HIT Policy Committee
FINAL
Summary of the May 6, 2014 Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 59th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment (limited to three minutes per person), and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking and recognized new ex-officio member Chesley Richards, representing the Centers for Disease Control and Prevention (CDC). Members introduced themselves.

Remarks

National Coordinator and HITPC Chairperson Karen DeSalvo thanked the members for sending feedback on the proposed re-organization of the workgroups. Staff is continuing to design the new structure. Staff is drafting standard operating procedures for the HIT FACAs.

Review of Agenda

Vice Chairperson Paul Tang thanked the three retiring members of the committee: Art Davidson for representing consumers and public health; Neil Calman for vulnerable populations; and Judy Faulkner, who represented vendors. DeSalvo presented certificates of appreciation signed by the secretary. Tang said that the retired members may continue to serve on select workgroups. GAO has announced the new members: Kim Schofield – consumer representative; Christoph U. Lehmann – vulnerable populations representative; and Neal Patterson – vendor representative. Tang 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 and received a motion to approve the summary of the April meeting. The motion was seconded and approved unanimously by voice vote.

Action item #1: The summary of the April 2014 HITPC meeting was approved.

Data Review - ONC Update

Jennifer King reported on early findings from the American Hospital Association health IT supplement survey conducted late 2013, which had about a 60 percent response rate. Non-federal acute care hospital adoption had increased more than 500 percent since 2008. Adoption varied by functionality from 10 percent adoption of the outlier VDT to 97 percent for recording vital signs. Overall, the Stage 2 functionalities had a high adoption rate. Adoption of select patient engagement functions varied, from a low in transmitting information online to approximately 90 percent of adoption of receipt of eCopy of discharge summary and eRecord. Although many EHs had adopted most Stage 2 functionalities, few had

adopted all of them. EH size, type, and location continue to affect adoption rate. King turned to slides on the status of 2014 Edition certification, emphasizing that the data should reflect certification only, not vendor roll-out or provider implementation. She estimated that 76 percent of EHs can upgrade their existing products to the 2014 Edition in order to meet 2014 requirements and that another 19 percent can do so by purchasing new products from existing vendors. The estimates were based on products EHs used to attest merged to the Certified Health IT Products List to obtain information on whether 2014 Edition versions of the products had been certified as of April 18, 2014. Estimates reflect certification status only and do not reflect vendor product roll-out or implementation timelines. EH size, type and location had limited effect on the estimates, which ranged from 70 percent of small urban EHs that should be able to upgrade existing products to 78 percent of medium-sized hospitals. However, 9 percent of small rural and 7 percent of small urban hospitals do not have 2014 Edition products available from their current vendors. She said that differences are decreasing from past years. Turning to EPs, she reported that 78 percent used products with 2014 Edition versions certified as of April 2014 and 17 percent do not have 2014 Edition products available from their current vendors. Considerable variation by type of EP was shown on one of the slides. King concluded saying that at the June meeting she will present a comprehensive analysis of three years of the EHR incentive programs.

In response to a question, she indicated that there is greater concentration of vendors on the hospital side compared to EPs. One of the slides showed that radiologists, pathologists and anesthesiology may have somewhat less access to 2014-certified technology in comparison to other medical specialties, and podiatrists and chiropractors even less. Nevertheless King concluded that there was not much disparity in vendor specialization and its effects. In addition to objecting to the categorization of dentists, optometrists, podiatrists and chiropractors as non-physicians, Troy Seagondollar asked what is being done to fix these differences. King said that RECs are informed of the data. CAHs have made great progress in closing the gap with other hospital types and are a priority for RECs. Paul Egerman referred to slide 6 and adoption rates. King confirmed that adoption of a functionality reflects installation and not necessarily use. http://dashboard.healthit.gov/
http://www.healthit.gov/sites/default/files/oncdatabrief17_hieamonghospitals.pdf

Data Review - CMS Update

Elisabeth Myers showed slides and presented the standard report. Through March 2014, nearly12,500 new registrations occurred. Ninety-five percent of EHs have registered and 91 percent have been paid. Sixty-eight percent of EPs have been paid. Through April, 225 EPs attested for the 2014 reporting year, of which 61 are new participants and 50 attested to Stage 2. Thirty EHs have attested for 2014; eight are new participants and four attested to Stage 2**.** Regarding hardship applications, 72 EHs applied and 66 were granted. The remaining applications were dismissed as having been unnecessary. Six hundred EPs have submitted hardship applications to date. EPs have until July 1, 2014 to apply.

