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

ATTENDANCE

Members present:

Madhulika Agarwal
Christine Bechtel
Neil Calman
Arthur Davidson
Paul Egerman
Judith Faulkner
Thomas Greig
Scott Gottlieb
Gayle Harrell
Charles Kennedy
David Kotz
David Lansky
Devin Mann
Deven McGraw
Jacob Reider
Troy Seagondollar
Robert Tagalicod
Paul Tang

Members absent:

David Bates
Patrick Conway
Aury Nagy
Marc Probst
Joshua Sharfstein
Alicia Staley

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the 54th 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 an opportunity for public comment and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking and announced that Paul Egerman had been reappointed by Representative Nancy Pelosi for his second term. Members introduced themselves.

Remarks

Acting Chairperson and National Coordinator Jacob Reider reflected on the work of ONC and HITPC. *Tribal Leadership* by Dave Logan et al. describes five types of leadership and organizational stages. Reider believes that ONC and the HITPC are working together toward a vision. Although members may

be competitors, they work together on the committee. The HITPC is a guiding light. He wishes to make meaningful use truly meaningful for providers and to avoid "make work." He acknowledged that people define "make work" in very different ways.

Review of Agenda

Vice Chairperson Paul 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 a motion to approve the summary of the November meeting. A motion was made and seconded to approve the meeting summary as circulated with the meeting materials. The motion carried unanimously by voice vote.

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

CMS Update

Robert Tagalicod, Office of eHealth Standards and Services, Centers for Medicare and Medicaid Services (CMS), talked about the increased use of HIT. The market is saturated with EHR products, large and small. CMS sees HIT as means to several ends—better access to care, higher quality of care, expansion of care, and lower expenditures. An estimated 30 percent of EPs are planning to change EHR vendors this year, something that the committee should keep in mind. As expected, there is increasing concentration in the field to which the growth in ACOs has contributed. Another trend is for EHRs to support both meaningful use and payment reform. Management of stage 2 implementation, transition to ICD-10, and other changes this year is challenging.

Robert Anthony, CMS, showed slides and presented his standard monthly report. As of October 13, total registration was nearly 431,000. Approximately 85 percent of all EHs have received an EHR incentive payment for either meaningful use or AIU. Approximately 60 percent of Medicare EPs are meaningful users of EHRs. Approximately 76 percent of Medicaid EPs have received an EHR incentive payment. Overall, 17 percent of Medicaid EPs are meaningful users. Over 64 percent of Medicare and Medicaid EPs have made a financial commitment to an EHR. Almost 330,000 Medicare and Medicaid EPs have received an EHR incentive payment. Comparison of early attesters across three years indicates considerable stability of performance.

ONC Update

Jennifer King showed slides and updated the numbers from her report at the November meeting on the status of the certification program based on a vendor-level analysis. As of November 13, 2013, 89 percent of EHs that attested to stage 1 used a primary vendor that had any 2014 Edition product. 70 percent of EPs that attested to stage 1 used a primary vendor that had any 2014 Edition. As of October, 78 percent of EHs had attested to meaningful use compared to 48 percent of EPs. CAHs and rural hospitals were somewhat less likely to have a 2014 Edition compared to other hospitals.

Q&A

In response to a comment that it is more important to think about improvement in health rather than registrations and attestation, and a question about tracking the relationships among investments, penetration, and health outcomes, Anthony said that CMS staff is beginning to look at the association between use of EHRs and reduction in costs and improved outcomes. More can be done in this regard in Stage 3.

Egerman noted that a stated goal of the George W. Bush administration was for every person in the United States to have an EHR by 2014. To what extent has the goal been achieved? Anthony promised to

provide some relevant information on that topic at a future time. Egerman reminded him that many people who are not affected by the incentive programs have EHRs.

Art Davidson suggested that the three public health submissions be combined for display on the slide since only one submission is required.

