the policies.

Joy Pritts, ONC, announced that materials to assist providers in helping consumers to understand and make choices will soon be released. Tang said that someone should give examples of situations in which providers do not have meaningful choice. He called for a vote on acceptance of the recommendation of the Privacy and Security Tiger Team that no additional policy on non-directed query is necessary at this time. Members voted unanimously in favor of accepting the recommendation.

Action item #2: The recommendation on non-directed query was approved.

Christine Bechtel asked about attestation of security risk assessment linked to objectives. McGraw explained that the recommendations on security risk assessment did not imply that every meaningful use requirement have a risk assessment, only when a new risk was to be introduced. The Tiger Team did not go through all of the objectives since the Stage 3 objectives have not yet been ruled. Bechtel asked about the interaction when objectives change. McGraw talked about an additive effect, saying that the assessment should not be a check-the-box. Bechtel indicated agreement with the concept, but questioned the process. Pritts interjected that the requirement for an across-the-board assessment would not change. But certain aspects would be called out for attestation. McGraw reiterated that an overall risk assessment is required. Mostashari asked whether the attestation would be done within the 90-day reporting period. Egerman indicated that it would have to be completed by the end of the 90-day period. He reported that the tigers felt very strongly about the need for these assessments. Mostashari instructed them to give CMS more information. Pritts declared that the recommendations were consistent with current requirements. Tang called for a vote on acceptance on the recommendations. A voice vote resulted in unanimous acceptance.

Action item #3: The recommendations (listed above) of the Privacy and Security Tiger Team on Stage 3 security risk assessment were unanimously accepted.

Public Comment

Richard Eaton, Medical Imaging and Technology Association (MITA), Arlington, said that his organization represents manufacturers of imaging devices. Bates' report represents the collaboration of many stakeholders. Any success must be attributed to collaboration. The effort should not cease with the report to congress. In this very complex environment, a balance of multiple goals is required. He made a plea for continuation of the process, saying that MITA supports the effort.

Mark Savage, Consumer Partnership for eHealth, asked the committee to support his organization's disparities action plan. He distributed materials.

Chantel Worzala, American Hospital Association, asked the committee to consider the pressing issue of the 2014 time crunch. All EPs and EHs must change to 2014 certification plus meet the new stage 2 requirements. October 1, 2013 is the start date for EHs. Yet only nine complete EHRs have been certified for EHs. Hospitals are reporting many delays in implementation and transition to ICD 10. Rushed implementation will have bad results. She referred to the July 23 letter co-signed by the AMA that made specific recommendations for stretching out the timeline. She strongly encouraged the HITPC to address those recommendations. The three-minute time limit was called.

Data Update

Robert Anthony, CMS, presented slides summarizing the most recent information on registration and attestation. There are more than 405,000 active registrants. Nearly 90 percent of EHs are registered; about 80 percent have received payment. 75 percent of EPs are registered; 58 percent received payment. About 61 percent are non-primary care EPs. 68 percent of Medicaid EPs have received payment. He noted a small drop in payments in July, similar to previous years. In response to a question about the core exclusions slides, Anthony told Mostashari that he would have to get back to him with more explanation. More information is available at cms.gov. Members had no questions.

Jennifer King, ONC, reported on progress on EHs, repeating some of Anthony's report. Nearly two-thirds have attested; 17 percent have received AIU payment. Over nine in 10 are engaged. 70 percent of EH beds have been attested to meaningful use. Since December 2010, the percent of hospitals not engaged with EHR Incentive Programs or Regional Extension Centers (REC) has dropped to about 10 percent with variation in hospital size and urban-rural location. About 16 percent of small urban hospitals are not engaged. For other hospitals, non-engagement is about 5 percent. As reported by Anthony, about 40 percent of EPs have attested, 56 percent of Medicare EPs and 12 percent of Medicaid EPs. A strong spike in attestation and engagement was observed at the end of 2012. Among EPs, little urban-rural difference was observed. Broad engagement is the experience.

Q&A

Referring to small urban hospitals, Mostashari speculated that their lower level of engagement may be due to REC being specifically directed to engage with CAH. Most likely, a rural gap would have existed without REC.

Harrell expressed concern with engagement of urban hospitals, saying that this was the first report to describe rural-urban differences. What other variables (in addition to Mostashari's speculation) might explain the variation? Location? Size? Ownership type? Can ONC expand REC engagement? King replied that she can examine those variables. In general, not-for-profits have a higher attestation than do for-profit hospitals. It is not known whether this is true for small urban hospitals as well. Mostashari reminded Harrell that no resources have been allocated to expand RECs.

According to Anthony, CMS is investigating the causes of deferrals. Theresa Cullen asked about the capability for exchange. In Stage 2, the bar will be raised; more information dissemination is necessary.