Egerman pointed out that only four EHs have attested to Stage 2, although according to King's report, they have the certified software: What can be said about the success or failure of the program? Myers responded that the data are not sufficient to draw conclusions. Furthermore, she indicated that she was restricted from discussing any possibility of changes to Stage 2. She admitted that the hardship application form caused confusion. The form has since been changed. King referred members to the ONC website and dashboard for more information and the most recent data brief (http://dashboard.healthit.gov/
http://www.healthit.gov/sites/default/files/oncdatabrief17_hieamonghospitals.pdf). In response to a query from Marc Probst, Myers repeated that the deadline for EH hardships for application has passed. The EP deadline is July 1, 2014.

2015 Edition NPRM Comments - Certification and Adoption Workgroup (CAWG)

Co-chairperson Larry Wolf showed slides and presented overall comments. Although the workgroup supports easing the burden of regulations and having a more incremental process, many of the proposed changes do not seem to support that goal. Certification is not the appropriate avenue to explore innovations. Certification is often prescriptive and overly burdensome. In and of itself, it will not incline technology developers to enter the field. In order to support and stimulate development of HIT, ONC could, for example, provide a roadmap, continue its efforts with the S&I Framework, support pilot programs and build on innovations in the marketplace. Software development and certification costs; provider implementation, training and rollout costs; and ongoing use, maintenance, support and service and subscription costs must all be considered. He referred back to the five-factor framework, saying that it should be applied to certification. Regarding its lack of support for the proposed incremental process, the workgroup members cited several issues. As a regulatory process, certification involves long-time periods and significant testing costs. Certification should not use Version of standards or new functionalities. Before certification is proposed, significant operational usage, not just pilots and balloting, should be required. Mandated standards can actually interfere with consensus-driven stakeholder standards development because less careful consideration is given to feedback and input once adoption of the standard is a given. The frequency of regulatory updates makes it difficult for vendors and providers to keep up. If ONC chooses to pursue incremental rule making, the CAWG believes it should *only* make: incremental certification program updates; minor technical updates and fixes—including minor updates to referenced standards, vocabularies, and data definitions; and error corrections. For all other items, an RFI or ANPRM is better suited. The workgroup failed to reach consensus on the proposal to discontinue the Complete EHR, noting that the purpose of a Complete EHR is to include everything that is needed for meaningful use under one certification. Wolf acknowledged that the discussion had occurred in the absence of representation from the certifying bodies, hence with a lack of relevant information. The workgroup asked ONC to consider the following: continue to have a concept of a complete EHR; single versus multiple certifications, separate process for CQMs, value in modular certification, value in components that work well together, and indicate if certified as modules, but not sold separately. Finally, what would be the result if Complete is discontinued? Wolf went on to explain that members agreed that the current Complete EHR definition was not appropriate, saying that the current definition does not represent Complete, will continue to be a growing disconnect, and is inconsistent with what is minimally necessary to meet the CEHRT definition. In addition, the current definition presumes that elements of a Complete EHR are well integrated although there is no testing for integration and providers may still have to purchase multiple products that do not function well together. Members believed that there needs to be some way to easily convey that a product has everything needed for meaningful use, either by using the complete label or finding a new name for it. Regarding single or multiple certifications, one vendor representative opined that certification is or will be more burdensome and costly if there were no Complete EHR certification. When a vendor needs to apply for certification and is using a complete EHR, there is only one set of paperwork and one charge, but with an EHR Module, there is repetitive paperwork. Unless EHR vendors can apply for all the modules in the same way they used to apply for the Complete HER, it seems the cost will much greater. Providers value components that work well together. This is implied by a complete EHR although depending on the actual construction of the EHR, it might not be well integrated. Similarly, some modules might work well together even from different vendors. In any case, testing for integration is complex and the workgroup recommended in the past that ONC not test or certify for integration. Vendors may certify components of their product as modules, but not sell them individually. Providers would like the CHPL to indicate if the module is available individually or only in combination with other

modules. If ONC discontinues use of the Complete EHR, it must find a way to effectively represent technology that was given a Modular certification but is complete on the CHPL.

Moving on, Wolf reported that the workgroup did not support the proposal around certification packages. Packages did not address underlying needs of providers. They were more likely to create confusion since the terminology used for packages (care coordination and patient engagement) does not fully represent the breadth of those concepts. Members opined that having more than one transmission criteria for care coordination undermines the concept of standardizing systems that can talk to each other. A fundamental concern is the separation of the transmission process. Packages would be useful for non-meaningful use providers if they are going to be required to have some meaningful use functionality in a grant setting. But it would be better to say these are still module functions, leave them as modules, and then be specific in the grant opportunity as to which module the grantee must have. Putting together care coordination packages is going to be confusing. It is hard to define package titles. For example, what constitutes patient engagement? A singular certification mark would be beneficial for consumers by providing certainty, clarity, and confidence that the product they are buying is certified. However, a singular certification mark might lead consumers to assume the product is a meaningful use product. The proposed requirements for vendors were not clearly stated. In addition, vendors voiced concerns about having to display someone else's logo.