Rural Hospitals

Anthony reported that CMS staff had talked to representatives of organizations that support small rural hospitals, both CAHs and small acute care hospitals. They talked to people who had implemented EHRs and meaningful use as well as those who had not. Acquiring HIT systems was cited as the most prevalent problem, especially finding an appropriate vendor. Other barriers to EHR implementation are capital, IT resources and personnel, system acquisition, and staff resistance. Additionally, these hospitals are experiencing barriers to meaningful use. Their managers refer to confusing and conflicting requirements, difficulties in meeting thresholds with their small patient populations, quality measures that they see as not relevant, and inability to leverage provider compliance. Being part of a larger system facilitates implementation. CMS is now designing resources to assist these hospitals. Hospitals also need information about how to select appropriate products and implementation planning; CMS is seeking partners to offer information that its staff is not able to provide.

Matt Kendall, ONC, reported that although they have limited resources, these hospitals are making tremendous progress. As of July 31, 2013, 62 percent of CAHs and 77 percent of small, rural hospitals (those generally with less than 50 staffed beds) had achieved meaningful use. ONC and the USDA rural development program launched an initiative to expand funding for CAHs and rural hospitals to help them meet HIT challenges. The most frequently observed challenge encountered by these hospitals is EHR implementation costs, followed by workflow changes. Broadband implementation costs and the lack of broadband, as well as a shortage of IT workers, continue to be problems in rural areas. In FY 2013, CAHs and rural hospitals in four states were awarded more than $38 million to help address these barriers. The initiative is being taken to scale nationwide this fiscal year. He emphasized that although these hospitals have much in common, their environments vary considerably by state, region, market penetration, and other factors. He said that HRSA staff has been very helpful in working with ONC staff to provide information and resources. He is working to partner with the Dept. of Veterans Affairs (VA) to leverage technology, since veterans residing in rural areas often use both VA and non-VA facilities. ONC is working with FCC on broadband expansion. Many resources are available at www.Healthit.gov/RuralHealth.

Q&A

Tang asked members to limit their questions because the agenda was behind schedule.

Judith Faulkner observed that the meaningful use measures may not be appropriate and helpful for small hospitals. Perhaps it would be more efficient to change the requirements for them rather than to provide more resources. Kendall replied that the hospitals appreciate the importance of HIT for integration with care systems. They are eager to participate fully. Anthony said that their individual situations determine their responses to EHR and meaningful use implementation. A three-bed hospital has a small denominator. EHs must consider these requirements in their implementation plans.

Gayle Harrell said that lack of broadband is a problem in rural Florida. The FCC should consider regional approaches. Tang moved to the next agenda item.

Office for Civil Rights Update

Susan McAndrew reported that OCR is working with CMS and ONC on HIPAA security and privacy requirements and the requirement for a security assessment in Stage 1. The final rulemaking for CLIA,

opening labs to access requirements for test results, is at OMB for clearance. OCR staff worked with Department of Justice staff and on April 19, 2013, issued ANPRM on whether HIPAA prevents some states from reporting individuals disqualified from having a gun for mental health reasons to the National Instant Criminal Background Check System (NICS). Staff also worked with the HITPC Privacy and Security Tiger Team on accounting of disclosures. In their enforcement role, ONC staff continued to focus on Security Rule and Privacy Rule compliance, resulting in several large fines and judgments. She reported that audits are increasingly being used with less reliance on following up complaints. In the recently completed audit pilot, security accounted for most of the findings. Lack of risk analysis is found frequently. For every finding and observation cited in the audit reports, the audit identified a "cause." The most common cause across all entities was the entity being unaware of the requirement (30 percent of findings and observations). This year OCR is focusing on business associates. OCR has designed and made available many resources for both consumers and providers. A more consumer-friendly privacy notice was designed. Information for law enforcement officers was released. An information campaign directed toward persons living with HIVAIDS was conducted. Additional campaigns for groups that have high rates of electronic interaction with health care providers are planned.

