

**HIT Policy Committee
DRAFT
Summary of the April 3, 2013 Meeting**

ATTENDANCE

The following Committee members attended this meeting:

- Terry Cullen for Madhulika Agarwal
- David Bates
- Christine Bechtel
- Christopher Boone
- Neil Calman
- Arthur Davidson
- Connie White Delaney
- Paul Egerman
- Judith Faulkner
- Thomas Greig
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Farzad Mostashari
- Marc Probst
- Joshua Sharfstein
- Robert Tagalicod
- Paul Tang
- Scott White

The following Committee members did not attend this meeting:

- Richard Chapman
- Patrick Conway
- Frank Nemec
- Latanya Sweeney

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 47th 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 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

Farzad Mostashari, Chairperson and National Coordinator, had no remarks, having recently returned from vacation.

Review of Agenda

Paul Tang, Vice Chairperson, noted the many items on the previously distributed agenda. He requested members' cooperation in maintaining the time allocations for presentations and discussions. He said that two new workgroups were being convened – the Accountable Care Workgroup and the FDA Safety and Innovation Act Workgroup. He mentioned each agenda item, saying that the presentation on CommonWell Health Alliance was requested by Mostashari.

Tang asked for approval of the summary of the March meeting, which had been distributed with the meeting materials. It was moved and seconded to accept the summary with no amendments. The motion was approved unanimously.

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

Special Report: CommonWell Health Alliance

Paul Egerman reported that he and Charles Kennedy had been asked by Mostashari to report on CommonWell Health Alliance, which was founded by McKesson, RelayHealth, Cerner, Allscripts, althenahealth, and Greenway as a solution for nationwide data exchange. Egerman was careful to say that he himself was not involved in the project and was attempting to explain it in a neutral manner. It is intended to be a trade association and its formation was announced at the recent HIMSS conference. It is very much a start-up in an early stage. For his report, he interviewed David McCallie and Arien Malec (members of the HITSC whose companies are among the founders) and others. Its intent is that providers can unambiguously identify patients and match them with their health care records as they transition through care facilities. It will use existing unique identifiers (salted/hashed) like cell phone number, email address, or driver's license swipe for identity management. Patients can manage consent and authorization by a HIPAA-compliant and patient-centered means to simplify management of data sharing consents and authorizations, focusing initially on the most common treatment situations. Providers will be able to locate patient records across care locations via a secure, thin nationwide records locator service. With appropriate authorization, providers can issue targeted (directed) queries that provide for peer to peer (e.g., EHR to EHR) exchange.

Charles Kennedy reported that he spoke to several founding CIOs. He probed to determine whether a private collaboration is a workable structure for national exchange. The founders' customers are reportedly interested in supporting ACOs in their interoperability at lower levels. He received no clear answers to his questions regarding the anticipated interaction across competitors. He indicated that one of the policy issues for consideration is the extent to which commercial interests can and should form a nationwide exchange.

They reported that they asked interviewees what the HITPC can do to support their efforts. Responses were summarized: clarify policy-related guidelines; leverage the Privacy and Security Tiger Team's work on targeted query; consider the effects on efforts like CommonWell when evaluating policy-related guidelines; and simplify the most complicated edge cases of data segmentation. Kennedy emphasized the importance of ensuring the Stage 3 exchange requirements can be met with existing and emerging services, such as CommonWell, by providing flexibility in attainment of measures.

Q&A

Mostashari called for clarifying questions before opinions.

Deven McGraw asked for clarification of the statement that data may not be consumable. Egerman responded that his impression was that the information would be visible in the workflow but not

consumed. The view, but not the actual data, may be incorporated. But he acknowledged that he was describing his impression only. More information is required to accurately answer the question.

Mostashari asked about an example. Egerman said that the founders want to be sure that vendors are committed to exchange. At the first patient visit, the provider could see, for example, the problem list or med list from another provider. Kennedy emphasized that the project is in a nascent stage. There is no inherent workflow; each vendor would determine how to insert this process into its own workflow.

The governance model is fluid, according to Egerman. There will be a board of directors with patient and vendor representatives. Regarding privacy and security, they are following HIPAA and ONC recommendations although they may push the edge of the envelope. He speculated that they may come to the HITPC for guidance. Kennedy reported that only the principles for governance have been stated and they are based on a commercial perspective; for instance, no individual vendor will be preferred. Egerman speculated that a process similar to DURSA might be used. Regarding the time frame, one CEO projected 18 months. The interviewees were enthusiastic.