Turning to the proposals for certification of non-meaningful use EHRs, Wolf acknowledged that the workgroup could not determine the impact on the market and the vendor community. Members were concerned that the proposal would create a binary certification program. They preferred conceptualizing the expansion as multi-factor, with many other programs and needs for CEHRT arising. Most likely, the development requirement and cost for non-meaningful use certification are smaller for vendors that are newly developing functionality. However, if a vendor is developing products for both meaningful use and non-meaningful use certification, the cost will likely increase. He pointed out that the term setting was used incorrectly for the Children's EHR and Practice Transformation. These are not settings. Certification continues to grow and requires new features that increase cost and may decrease usability of HIT. ONC should seek ways to manage this complexity. The expanded concept of an EMR ecosystem can create a usability burden on the core EMR functionality. The workgroup understands that a Children's EHR might decrease the patient safety risks of using adult EHRs for pediatrics, and is pleased that HHS has undertaken a trial and evaluation of such technology. However, due to time limitations, the work was not reviewed. Regarding practice transformation certification, it may be too prescriptive and limit innovation in this area. Creating certification criteria and incentivizing use of technology with no evidence it will improve care is risky. Successful operational pilots are required. The workgroup agreed that there was value in collecting disability, sexual orientation and gender identity, occupational, and military data about patients. But the reasons for collecting each of these data elements differed, and are likely not a good fit for a demographics criterion. Their collection raises privacy, implementation, and workflow concerns. If this information is collected, it is important to focus on the capture of data, and not how it is collected or where it is stored. That is, to not predetermine who collects the information and the workflow used. The information needs to be coordinated with CCDA requirements and coded in accordance with the CCDA. Certification for BB+ would be premature at this time. Wolf reviewed a slide that listed the pros and cons of BB+.

Discussion

Tang talked about a different purpose for meaningful use and non-meaningful use certification. CCHIT was created for a general purpose. The meaningful use certification is more of a floor and is not comprehensive. CCHIT fills a marketing enabling purpose. Regulations are the floor to meet a

programmatic need, for example, to enable measurement of disparities. This distinction is relevant to the issue of Complete EHR and applies to other questions as well. Egerman talked at length about the workgroup understanding and confusion regarding Complete EHR. The workgroup did not have an easy task. It worked with strong opinions within a tight schedule. He wished it had focused exclusively on process rather than minutia of content. He noted that Wolf had left out his observation that the NPRM is very difficult to decipherer. It is dense with many references, one of which is not yet published to an IG. How can one comment on something not yet published? Small vendors cannot realistically comment on such a document, which contains much that is new and untested.

Troy Seagondollar referred to slide 11, point 5 on integration, saying that testing should be essential to know whether a product is viable. It is time to start sharing and integrating these data. Wolf replied that his comments referred to the integration of modules. He agreed about the need for clear standards for certification. Customers need to be assured of interoperability. Judith Faulkner exclaimed that the current standards for interoperability are too loose. There are too many standards to test. The number should be reduced.

Deven McGraw asked what action the workgroup expected of the committee. Although she personally agreed that certification should be lean and mean, she sees a role for meaningful use to do what the market has not done. The point is to have meaningful use of certified technology. There is too much in the report to expect consensus. Tang said that the committee reorganization may result in clarified charges. ONC staff was present and heard the workgroup's deliberations. Now ONC officials want a response and direction to the NPRM. Wolf observed that certification can occur in the context of clear policy. But certification to justify cool stuff would not be helpful

DeSalvo noted that although the comment period is closed, she welcomed the members' comments even without consensus. Gayle Harrell exclaimed that from the view of a legislator rule-making must be based on the law. What is the role of certification as specified in the law? HITECH specifies that certified products are required to quality for incentive payments. The purpose of certification is to communicate and exchange information. Rule-making is the implementation of legislation. Jodi Daniel explained about two separate authorities—the meaningful use program and certification of HIT. ONC was given broader certification authority for purposes other than meaningful use. According to David Bates, certification has been good for breadth, such as including public health. But there are deficiencies. Now the point is how to use the records to exchange information.

Egerman said that he was responding to all comments made so far. How much testing is necessary is a policy discussion the HITPC has not had. Much in the NPRM has not yet been used. The unique identifier is totally new. It takes time to find out how these new items work. Certification is not an avenue to promote innovation. It is too expensive. Faulkner opined that meaningful use has helped to establish a baseline. She repeated comments about its limitations. Innovation comes from ideas, sometimes from customers' ideas. DeSalvo said that ONC is fixing the certification process, with attention to the time, cost and burden involved. A hearing on May 7 will receive formal input.

Devin Mann argued that there is a role for policy in innovation. Setting a bar can stimulate innovation. Art Davidson referred to the legislation, pointing out that factors, such as public health and disparities, are not recognized in the market. The public health community is trying to be part of meaningful use by creating the environment to address elements of the legislation. Although a Complete EHR may be ideal, modules can work if they are interoperable.