Q&A

Tang called attention to the audit findings on the lack of compliance with the security analysis requirement. Neil Calman asked about self-reporting and external reporting requirements. In New York, the issue with the Affinity copy machine memory sent shock waves throughout the system. Are there other such things waiting to be discovered? Many providers are totally unaware of these risks. McAndrew said that the goal of the audit pilot was to design something that could be used for self-correction. Currently, self-reporting is required only when a breach occurs. Calman referred to medical liability having created a protected place for self-correction. There should be a process for covered entities (CEs) sharing and correcting, and a mechanism for learning about vulnerabilities without incurring fines and settlement agreements. McAndrew replied that the vast number of breaches and complaints do not result in fines. Security rules are flexible and scalable, but they have been in place for some time. Typically fines are incurred when there are broad management concerns, not for a single violation. Joy Pritts, ONC, reported that ONC has several fora to provide information on these topics.

Devin McGraw commented that in terms of patients' access to their lab data, a PDF should be the floor, not the ceiling. McAndrew declared that labs are subject to the same requirements as other entities.

Harrell commented that the pilot findings are frightening for small providers. The RECs are geared to primary care providers. Many small specialty groups are concerned with OCR's rules and enforcement. More outreach is needed.

Faulkner said that it is difficult to control a large number of employees. Large organizations need help, not penalties.

Privacy and Security Tiger Team – Accounting of Disclosures Update

Tiger Team Chairperson Deven McGraw showed slides and gave the background for the team's work, explaining relevant aspects of HIPAA, HITECH, and the NPRM. She described the results of a hearing held September 30 and themes from the comments solicited via the HIT buzz blog and went on to explain the relevant laws. The HIPAA Privacy Rule currently requires covered entities to make available, upon request, an accounting of certain disclosures of an individual's PHI that have been made up to six years prior to the request. This accounting should include the date, the name of the recipient (and the recipient's address, if known), a brief description of the PHI disclosed, and the purpose of disclosure. The Privacy Rule accounting requirements apply to disclosures of both paper and electronic PHI, regardless of whether such information is in a designated record set (DRS). A DRS is a group of records maintained for

or by the covered entity in order to make decisions about the individual (such as decisions about medical bills or billing records).

The HITECH Act requires new rulemaking to implement changes to the Accounting of Disclosures requirements. This new rulemaking, as reviewed by Chair Deven McGraw, includes three components. First, the exception for disclosures to carry out treatment, payment, or operations (TPO) would no longer apply if made through an EHR. Second, individuals would have a right to receive an accounting of disclosures made during the three years prior to the request (as opposed to six years). Third, covered entities would be required to provide either an accounting of a business associate's disclosures or a list and contact information of all business associates to the individual requesting the accounting. She continued. The HITECH Act also requires the adoption of an initial set of standards, implementation specifications, and certification criteria for accounting of disclosures in EHR technology. The NPRM would provide individuals with two rights: An accounting of disclosures, and an "access report."

Co-chairperson Paul Egerman presented the following recommendations, which focus on the patient's right to a report of disclosures outside the entity or OHCA and the patient's right to an investigation of accesses inside the entity:

- Given the uncertainties and complexities involved in implementing the HITECH requirements, HHS should approach this in a step-wise fashion, initially pursuing an implementation pathway that is workable from both a policy and technology perspective.
- The Tiger Team does not believe the proposed access report meets the requirements of HITECH to take into account the interests of the patient and administrative burden on covered entities (CEs).
- Instead, we urge HHS to pursue a more focused approach that prioritizes quality over quantity, where the scope of disclosures and related details to be reported to patients provide information that is useful to patients, without overwhelming them or placing undue burden on CEs.
- In responding to the HITECH requirement to account for disclosures for TPO, HHS should focus, at least initially, on EHR disclosures outside the CE or OHCA.
- HHS should pursue a "Follow the Data" approach. When control of patient data is transferred to another entity, the recipient of the data should be part of an Accounting of Disclosures report.
- Patients should also be able to obtain an Accounting of Disclosures report from such recipients if they are (1) business associates and (2) have further disclosed the data outside of their compliance environments and the subsequent recipient controls and could potentially disclose the data. (Per HITECH, covered entities have the option of gathering and providing this information to patients vs. the obligation being on the business associate to provide information about subsequent disclosures.)
- Right to report of external disclosures: Technologies and policies to accomplish this should first be piloted by ONC. (The team listed several recommended areas for pilots.)
- Content of the report: The accounting of disclosures should require only an entity name rather than the specific individual as proposed.
- Content of the report should be tested in the pilot; such testing should include the possibility to group similar disclosures together (vs. reporting individually), as permitted by the proposed Accounting of Disclosure rule.
- The Tiger Team also reinforces the importance of the right of an individual to an investigation of alleged inappropriate access. The Tiger Team notes the ability of patients, under the accounting of disclosures proposed rule, to obtain a report that includes disclosures that would be considered breaches but are not required to be reported to patients.
- To improve the ability of covered entities to do investigations of inappropriate access, the Tiger Team recommends that the Office for Civil Rights add two implementation specifications to the