Mostashari referred to an article in *Health Affairs* about the need to make sharing information with partners profitable. Anthony reported that deferrals on the exchange objective have declined.

Meaningful Use Workgroup Update on Stage 3 Recommendations

Chairperson Mostashari called on Tang, in his role as chairperson of the Meaningful Use Workgroup. Tang reiterated that the Stage 3 goal is to improve outcomes. He showed slides that repeated the original principles for meaningful use and lessons learned from Stage 1. Additional goals for Stage 3 are:

- Address key gaps (e.g., information exchange, patient engagement, reducing disparities) in EHR functionality that the market will not drive alone, but are essential for all providers
- Simplify objectives where higher level objective implies compliance with subsumed process objectives
- Consider alternative pathway where meeting performance and/or improvement thresholds deems satisfaction of a subset of relevant functionality implicitly required to achieve performance and improvement

George Hripcsak, co-chairperson, explained simplification and consolidation. He reported that after vendors reported that consolidation sometimes made their work more difficult, the members reexamined what had previously been done for consolidation. They reviewed items consolidated and categorized them into removal; removal as a use requirement; no reporting requirement, but there is an expectation that it will continue to happen; and consolidated with another item and it needs to be measured. He showed slides and described the changes in Subgroup 1's objectives since the previous presentation—113, 116, 117, 118, 120, 121, 122, 123, and 104.

Tang showed slides and described changes under Subgroup 2—204, 205, 206, 207, and 209. Changes by Subgroup 3 (improving care coordination) were described by Tang—302, 303, and 304, 127, and 125. Hripcsak reported on the public health objectives and the changes in 401, 402, and merged registries (404, 405, and 407).

Tang reported on deeming for which the following were assumed:

- Providers have already met all functional objectives in Stages 1 and 2
- Effective use of HIT can reliably assist in the achievement of good performance (or significant improvement)
- To promote innovation, reduce burden, and reward good performance, deem high performers (or significant improvers) in satisfaction of a subset of objectives as an optional pathway to qualifying for meaningful use
- CMS selects appropriate outcomes-oriented CQMs as deeming performance measure and may have to contract for appropriate measures to be developed

Deeming would be demonstrated in one of three way: high (top quartile); improved performance (20 percent reduction of gap between last year's performance and the top quartile); and reduction in disparities over a 12-month period. Providers anticipating that they will participate in the deeming pathway are advised that the deeming program uses the prior year's performance as the baseline for determining improvement in performance. Specialists may have fewer options for deeming as determined by available NQF quality measures. If not able to report on at least four performance measures, they may not be eligible for the deeming pathway. Additionally, since effective use of HIT is an enabler for many of the CMS performance improvement programs, the workgroup recommends that qualification for meaningful use in a given year should be deemed partial satisfaction of other CMS programs (e.g., ACO, PCMH, eRx, CPCI, PQRS).

Tang went on to say that the workgroup will discuss timing of Stage 3, but not Stage 2. A tiger team has been formed to examine readiness of quality measures and will report in October.

Discussion

Mostashari reiterated that Stage 3 will focus on outcomes and improvement. Presentation of the requirements is important to show people how requirements will affect outcomes. The presentation should start with why—the outcomes, and work back to the contributing factors. The workgroup's product does not sufficiently signal the goals. Tang responded that the workgroup members certainly understand the relationships among the measures and outcomes. Better measures are needed to know how well providers are performing. This is setting up the framework and incentives. Intrinsic rewards also drive performance. Mostashari asked whether deeming must come from EHR measures. Tang talked about changing the medical model, which is out-of-scope. But at least things that matter can be measured.

Hripcsak talked about constructing a narrative to explain the matrix. Some objectives may fall out if they cannot be justified in the narrative. Tang talked about an intermediate step of tools to outcomes.

Egerman announced his agreement with Mostashari. Referring to slide 46, he wondered how enrollment in clinical trials relates to outcomes. Tang corrected Egerman, saying that nothing was said about enrollment. The idea is to provide information. Advancement and application of science is the goal. That is the logic. Egerman then observed that the hearing brought out a bloat-ware problem. If the focus is on outcomes, why does not certification do the same? Hripcsak suggested looking more closely at the certification criteria.

Bechtel declared her support for Hripcsak's idea of a narrative. However, rewards and penalties are the only things that will change behavior. Now patients expect to have PHRs.