Tang declared the discussion a rich one, seemingly representative of the discussion in the workgroup. He suggested that members' comments could be appended to the slides. In response to a question from

DeSalvo, Wolf assured her that interoperability was a strong component of the discussion. Egerman referred to data definitions. Wolf acknowledged the importance of capturing demographic variable in coordination with CCDA standards, templates and data sets. Wolf said that he will work with staff to add members' comments to the slides and circulate for final input. The slides will then be forwarded to ONC without a formal recommendation.

FDASIA Update

Tang announced that Bates will lead a select group to respond to the FDASIA report and recommendations. Jodi Daniel, ONC, reported on the FDASIA report. Congress charged FDA, in consultation with ONC and FCC, to develop and post on their respective websites "a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication." She reminded the members that a FDASIA Workgroup was convened under the auspices of the HITPC and chaired by Bates. She reviewed a slide that summarized the recommendations that the HITPC had signed off on and informed the staff work:

- Scope of risk-based oversight should be based on functionality
- Agencies should address current deficiencies, ambiguities, and duplications
- Substantial regulation beyond current FDA regulations is not helpful
- FDA should expedite guidance on mobile medical apps
- Agencies should reevaluate and clarify current regulations
- Implement IOM health IT safety recommendations to create a learning environment
    - Listing of health IT products
    - Better post market surveillance
    - Allow aggregation of safety issues
    - Agencies should discourage vendors from limiting free flow of safety-related information
    - Cross-agency group should establish governance of health IT safety

Following receipt of public comments, officials from the three agencies convened and drafted the draft report. They grouped IT functions into three categories: administrative, health management, and medical device. The first was determined to be deserving of no particular attention. The third is within the traditional purview of FDA responsibility. They deliberated primarily about those in the health management category: health information and data management; data capture and encounter documentation; electronic access to clinical results; some clinical decision support (CDS); medication management; electronic communication (e.g. provider-patient, provider-provider, etc.); provider order entry; knowledge management; and patient ID and matching. With regard to quality management, the proposed action is: The agencies will work with health IT stakeholders to identify the essential elements of a health IT quality framework, leveraging existing quality management principles and identifying areas where quality management principles can or should be applied. For consensus standards, the proposed action is: The agencies have identified specific focus areas for standards and best practices implementation: health IT design and development, including usability; local implementation, customization and maintenance; interoperability; quality management, including quality systems; and risk management. Interoperability supports improvements in safety, encourages innovation and facilitates new models of health care delivery by making the right data available to the right people at the right time across products and organizations in a way that can be relied upon and used by recipients. The agencies recommend that entities be identified to develop tests to validate interoperability, test

product conformance with standards, and transparently share results of product performance to promote broader adoption of interoperable solutions. Regarding local implementation, customization and maintenance of health IT, they recommended that they seek public input on the areas where non-governmental, independent conformity assessment programs could be developed to fill current gaps. Another recommendation is the establishment of a public-private entity – the Health IT Safety Center – that would serve as a trusted convener of health IT stakeholders and identify the governance structures and functions needed for the creation of a sustainable, integrated health IT learning system. The entity would be created by ONC, in collaboration with other agencies and stakeholders to serve as a trusted convener of health IT stakeholders and a forum for the exchange of ideas and information to promote health IT as an integral part of patient safety. Daniel reported that ONC already has funded the Joint Commission and patient safety organizations for related work. A contract was recently negotiated for a study of the feasibility of a safety center. She announced a workshop May 13-15 hosted by NIST, and invited comments on the draft report.

Discussion

Tang suggested a change in the slide's colors. He wondered whether the safety center would have lessons learned and investigative functions. Daniel reminded him that ONC does not have authority for an investigative function, which would require enabling legislation. The safety center is included in the 2015 budget, but there are not funds for investigation.

Mann observed that the description of functions go way beyond patient safety. Innovations should not be overly restrained by a concern with safety. For example, safety is not the first concern for quality management functions since there are different ways to ensure safety without it being an initial constraint. He requested greater clarity of purpose. Tang called for volunteers for a task force to respond to the draft report and recommendations to so indicate to Consolazio. In addition, members can submit responses directly.

Public Comment

None

Remarks

Howard K. Koh, Assistant Secretary for Health, U.S. Department of Health and Human Services, gave his perspective on BH EHR certification. There is a department-wide BH coordinating committee. He referred to the fragmentation of the health care system. The Mental Health Parity Act and ACA greatly expanded access to BH and substance abuse services. BH patients experience high rates of co-morbidity. BH has been excluded from incentives to date. BH providers need to adopt systems that are compatible with other providers. Interoperable systems are needed. Privacy and security should not be insurmountable barriers. DeSalvo referred to the three part aim, for which the incorporation of BH is essential.