current audit control standard in the HIPAA Security Rule (164.312(b)): (Addressable) Audit controls must record PHI-access activities to the granularity of the individual user (i.e., human) and the individual whose PHI is accessed. (Addressable) Information recorded by the audit controls must be sufficient to support the information system activity review required by §164.308(a) (1) (ii) (D) and the investigation of potential inappropriate accesses of PHI.

Egerman concluded by showing that the recommendations are consistent with earlier recommendations.

Discussion

Tang asked about the recommended pilots. Egerman said that no recommendations are being made on certification. McGraw said that a pilot would help providers to implement reports. A pilot should be completed prior to publication of the final rule.

Bechtel asked about the individual's right for an investigation: Who does it and what is the time frame? McGraw replied that there is not much detail about requirements. The investigation is in response to a complaint. Providers indicated they take this responsibility seriously. Patients can always report to the regulators if they are dissatisfied. Bechtel expressed concern about the lack of specifics regarding the report. She suggested that more information is needed about the extent to which the response to complaints may be a problem. Egerman said that providers are reportedly proactive when a well-known person is a patient. Pritts suggested that OCR may have relevant data on complaints about non-response to breaches. She offered to request the data.

Neil Calman talked about things that happen through the EHR. Breaches could occur around quality improvement reports. An audit would show who printed the report but not who read the report. Egerman acknowledged that PHI is often disclosed via print, which would constitute inappropriate use of a report, not inappropriate access to the record. McGraw emphasized that the team is giving HHS a pathway of ways to address these concerns, including pilot-testing of the recommendations. Regarding the question of through versus from, the team decided from is sufficient.

Someone asked whether disclosures from a warehouse would be covered. Egerman observed that a warehouse is not an EHR. McGraw repeated that the recommendations are conceptual. HHS staff must figure out the specifics. Warehouse is not universally defined. The principle is to follow the data. The provider does not control the warehouse. Is the warehouse in the compliance environment? Egerman said that the patient should know where her data go.

Troy Seagondollar asked about consent and whether the report is automatic. Egerman emphasized that the patient has the right to an accounting of disclosure report. Its production could work in different ways. It would have to be automated because of the burden of producing a non-automated report. McGraw explained that a report is produced only upon request of the patient. It is not an affirmative right. The recommendations do not interfere with any of the HIPAA rights. Tang called for a vote. McGraw agreed to add per Bechtel's point a recommendation that OCR further explore whether patient requests for investigations of inappropriate access to their records are being honored.

> **Action item # 2: Bechtel moved to accept the recommendations of the Privacy and Security Power Team with the addition that OCR explore whether patient requests for investigations are being honored. The motion was seconded and approved unanimously by voice vote.**

Certification and Adoption Workgroup – Framework Review

Co-chair Larry Wolf referred to the membership roster and noted that new expertise had recently been added to the workgroup. He reported on the framework the workgroup is using to consider a new certification program for ineligibles (long term and post-acute care (LTPAC) and behavioral health (BH) providers).