Faulkner compared the draft recommendations with the unintended changes that result from the introduction of a new species in an environment. Only 5 percent of EPs sent secured messages. She heard that providers insist on patient visits for giving important information. She also heard about EPs having raffles to encourage patients' e-mail. She suggested obtaining more input from providers and developers for a reality check. For instance, the preliminary recommendations for CDS indicate that many new things that are not simple to do will be added. There are better ways to do (122) order tracking, such as alerting patients to take responsibility. All of this requires much more review by knowledgeable persons before its use. She went on to complain about not having received some of the meeting materials in time for review. If recommendations are to be acted on at the August meeting, she requested receipt well in advance of the meeting.

Mostashari pointed out that there will be no rule-making in 2013. HITPC does not make the rules. He suggested taking a step back and acting on the narrative suggestion. Refactoring should be considered. He indicated that he will discuss the approach with colleagues. Tang told Faulkner that her company's product does all of the recommendations for CDS. The point is to set a floor of tools.

Harrell announced that she, as well as providers, is overwhelmed. She voiced concern that products are not ready. She also complained about getting materials on the morning of the meeting without sufficient time to review. Someone needs to look at the entire picture and how meaningful use can coordinate and integrate with other programs. She questioned how outcomes for specialists would be improved. Much more discussion is needed. Mostashari agreed. Providers are just now gearing up for Stage 2. CMS and ONC want to signal for Stage 3, but the signal must not be unnecessarily overwhelming and discouraging to providers and vendors. Harrell observed that evaluation has been overlooked. How are the measures actually affecting outcomes?

Charles Kennedy talked about deeming for ACOs. His organization generates efficiency and effectiveness models to shows what an ACO must do. Although claims based data are used, the model can help a delivery system become an ACO. Technology is more of a mechanism; many of the quality measures and meaningful use requirements are treated as things to do to get paid rather than drivers of strategy. Most ACOs value the claims data as being as important as or even more important than clinical data. Deeming that is tied to a business model will be more effective. He recommended even more flexibility than offered with deeming. He acknowledged that the quality measures align somewhat with ACOs, and suggested firming up the alignment. Mostashari said that CMS officials desire harmonization as well.

Cullen cautioned against creating fear. This is a dialogue stage. She acknowledged that she was intrigued by deeming because the focus is on outcomes.

Bechtel said that the workgroup should ask ONC staff to help with the implications of timing and changes to the schedule. Stage 2 is the most difficult stage. She wanted to keep the focus on Stage 3. Input from CMS on other programs is needed to understand the relationship across programs and the effect on payments. Providers need meaningful use tools to perform. Mostashari said that it needs to be made clear that meaningful use is what is needed to succeed as an ACO. Tang explained that he wanted to respond to people wanting to know in advance what will be required.

Mostashari declared that thresholds do not matter that much. Reports indicate that few providers are on the cusp of a threshold. A lot of time was wasted in talking about thresholds. Change in the workflow is the critical factor. He told Hripcsak that objectives with specific numbers were not productive; they encourage check offs.

Harrell talked about the change in payment models being the main driving force. CMS staff should inform the discussion. Although there may be coordination, it must be articulated.

Information Exchange Workgroup (IEWG) Update

Chairperson Micky Tripathi, IEWG, reported that the workgroup had recommendations on provider directory and data portability. At the July HITPC meeting, the provider directory recommendation was approved, but the HITPC asked the workgroup to revisit its principle on authentication. The workgroup members invited S&I Framework staff for a discussion, and as a result, reaffirmed its recommendation to include the capability for authentication, and further amended the recommendation to also require authentication of the provider directory-holding entity (i.e., not just the requesting entity). The recommendation aligns with the S&I approach, which already included authentication of data source. It will protect against spoofing of provider directories. The recommendation is solely about the *capabilities* that certified EHR technology should have. They are not recommendations about use. The recommendation is not a policy requirement that authentication should be used.

Tripathi paused for questions. None were heard. He continued with the two additions or clarifications. One was in the recommendations under transactions and stated that querying systems must have the ability to validate authenticating credentials of a provider directory-holding entity. The other addition is that provider directory must have the ability to present authenticating credentials to the requesting entity. Chairperson Mostashari ruled that this was a clarification to recommendations that were previously approved. Therefore, a vote was not required.

Tripathi moved to data portability. He referred to two use cases: provider-centric, when a provider switches from one EHR vendor system to another, and patient-centric, when a patient requests migration of records. Demand for portability across vendor systems is expected to increase. Currently, portability is an ad hoc process that is highly variable and fraught with potential for errors and lack of continuity in medical record completeness. A standard for data portability would set a common baseline for medical record continuity that will be vital as the EHR user base grows and matures, and the industry comes to

increasingly rely on electronic medical records and meaningful use-related EHR functions. Although needs are expected to vary locally, setting a floor will inspire greater market dynamism by lowering barriers for providers and patients, and promote safety and continuity of care by reducing opportunities for errors.