Behavioral Health (BH) Data Segmentation Update - Privacy and Security Tiger Team (PSTT)

Chairperson Deven McGraw announced that she was reporting on the team's discussion of certification of EHRs to enable exchange of BH data, but that she was not submitting recommendations for the committee's action at this time. Rather, she sought members' feedback. The Certification and Adoption Workgroup requested that the tiger team examine the proposed areas for certification for all providers, both meaningful users and non-meaningful users, and make recommendations to the HITPC on the following:

- Use of the HL7 privacy and security classification system standards to tag records to communicate privacy related obligations with the receiver
- Standards for controlling re-disclosure of protected data
- Support of equivalent functionality in Stage 3 for standards for communicating privacy policies and controlling re-disclosure of protected data
- Developing consensus on standards for consent management functionality needed by BH providers to comply with diverse federal and state confidentiality laws , including the Data Segmentation for Privacy Standard (DS4P)

She reviewed CFR 42 Part 2, which applies to facilities and providers that receive federal funds for substance use treatment, and related recommendations by the committee from 2010. She described the emerging technology. DS4P is an initiative of the S&I Framework to pilot promising technologies for enabling the disclosure of records covered by 42 CFR Part 2 (and potentially other granular consent requirements). Six pilots are underway: VA/SAMHSA Pilot, SATVA Pilot, Netsmart Pilot, Jericho/UT Austin Pilot, GNOHIE Pilot, and Teradact Pilot. A recipient provider using DS4P would have the capability to view the restricted CCDA (or data element), but the CCDA or data cannot be automatically parsed, consumed, or inter-digitated into the EHR. Doing so would risk possibly re-disclosing sensitive data without patient authorization. Implementation to date has largely been all-in or all-out with respect to disclosure of information from BH providers. The restriction tag in the CCDA applies to the entire document. Although granularity with respect to information shared by a BH provider might be achieved by omitting information from the CCDA, providers would not know that data were omitted. She said that to date the tigers have talked about these straw person recommendations, but have not finalized them. Deliberations continue. The straw person recommendations consist of the following:

- DS4P is not a perfect solution, but it could be the first step to enable sharing of information by BH providers with other providers caring for BH patients.
- View only is less than ideal, but many providers may feel that having access to some data about their patients is better than having none.
- All or nothing is also less than ideal, but it provides a way for information to be disclosed from BH providers when patients provide authorization (which occurs more than 90 percent of the time).
- Certification of both BH EHRs and other EHRs for the DS4P technical capability will enable the sharing of data protected by Part 2. Should this be mandatory for CEHRT?
- Functionality will be present, but providers that are still reluctant to accept data that cannot be populated into the EHR should not be required to use it.
- Education of providers and patients is key.

As a result of inconclusive discussions, the tigers will continue the discussion in May with a goal of presenting final proposed recommendations to the HITPC in June. McGraw invited comments.

Discussion

Egerman asked about the pilot organizations. McGraw said that the pilots were launched by vendors. One was in a VA facility. Joy Pritts, ONC, added that another was located in a Florida county in which a Part 2 facility sent patient data to a non-Part 2 facility. Egerman talked about transitions from acute care to LTPAC facilities. Sometimes the patient is unable to give granular informed consent. What is the impact on the patient? Is the transition delayed? He favors finding classifications of disclosures that can

be exempted from Part 2. For example, if a patient agrees to the transfer, she also agrees to disclosures. McGraw said that SAMHSA has been urged to issue a new guidance. Pritts pointed out that the requirements are statutory.

McGraw explained again that if the document is tagged, it cannot be read by the recipient without the software and if read, it cannot be used by the EHR. If a physician reads the tagged information and incorporates some of the information in her notes without the patient's consent, it is a violation. Tang wondered about the receiving EHR indicating in some way that there is protected information that cannot be incorporated. McGraw said that she did not know the answer. Tiger Team Co-chairperson Micky Tripathi said that approaches in addition to DS4P may be possible. He suggested conferring with the HITSC.

In response to another question, McGraw said that the original recipient is authorized by the patient so that the sender and the first order recipient can exchange information. The later steps are the issue. DeSalvo asked about levels of permissions. McGraw said that the law applies to the entire CCDA document. Pritts added that although there is capability to tag within the document, the capability has not been implemented in the pilots.

Faulkner asked about patient authorization to re-disclose. McGraw explained that a general authorization is not allowed; it must be for a specific purpose. Regarding who is a provider, she reminded Faulkner that they were discussing Part 2 and not HIPAA. She offered to get clarification as to who is the provider under Part 2. Nevertheless, controlling for disclosures is the concern. Pritts informed them that SAMHSA has issued many guidances through the years. Authorization does not require designation of an individual doctor.