Wolf explained that the HITPC charged the workgroup to recommend a process for prioritizing health IT capabilities for EHR certification that would improve interoperability across a greater number of care settings. Recommendations are to 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

The workgroup agreed to apply a five-factor framework:

Advance a National Priority or Legislative Mandate: Is there a compelling reason, such as a National Quality Strategy Priority, that the proposed ONC certification program would advance?
Align with Existing Federal/State Programs: Would the proposed ONC certification program align with federal/state programs?
Utilize the existing technology pipeline: Are there industry-developed health IT standards and/or functionalities in existence that would support the proposed ONC certification program?
Build on existing stakeholder support: Does stakeholder buy-in exist to support the proposed ONC certification program?
Appropriately balance the costs and benefits of a certification program: Is certification the best available option? Considerations should include financial and non-financial costs and benefits.

The workgroup is gathering information from invited presentations. A hearing on LTPAC HIT is scheduled for December 12. Work on BH will commence in January.

Discussion

Egerman declared that certification does not necessarily lead to adoption. Incentives drive adoption and there is not an incentive program for ineligibles. What would drive optional certification? ONC should limit its scope to information exchange with EHR systems, along with some security aspects, within existing standards. Functionality should not be an aspect. It was a mistake to certify for functionality in meaningful use. Vendors would not cooperate. LTPAC and BH providers consist of a wide range of customers with different needs.

David Lansky asked what policy issues would be addressed with certification of ineligibles. Interoperability and the flow of information are needed. He recommended concentrating on the first two factors in the framework. The workgroup should consider the federal requirements that apply to LTPAC and BH and use that information to narrow the requirements to which certification should speak. Payers need to be involved in any discussion of ineligible certification. They extract data for longitudinal records. The purchasers with which he works are interested in the current disconnect between BH and other medical services. Wolf acknowledged the need to define scope.

Harrell talked about this opportunity to expand certification to the continuum of care. The patient record should ingest information from different sources. Exchange across a continuum, including hospices, is essential. The ACA requires coverage of BH services. She asked that the workgroup include privacy and security requirements in BH, including a consideration of variation in state law.

Reider emphasized that ONC had asked the workgroup for recommendations because comments received in a recent RFI overwhelming urged certification. BH and LTPAC providers want interoperability. Without certification, they say they can have no confidence in the products marketed to them. ONC absolutely does have the authority to do this. Meaningful use is not the only program to leverage certification. To further emphasize his point, he read an opinion from legal counsel confirming ONC authority to certify.

Faulkner talked about vendors dropping out if the scope were overly broad.

Egerman objected to references to certification as a good housekeeping seal of approval. Certification indicates nothing about quality. It is a minimalist approach to meet requirements. Certification by government has to be completely objective and any seal of approval must have some subjective elements. He urged clear labeling of certification.

Reider acknowledged that good housekeeping seal of approval is not an appropriate term. Any certification of LTPAC and BH would focus on some very explicit, specific tools. Several members repeated their opinions about good housekeeping.

Faulkner pointed out the LTPAC and BH include many different kinds of services and settings. The terms have no well-accepted definition. She urged that they be defined less broadly.

Tang declared that the members seemed to agree on certification for ineligibles to exchange with meaningful use-certified providers. Reider added that ineligibles need be confident that they can do what needs to be done. Today, interoperability and security are the main needs, but the needs could expand in the future. ACOs representatives are saying that the tools they purchased are not doing what vendors say they do. The market failed in this regard. Although there is a private certification program, many in the LTPAC and BH industries asked ONC to take on certification.

Egerman questioned the scope of the charge to the workgroup. Judy Murphy, ONC, asked whether the workgroup members favored a narrow or broad scope. Wolf replied that members' opinions cover the spectrum. He added that the Substance Abuse and Mental Health Services Administration (SAMHSA) is requiring use of certified EHRs is its BH grants. Therefore, some minimum standards are needed. Federal agencies and states are increasing requiring the use of EHRs. An ONC staff member said that at this time the goal is to examine the needs of LTPAC and BH in a variety of settings.