Egerman asked how portability related to information exchange. Tripathi reported that the HITPC had asked the workgroup for recommendations. Mostashari said that high switching costs are a frequent cause of market failure. There are also safety and continuity of care issues.

Tripathi presented the recommendations:

> EHR systems have the ability to electronically export and import medical record and administrative information across EHR vendor systems to enable migration of patients' records without significant or material loss of clinical or administrative data.

He recommended that the following principles be used for establishing requirements and standards for data portability across EHR vendor systems:

- Consistency: build on the CCDA approach in alignment with general HITECH direction. Perhaps consider CCDA templates specific to "Cross-System Data Portability"
- Content: encompass all clinically and administratively-relevant information that can be reasonably transferred across systems without loss of essential patient, clinical, and administrative context or meaning
- Add flexibility: allow user-configurable setting of time period to cover legal medical record retention requirements as well as to support look-back periods for decision support, CQMs, and care management (e.g., last 10 years only); allow user-configurable setting to create CCDAs based on a particular encounter and/or types of encounter (e.g., face-to-face visits but not telephone encounters); and allow export and import of a single patient in order to facilitate patients bringing "their entire record" with them (e.g. to a new PCP)

Discussion

Mostashari asked how migration is done today. Tripathi described a wide range of approaches from print and scan to enterprise transport in which the receiving and sending systems can migrate structured data. Due to customization, the latter is unlikely. Mostashari referred to the EHR Association's code of conduct, wondering whether vendors have a standardized approach for making data available to providers. Tripathi replied that he was not aware of a standardized approach across vendors. Each probably has its own standard way, but in practice even that will vary.

Egerman stated that he was uncomfortable with the recommendation because of the focus on design. A better approach would be to look at how receiving systems can consume data. Such an approach would create building blocks by focusing on consumption as a component of exchange with portability as a byproduct. Tripathi agreed, saying he meant exactly that when he referred to consistency. Mostashari talked about the CCDA approach being a step backwards for migration. Tripathi said that open publishing of schemas would be another approach: But is that realistic?

Faulkner said that it is hard to be portable when an element is structured in one product and unstructured in another. She urged caution in specifying what should come over in portability. There are reasons for doing things in a certain way.

Cullen referred to Egerman's statement. The need to consume is critical. Portability should be part of information exchange. The VA is struggling with the topic. More work is needed. Tripathi acknowledged that the HITSC will have to deal with standards. Tang said that advice from HITSC should be obtained

before acting on the recommendations. Egerman opined that the recommendation is not necessary. One way for portability should not be specified. He emphasized that he was questioning whether the recommendation was doable or necessary. He repeated his suggestion about a focus on consumption. Tang asked Faulkner and Cullen to state their reasons for objections. Cullen replied that sufficient information was lacking. Faulkner agreed with Egerman. Many mergers and acquisitions are occurring. Tang asked whether the next step should be to get more information or not to accept the recommendations. Claudia Williams, ONC, said that she understood the purpose of the recommendation was to enable more coded data to be moved, not to solve everything in portability. Tang ruled that there was no consensus on approving the recommendation as presented. He told Tripathi to seek information from HITSC.

Staley asked about the patient's access to information when mergers and acquisitions occur. How can the patient determine the correctness of the information being moved? Tang said that under VDT, the patient can examine the information. Bechtel declared that was not a great solution. Patients should not have to be responsible. The patient would have to know that migration had occurred.

Someone pointed out that portability and migration are different. Portability is letting the patient take her data. Migration depends on the specialty. Members should clarify their vocabulary. He said that the EHR Association code of conduct needs clarification as well. Faulkner suggested getting information from the EHR Association. Tripathi agreed to follow-up with the IEWG.

Public Comment

David Howell, from a lab organization, reported that there are very few certified vendors and products for the 2014 Edition. CHPL lists only 136 products (Amb + IP), only 21 complete EHRs; and 14 complete EHR vendors (8 amb + 6 IP). In contrast, the 2011 Edition has 4,431 products, of which 2,023 are complete EHRs. This difference in availability of certified products indicates the difficulty vendors will have meeting the 2014 bar before the start of Stage 2. What percentage of hospitals and providers, using their current vendors, will be unable to attest 2014? Careful analysis should be given to these stats and trends. He suggested working with the ACBs to understand the pipeline for additional product certifications for 2014. The information should inform decisions about requirements for Stage 3.

SUMMARY OF ACTION ITEMS

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

Action item #2: The recommendation of the Privacy and Security Tiger Team on non-directed query was approved.

Action item #3: The recommendations (listed above) of the Privacy and Security Tiger Team on stage 3 security risk assessment were unanimously accepted.

Meeting Materials

- Agenda
- Summary of July 2013 meeting
- Presentations and reports slides
- Unsolicited submission from Consumer Partnership for eHealth