Harrell asked about tagging and recognizing discrete elements. McGraw repeated that although the capability may be there, it has not been tested. Tagged information can be recorded and disclosed provided the patient consents. However, this area is somewhat ambiguous because it presents the possibility of doing an end run around the requirement. Guidance from SAMHSA has been requested.

David Kotz asked about mobile apps to monitor behavior. They provide continuous flows of BH data. Did the tiger team considered these apps? McGraw said that when a patient collects her own data and gives it to a doctor, that doctor is not bound by Part 2, although she may be subject to state laws. It is important not to close the door on new tools.

Long-term post-acute care (LTPAC) and BH Update - Certification and Adoption Workgroup

Co-chairperson Larry Wolf repeated that the workgroup was charged to recommend a process for prioritizing health IT capabilities for EHR certification that would improve interoperability across a greater number of care settings. The recommendations shall take into account previously adopted ONC certification criteria and standards and identify the key heath IT capabilities needed in care settings by providers who are ineligible to receive EHR incentive payments under the HITECH Act. He reminded them that he had previously reported about the certification criteria principles and organizing principle. Eventually, the workgroup will make recommendations in sets—all providers, BH specific, LTPAC specific, and a subset of BH and LTPAC. The workgroup has progressed to the point of considering recommendations for transition of care (ToC) that apply to all providers. They are:

- Support the ability to receive, display, incorporate, create and transmit summary care records with a common data set in accordance with the CCDA standard and using ONC-specified transport specifications. (reference: §170.314(b)(1) , 45 CFR §170.314(b)(2))

- And new from the report at a previous meeting, if approved by HHS for meaningful use, support the inclusion of emerging HL7 ToC and care planning standards when standards become mature.

In addition, alignment of standards and certification criteria across all heath providers is essential for ToC. Refinements to the ToC and care planning standards in the Fall HL7 2013 CCDA ballot will support care coordination for LTPAC, BH and other health care providers across the care continuum. Operational experience with emerging standards is needed before their inclusion in certification. ONC should assess emerging standards maturity. Standards development cycles may vary (e.g., standards that have never been collected versus vocabularies in use by a sector, but newly added to the CCDA).

And for privacy and security for all providers to support existing ONC-certified privacy and security requirements, the workgroup recommended:

§ 170.314(d)(1) - Authentication, Access Control, and Authorization
§ 170.314(d)(2) - Auditable Events and Tamper-Resistance
§ 170.314(d)(3) - Audit Report(s)
§ 170.314(d)(4) - Amendments
§ 170.314(d)(5) - Automatic Log-Off
§ 170.314(d)(6) - Emergency Access
§ 170.314(d)(7) - End-User Device Encryption
§ 170.314(d)(8) - Integrity
§ 170.314(d)(9) – Optional: Accounting of Disclosures

In addition, HHS should support educational awareness initiatives for LTPAC and BH providers, including how certification supports the technological requirements of HIPAA. Compliance with HIPAA requires actions that extend beyond the ONC.

Discussion

In response to a comment by DeSalvo, Wolf said that he intended for the recommended standards to change in accordance with development of the EHR incentive program certification, something that he agreed should be made explicit in the recommendations. He explained that the recommendations mean that certification is evolving beyond HITECH and meaningful use. He acknowledged that non-meaningful use is not a good label. Tang clarified that the requested action is to approve two recommendations to certify BH and LTPAC EHRs for ToC and privacy and security, tracking for Stage 3. He asked Wolf to clarify what was actually being recommended by tracking and assessment of standards for care plans. After Wolf attempted to explain, Tang suggested that tested be added to the phrase when standards become mature. Wolf agreed to the addition, citing the sense of the committee indicated in the discussion of the 2015 Edition. Egerman suggested that the 2014 Edition be specified for ToC. If 2015 goes into effect, then it would be extended to BH and LTPAC. He pointed out that some vendors have products in more than one environment. Tang asked for a motion to approve the recommendations. Christine Bechtel moved to accept the recommendations and another member seconded the motion.

Seagondollar objected that the phrase when standards for care planning become mature is ambiguous. Wolf then suggested striking the second point and accepting Egerman's concept, which allows for change over time. Seagondollar indicated that the change was acceptable to him. Discussion, along with some confusion, ensued as to the proper procedure for changing the motion—a friendly amendment, withdrawing the motion, voting, or other possible actions. DeSalvo asked that they follow proper procedures. Tang asked Bechtel if she would accept an amendment to strike the second part (care plan