Egerman told Reider that certification is appropriate only for products that are already operational. Certification cannot be used to force design.

Consolazio pointed out that the purpose of the discussion was to approve the five-factor framework for use by the workgroup, not to decide whether to certify LTPAC and BH EHRs.

Tang said that something should be added to the framework about the needs of the market. In response to a question, Wolf acknowledged that the five factors are not necessarily hierarchical. The workgroup has not discussed an algorithm.

Harrell repeated her comments about the importance of privacy and security, interoperability, and coverage of existing state laws. She went on to note that LTPAC is not restricted to the elderly. Long term care for children requires attention.

Tang summarized that there was agreement that ONC has the necessary authority to certify beyond meaningful use and the scope of the workgroup is not limited at this point.

Public Comment

Gary Dickerson, Centra Health, commented about a HL7 functional EHR model being in place. CCHIT has had a certification program since 2009. The current certification system in the United States is largely based on meaningful use and does not reference the HL7 functional model. Two new versions have been released and are being balloted. There are models for LTPAC, BH, child health, and pharmacy as well although they have not been updated. He urged the Certification and Adoption Workgroup to explore these models.

Mari Savickis, American Medical Association (AMA), said that physicians are having trouble with the risk analysis requirement. AMA has made a tool kit, but doctors need a checklist. She requested help in constructing a checklist. She thanked CMS and ONC for being good listeners. A RAND physician

satisfaction survey and report found high dissatisfaction with meaningful use and EHRs. Doctors are looking for a seal of approval. She asked that CMS provide data on dropouts.

Richard Brennan, National Association for Home Care and Hospice, reported that prior to meaningful use 43 percent of the association's home health members had EHRs, a higher rate than for physicians and hospitals. Even though home health providers were overlooked for meaningful use, they want interoperability. Although there is a voluntary certification program, vendors' participation has been limited. ONC certification would help home health. He agreed that there is much variation within long term care. Several ACA-supported programs and the state of Minnesota are requiring use of EHRs by January 2015.

Carol Bickford, American Nurses Association, said that the perspectives of consumers and families, all nursing occupations, and social workers—the full spectrum of LTPAC workers—must be included in discussions of certification.

Chantal Worzala, American Hospital Association, compared a recent GAO report (October 24, 2013) and the CMS report presented earlier. The later shows accumulated data only. EHs must attest each year. The GAO report shows information for 2011 and 2012 separately. According to the GAO data, only 48 percent of all EHs and 28 percent of CAHs attested and received payment in 2012. The HITPC should request annual data from CMS, as well as read the GAO report. She went on to point out that the ONC data on certification pertains to base certification, which in itself is not sufficient to meet meaningful use requirement. For instance, the VDT portal, the public health objectives, and the complete set of quality measures are not a part of base certification. The HITPC should pay more attention to these reports and request complete data. She was cut off when her comments extended beyond the three-minute limit.

Appreciation of Mary Jo Deering, ONC

Reider added this agenda item. On behalf of ONC and the HITPC, he thanked Mary Jo Deering, upon her retirement, for her tireless service. Others concurred. Bechtel added that over the years Deering has been the number one advocate for consumers in the federal government.

Patient Generated Health Data Update (PGHD)

Consumer Empowerment Workgroup Chairperson Christine Bechtel reminded the members that the workgroup was asked to provide feedback on two draft Stage 3 recommendations for PGHD and to identify any policy issues needed to facilitate more widespread use of PGHD. She showed slides and described the main points from a public hearing on PGHD, which informed the workgroup's recommendations. The HITPC workgroup coordinated with the HITSC Consumer Technology Workgroup to ensure that standards are available to support policy recommendations. Consumer Technology Workgroup Chair Leslie Kelly Hall described the work and conclusions of her group. She presented standards recommendations:

- ONC should consider the Direct transport standard for secure messaging and data from devices
- ONC should consider the HL7 Care Team Roster standard
- ONC should consider the HL7-CCDA for structured and unstructured questionnaires
- ONC should consider the Continua standard for data from devices
- We encourage standards that support mobile access to patient data and PGHD given the proliferation of mobile devices. However, we do not recommend mandating a specific standard at this time given that might stifle innovation.
- ONC should consider an S&I Initiative to create needed collaborative care document structure to address versioning, expanded provenance, reconciliation, data governance and curation.
- ONC should consider creating a process to align consumer product and provider standards
- ONC should consider using BlueButton+ API approach to accommodate PGHD

- Trust Framework expanded for consumer/patient adoption in emerging technologies (BB+)
- ONC should ask the HITSC to prioritize consumer vocabularies to support wider consumer, patient and family engagement

Bechtel explained that the HITPC members do not need to be concerned with the standards recommendations, which will be submitted to the HITSC. According to her, the point is that the standards are ready for PGHD criteria in Stage 3, with some modifications. She presented the following recommendations:

- The Meaningful Use Workgroup should expand the objective to also give providers additional options for incorporating PGHD through secure messaging and provider-approved devices*, in addition to structured and semi-structured questionnaires.
- We also support Meaningful Use Stage 3 certification requirement that addresses amendments/corrections, and note that our recommendations for how to handle PGHD also apply to the amendments criterion, since they too are a form of PGHD.
- EHR technology should allow providers to receive, review, respond (acknowledge), and record all PGHD, including amendments and corrections. The standards are there for these functions.
- For provider organizations that choose the menu item for PGHD in Stage 3, they should establish policies and procedures for handling PGHD in advance of or during implementation of Stage 3, including, but not limited to, the content to be received; the mechanisms by which it can be submitted/received; and how it will be received, reviewed, acknowledged, and recorded (including but not limited to provenance).
- Providers should collaborate with patients in implementation and crafting of policies and procedures, to ensure PGHD collection and use works for both parties. This should include selecting PGHD type as well.
- Sourcing of data as PGHD should also apply if those data are later shared for Treatment, Payment and Operations.
- ONC should work through its own channels and with federal partners (CMS and others) to equip providers with clear guidance on how to implement the PGHD menu requirement, including what PGHD is, why it's useful, the need to establish clear policies and workflows.
- New policies for PGHD are not needed for Meaningful Use Stage 3; HIPAA should govern that data as it does other data in the record. But for the future, ONC and the Office for Civil Rights should undertake work to address data sharing by consumer devices and apps that providers may also use in clinical care.
- Work is also needed in the medium term to examine policy, workflow and liability issues around unsolicited PGHD.
- The work to provide patients with interoperable Direct email addresses should continue in order to open up more options for efficient and effective collection of PGHD in the future.

Additional work is needed in the short to medium term to explore shared care plans and standards to integrate consumer biometric/device data. or shared care plans – need to consider version control, reconciliation and harmonization, etc. Further work needs to be done on the inclusion of consumer product industry standards for inclusion of device data. For provider-approved devices, standards exist, and the group is recommending Continua standards.

Discussion

The workgroups did not consider the FDA guidelines on apps. The recommendations pertain to those devices in which the provider is involved. ONC staff will look into the apps issue. Secure messaging is used as an example. PGHC is considered broadly.

In response to Tang's questions about approved devices and a subsequent burden on vendors to accommodate all such devices, Bechtel told him to focus on the policy and leave standards to the HITSC. She agreed that provider selected could be substituted for provider approved. She and Kelly Hall acknowledged the need to do more work on the recommendation. The outcomes from ongoing pilots may be instructive. The HITSC needs to discuss the "asterisk." Bechtel asked for approval of the recommendations.

Kelly Hall explained that the CCDA allows different structured templates, including for questionnaires. This structure enables creating and incorporating responses. The recommendations do not specify content. Unstructured data can come in via secure messaging or the use of a structured envelope. There is no need to accommodate completely unstructured data.