Neil Calman inquired about the relationship between this exchange and other exchanges. Would it be supplemental to or instead of regional exchanges? Egerman replied that the FAQs on its website indicate that it would be used in conjunction with local exchanges, but the interviews indicated that the intent is to go national with one set of rules. Calman wondered about the effect on regional exchanges and what would happen if one's EHR vendor was not a member. Kennedy said that being "open" is a founding principle. The founders see local exchanges struggling with their business models. The nationwide exchange could replace or compete with local exchanges. This exchange is expected to be more sustainable. But since commercial interests will prevail, the outcome cannot be predicted. Egerman opined that vendors will be responsive to their consumers' desires.

Mostashari commented on the need to dig deeper. Is this a service that is severable or an exclusive network for exchange? Is it a layering on of an optional service? Egerman said that it is structured to be an add-on service that is flexible. Kennedy referred to it as sort of a certification of an alliance. Individual members will be required to work on a national infrastructure and to incorporate and support national standards.

Josh Sharfstein wondered about state HIEs plugging in. Egerman reported that he had heard nothing about HIE organizations plugging in. Sharfstein spoke about the need to think about the overall goal of exchange. This business is creating private value and may create a competitive advantage that is adverse to the ultimate goal. Kennedy reported that the CEOs interviewed denied that intension, saying that they asserted that the concept complements HITPC policy recommendations. Sharfstein noted unintended consequences. Kennedy opined that the system would be useful.

Marc Probst observed that the plan for the use of a national identifier would require rebuilding another standard. He suggested that the HITPC bring in like parties to discuss the issue and to design a national solution.

Someone referred to ACOs being responsible for 14 percent of all U.S. health delivery. What about analytics? Egerman responded that he had heard nothing about plans for analytics. Probably outcome measures are out of reach. Kennedy noted that these vendors are working on ACO enablement, which will eventually include analytics. To do meaningful analytics, data liquidity is required. This business could enable analytics.

Judy Faulkner agreed to Tang's request that she be brief. She relayed that her employer (Epic Systems Corporation) had been criticized at the HIMSS conference for not being in CommonWell Health Alliance. She purported that Epic had not been invited to join and that she was unaware of its formation. She said that it felt like a business and that it is expensive to participate. What components of businesses will be in it? Will data be sold? What about the interests of patients? Will the structure and results be partial to

founders? If it is a business, is it appropriate for the HITPC to be involved? Egerman asserted that it is not inconsistent for ONC to consider the interests of this group. The consideration of vendor interests is within the purview of the HITPC per the stakeholder representation set forth in the law.

Tang summarized. The CommonWell Health Alliance is an emerging concept. Much remains undefined. The HITPC is interested in information exchange and in the role of the private sector in exchange. It would not be appropriate to endorse the organization or to do more at this time.

Members continued to comment. Someone emphasized the possibility of creating barriers no matter how well intentioned the effort. This is only one of many attempts for national exchange. Mostashari wondered whether the CommonWell Health Alliance will help to move exchange forward if it does not encompass everyone. Will it contribute to fragmentation? Faulkner opined that participation in the CommonWell Health Alliance would preclude participation in other efforts.

Gayle Harrell talked about her support for ONC playing a part in innovations. Doors should not be closed. A few vendors controlling the marketplace and pushing out small businesses is not good, but balance and a level playing field are.

Data Update

Tang appealed for brevity in the presentations. Robert Anthony, CMS, moved through his updated slides. There were nearly 16,000 new registrants in February. Eighty-five percent of eligible EHRs are now registered, along with 73 percent of eligible EPs. Registrations and payments continue to increase. Seventy-three percent of EHRs are meaningful users. Approximately 36 percent of Medicare EPs are meaningful users of EHRs. Approximately 44 percent of Medicare and Medicaid EPs have made a financial commitment to an EHR. Regarding performance, EHRs are coming in over the thresholds.

Matt Kendall, ONC, reported that RECs have worked with over 133,000 primary care providers in more than 50,000 different practices, representing approximately 44 percent of primary care physicians and 49 percent of nurse practitioners. A GAO report found that Medicare providers working with RECs were over 2.3 times more likely to receive an EHR incentive payment than those that were not working with an REC. RECs are working with over 80 percent of Federally Qualified Health Centers (FQHC) and over 73 percent of Critical Access Hospitals (CAH). Staff is designing and targeting tools to assist providers. Staff set up monthly meetings with federal partners in order to better focus efforts. RECs are being used to test tools. Staff has identified a number of challenges on which to focus. Small practices have many competing needs, and meaningful use is not necessarily a priority. Providers have difficulty with the smoking status measure. CAHs and rural hospitals lack the capital for EHR infrastructure and adequate connectivity. Providers are confused by quality reporting requirements of different federal programs. Providers and vendors need education on the new HIPAA regulation. RECs and providers need to better understand documentation requirements for audits. Medicaid providers are slow to progress from AIU to MU. RECs need additional education on Stage 2 requirements on information exchange. ONC staff is designing various trainings, tools, and reports. Web-based training to prepare for Stage 2 is available.