mature standards) of the recommendation. She agreed to an amendment. Faulkner wondered what would be left. Bechtel said that tracking would remain. Wolf then added a statement about to the extent that ONC has authority for certification of ToC, it should track those standards for all providers as they change over time. According to Tang, the purpose of the recommendations is to offer a way for non-meaningful users to participate in information exchange. Pritts cautioned that to do this for BH may lead those providers to assume the certified EHR will fulfill their requirements for enhanced privacy and consent. Tang agreed that it can be confusing. The purpose is to be interoperable with other ToC-certified systems and no more. Wolf emphasized that state laws are not addressed. Various opinions were expressed again. DeSalvo spoke about the national goal of an EHR for everyone in the United States. The recommendations pertain to a voluntary program. Josh Sharfstein spoke about the importance of changing financial incentives. In Maryland, BH providers can obtain bonuses for controlling medical costs. In the future, exchange of information across systems will help to reduce ED visits and hospital admissions. Tang stated the motion as certification for ToC, minus care planning, and privacy and security. The motion was approved unanimous by voice vote.

Action item #2: The HITPC approved the recommendations put forward by the Certification and Adoption Workgroup to certify BH and LTPAC EHRs for ToC, except for care planning, and privacy and security to be compatible with those functionalities so certified for meaningful use.

LTPAC and BH Quality Measures and Stage 3 Quality Measures - Quality Measures Workgroup

Co-chairperson Terry Cullen reported on the workgroup's response to a request for recommendations on certification for quality measures for LTPAC and BH EHRs. To begin with, the two environments are different in that LTPAC is largely influenced by the standardized assessment data sent to CMS. CMS calculates measures for LTPAC providers based on the data they submit. Thus, the focus is more on standardized data elements and assessments. But BH settings have not traditionally reported quality measures to external bodies with two major exceptions: reporting to Medicaid agencies in some ambulatory settings and inpatient psychiatric hospitals reporting to CMS. EHRs should be able to support the following: common definitions for data elements from assessment tools across care settings; standardization of elements; semantic interoperability; data elements from assessment tools collected seamlessly through the EHR at the point of care; and an electronic ToC document capturing longitudinal care across care settings through best-in-class standard data elements. For LTPAC, the workgroup recommended certification of an LTPAC Data Submission Module with the capability to collect and send interoperable, standardized data elements for a small number of measure domains and a small set of common data elements to support transitions in care. Also, the workgroup recommended that CMS consider certifying the free CMS patient assessment submission tools to perform these functions. Other considerations, and possible barriers, are: the need for a new eCQM for the timely electronic exchange of interoperable ToC documents, the current specifications and requirements of the CMS LTPAC program, and harmonization of versioning of LTPAC data elements with CCDA and other standards already established for meaningful use.

Moving to BH, Cullen said that these options were discussed: certify the functionality to collect and send a small set of common data elements; certify the functionality to collect, calculate, and send a small number of clinical quality measures; certify the functionality to capture a small set of key patient assessments; and a combination of the three. For the short term, the group recommended certification of the functionality to collect, calculate, and send a small number of clinical quality measures relevant to BH and in parallel to begin to standardize common data elements relevant to BH that could be used to build new clinical quality measures. She mentioned other considerations as well. Data sharing and

coordination of care is critical, but concerns remain around data privacy. 42 CFR Part 2 can prevent the sharing of patient level quality data. Unlike HIPAA, which allows for sharing data for treatment, payment or operations, Part 2 requires that the client indicate the purpose for sharing records. Not all clients may allow sharing the data for quality measurement and currently EHRs and HIEs do not have a mechanism to segment the data to manage these requests. Experts suggested that without incentives, voluntary certification may have low uptake. There is a need for central organization or stewardship of BH measure development. Specialized clinical registries should be a capability inherent within health IT. Measures of non-traditional determinants of health should be available and incorporated into the HIT system with endorsed standards (e.g., psychosocial factors, housing status).

Discussion

David Lansky pointed out that small number of measures was not defined. He wondered about Option 3— key patient assessments. Cullen replied that the number of measures was not discussed. Key assessments attempt to determine how well a patient is doing. Lansky voiced opposition to extending process measures, not all of which are tied to outcomes, to BH and LTPAC. A voluntary program should be thin and elegant. Cullen referred to some ongoing report that the workgroup did not investigate. Lansky advocated for focusing on key assessments. Burstin said that some of the measures depicted on the slides are in Stage 2.

Harrell asked about CMS levers being in place insofar as LTC is financed to a large extent through Medicaid. According to Cullen, that reporting often occurs outside of HIT. The goal is to push toward standardized HIT measures.

Seagondollar said that one should consider what is being collected, how it is transmitted and to whom. Is the recipient ready to receive information? Cullen agreed, saying that CMS is receiving reports mostly from secondary systems. The workgroup did not look at or crosswalk the measures. Faulkner talked about having an international perspective and avoiding siloes in order to have a holistic model. Cullen referred to work of the Accountable Care Subgroup. Kevin Larsen, ONC, reported that CMS has a project for common data elements for LTPAC.