When Tang continued to express his reservations about the recommendations, Kelly Hall assured him that she was confident about the readiness of standards although she acknowledged that she may not have explained it well. Bechtel continued to argue for the separation of action on policy and standards. Tang pointed out that the HITSC had yet to accept the recommendations of the Consumer Technology Workgroup.

Jodi Daniel, ONC, pointed out that the committees' charges are not limited to meaningful use. Judy Murphy, ONC, observed that the development recommendations go beyond Stage 3. Tang called for action.

> **Action item #3: It was moved and seconded to approve the recommendations of the Consumer Empowerment Workgroup (clarifications expected from HITSC). The motion carried unanimously by voice vote.**

Quality Measures Workgroup

Chairperson Helen Burstin reviewed the recent efforts of the workgroup. Following several meetings during which the members worked on the deeming assignment, they were instructed by the Meaningful Use Workgroup that deeming was not to be pursued at this time. Although deeming is still a goal, no one knows how to get there. Workgroup members were surveyed about measure concepts. Burstin showed a color-coded slide summarizing their responses concerning readiness. The responses indicate that much is to be done. As a result of the survey of workgroup members, subdomains were added to the previously-agreed on domains. Community health measures was added to population and public health. Management of shared care plan and multi-provider care planning and execution were added to the domain of care coordination. Shared decision-making and patient understanding, experience of care, and patient and family governance were added to the domain of patient and family engagement. No subdomains were added to effective use of resources, patient safety, or clinical effectiveness.

She presented a list of gaps and concepts needed:

- Consistently capture variables required for stratification
- Population metrics meaningful at the point of care
- Optimal management
- Appropriateness of care
- Patient safety defect rates
- Measures across patient-centered episodes of care
- Patient-reported outcomes (e.g., care coordination)
- Cardiovascular risk, including patient activation and treatment goals
- Post-procedure functional status and recovery times
- Delta measures (improvement from baseline or prior year)

Burstin affirmed that the members support the inclusion of patient reported outcomes as an objective, core or menu, as well as hybrid measures. Meaningful use participants should be able to waive one or more objectives by demonstrating that they are collecting data for measures used for internal quality improvement or by integrating with a clinical data registry. One approach may be to allow "Certified Development Organizations" to develop, release, and report proprietary CQMs. An alternate approach might open the process to any EP and EH, but constrain allowable eCQMs via measure design software (e.g., Measure Authoring Tool).

Discussion

In response to a question from Harrell, Burstin confirmed that the green categories on the slide denote e-measures that are ready for Stage 3. The validation process will be the same as in Stage 2. Observing that few measures are available, Harrell wondered about menu or core, and options. She urged flexibility. Reider responded that the purpose of the HITPC is to advice on such matters.

McGraw noted that Burstin had presented a bigger picture of what to accomplish in Stage 3 than had previously been discussed.

Tang talked about quality measures in payment reform. Although the HITPC can go beyond Stage 3, Stage 3 is the most urgent item to consider now. There are and will be multiple opportunities to consider quality measures. A pathway for improving quality measures is needed.

Lansky suggested that they focus less on the measures themselves and more on the capability of the IT environment to propagate measures and what can be done to stimulate capacity. The HITPC can push industry to be more flexible.

Devin Mann inquired about the domain of efficiency. Burstin said that the workgroup is focusing on clinical measures. Mann referred to the efficient use of facilities and provider's time.

Burstin responded to a question from Harrell about duplication of PQRS measures by saying that since CMS is represented on the workgroup, harmonization can be considered.

Tang asked the committee members to submit topics for strategic discussions to begin in January.

Public Comment

None

SUMMARY OF ACTION ITEMS

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

Action item # 2: Bechtel moved to accept the recommendations of the Privacy and Security Power Team with the addition that OCR explore whether patient requests for investigations are being honored. The motion was seconded and approved unanimously by voice vote.

Action item #3: It was moved and seconded to approve the recommendations of the Consumer Empowerment Workgroup (clarifications expected from HITSC). The motion carried unanimously by voice vote.

Meeting Materials

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