Chairperson Helen Burstin showed slides and reported on Stage 3 quality measures, explaining that the members had reviewed the measures under development by CMS. The measures will be fully e-specified by fall 2014. Some are already available and open for public comment: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html; http://ushik.org/QualityMeasuresListing?draft=true&system=dcqm&sortField=570&sortDirection=ascending&enableAsynchronousLoading=true.

Others will be going through the feasibility and validity testing process. But NQF endorsement in time for the Stage 3 NPRM is unlikely. She went through measures under development by domain and subdomain and recommendations for future development. She emphasized that these were not final recommendations. The workgroup is continuing to deliberate and recommendations for action will be submitted for the June meeting. Finally, she presented the following broad recommendations and needs beyond specific subdomains:

- CDS in lieu of or linked to a measure
- Way to measure patient's experience of care coordination through CAHPS – need a way to connect to these data

- Composite global measures
- Standards to support transport of data elements (goal setting, care coordination)
- Platform for PROs – PROMIS
- Building PGHD into measures

Discussion

Tang noted that the measures under development are primarily process measures. He referred to pushing versus waiting. Burstin offered to look for measures that organizations are currently using to bring forward for Stage 3. DeSalvo asked about to mapping to VA efforts. Cullin talked about bringing in seven domains and mapping them to trigger CDS. Although external data can trigger CDS, they are difficult to assess. Burstin said that the Accountable Care Subgroup recommended measures require interoperable systems. They are the right approach. Tang asked that the workgroup put more push in the recommendations for action in June. The workgroup will be handing its work off to a newly structured group (or not) and the measures should be ones that matter. Cullen indicated that to comply with Tang's direction would be a big push.

Lansky requested that they flag promising or longitudinal measures that combine data sources, which could eventually be used for menu items. Cullen acknowledged that they had not done that; she suggested identification of a very few core measures. Lansky talked about bringing in cost data to a quality measure. Tang referred to an NIH project on development of core measures. Bechtel brought up a previous recommendation for establishing a platform for patient experience data collection. Stage 3 includes a recommendation for PGHD capacity and the need for a data collection tool. The question is how to use EHRs for providers who want to collect patient experience data. Cullen confirmed that hard coded measures are not desirable. The goal is to expand system capability with the goal of health.

DeSalvo referred to the VA example of exchanging core measures that are useful across systems. Cullen observed that there are measures in seven domains to standardize. Even vitals are difficult to standardize. Granular measures are required for CDS. The VA does not currently have a core minimum data set. The goal is a de facto minimum data set to report on eCQMs. An HHS group is working on quality measures across programs and agencies. DeSalvo asked about measures of hospital acquired conditions. Burstin said that CDC uses the NHSN. Cullen talked about using ONC resources to drive to the next level. Regarding the importance of capturing information on homelessness for VA and SAMHSA patients, a common definition and measure would be progress. Tang talked about prospecting, innovation and credit for sharing alternatives.

Burstin said that the workgroup will prepare a comprehensive summary report for hand-off as the group is disbanded.

Public Comment

Donna Doneski, National Association for Support of Long Term Care, offered to work with the committee on QMs and other LTPAC items.

Tang thanked the staff, especially Consolazio, for their support.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the April 2014 HITPC meeting was approved.

Action item #2: The HITPC approved the recommendations put forward by the Certification and Adoption Workgroup to certify BH and LTPAC EHRs for ToC, except

for care planning, and privacy and security to be compatible with those functionalities so certified for meaningful use.

Meeting Materials

- Agenda
- Summary of April 2014 meeting
- Presentations and reports slides

Meeting Attendance

Meeting Attendance						
Name	**05/06/14**	**04/09/14**	**03/11/14**	**02/04/14**	**01/14/14**	**12/04/13**
Alicia Staley	X	X				
Aury Nagy				X	X	X
Charles Kennedy	X	X		X	X	X
Chesley Richards	X					
Christine Bechtel	X	X	X	X	X	X
Christoph U. Lehmann						
David Kotz	X	X	X	X	X	X
David Lansky	X	X	X	X	X	X
David W Bates	X					
Deven McGraw	X	X	X			
Devin Mann	X		X	X	X	X
Gayle B. Harrell	X		X	X		
Joshua M. Sharfstein	X	X	X	X	X	X
Karen Desalvo	X	X	X	X		
Kim Schofield						
Madhulika Agarwal	X	X	X	X	X	X
Marc Probst	X	X	X	X	X	X
Neal Patterson						
Patrick Conway						
Paul Egerman	X	X	X	X	X	X

Paul Tang	X	X	X	X	X	X
Robert Tagalicod	X	X	X	X	X	X
Scott Gottlieb		X	X	X		
Thomas W. Greig	X	X			X	X
Troy Seagondollar	X	X	X	X		
Total Attendees	**19**	**17**	**18**	**19**	**16**	**16**