Q&A

In response to Kennedy's question about deployment of tools to reach underserved populations and communities and how to respond to advocates on behalf of these communities, Kendall said that the RECs are reaching out to everyone. ONC uses GIS analysis to track these efforts. He repeated that RECs are working with more than 80 percent of FQHCs and targeting Medicaid providers.

Mostashari acknowledged the need for more analysis on mitigation of the digital divide, some of which is underway. He offered to report on these results at a subsequent meeting. Anthony indicated that CMS staff is examining attestation and performance data by zip codes.

Harrell inquired about variation in the performance of RECs, saying that she has heard that some are low performers. Kendall referred her to data available on the ONC website. ONC is targeting lower performers with technical assistance. Congress mandated evaluations. Staff is looking at the effects of REC staffing patterns and local market concentration. Harrell referred to the time-limited grants to RECs and asked about their sustainability. Kendall responded that he is looking at business models and the variation in needs across regions in four areas: interoperability support, privacy and security assessment, consumer engagement, and new payment models.

A member asked about pediatricians' participation, saying that she had made several requests for this information to no avail. She said that since pediatricians are caring for a large proportion of the Medicaid population, she wants to be sure they are not left behind. Pediatricians attend newborns at multiple hospitals and have to learn multiple EHR systems, which is reportedly a problem for them. Anthony acknowledged that compiling the information on pediatricians is more difficult than he anticipated. Staff will continue to work on an answer. The information on meaningful use pertains to Medicare providers. Attestation data from Medicaid EPs is reported to states. Additionally, the issue of using multiple systems is one of EH reporting. Regarding the reasons for the 90-day dropoff in public health reporting shown on a slide, he reminded her that he had given an explanation at the March meeting. The decrease may be due to normalization as the number of providers reporting increased. The time frame for reporting and the opening and closing of registries may account for some variation. Kendall said that REC staff report having worked with 46 percent of U.S. pediatricians.

Information Exchange Workgroup Comments on Joint CMS and ONC RFI on Interoperability and Exchange

Micky Tripathi, Chair, Information Exchange Workgroup, explained that the workgroup had been asked to comment on the RFI in a much abbreviated time frame. The members narrowed their focus to four areas of potential federal action to advance HIE: payment policy, providers ineligible for meaningful use, state-level program and policy variation, and leveraging HHS infrastructure. The workgroup considered the following levers: regulation, payment, certification, state action, reporting and public reporting, and convening authority. Regarding payment policy, Tripathi said that the diffusion of advanced payment models has successfully spurred provider demand for information exchange through a combination of carrots and sticks. These models are still nascent, however, and there are a number of areas where they could be improved. The following recommendations were made:

- HHS should work to simplify and harmonize requirements across advanced payment models for public and private payers. This will help providers focus on the desired outcomes rather than the often complex mechanics of the current programs.
- Since there is still a lag in adoption of HIE capabilities through advanced payment models, highly focused supplemental payments to capitated and fee-for-service models to motivate HIE-enabled activities (e.g., higher E&M coding for “cognitive activities” using HIE, such as information reconciliation) should be used.
- Voluntary certification program for HIE functions that enhance enablement of value-based purchasing activities should be used.

The inapplicability of meaningful use to LTPAC providers, pharmacists, commercial labs, and others leaves gaps in the HIE incentive and regulatory framework that result in structural impediments to progress in interoperability across the care continuum. Therefore, they recommended:

- HHS should harmonize required documentation and reporting across programs and with the MU framework, including harmonization of CMS-required documentation with CCDA, incentives to Part D providers to motivate HIE-enabled and HIE-enabling activities, and advance administrative simplification where it intersects with clinical standardization, such as prior authorization documentation requirements
- Regarding laboratories, HHS should provide safe harbor from certain CLIA requirements if providers are compliant with MU and using certified technology and increase aggressiveness of Stage 3 eligible hospital laboratory results delivery requirements to move the market faster
- HHS should require (if possible) or facilitate (if not) voluntary certification of technology used by providers ineligible for MU, in alignment with MU requirements

State-level variation in program requirements and policies impedes HIE adoption by making it more difficult for multi-state care organizations and technology vendors to design scalable processes, services, and products. He said that some variation lies in differences in programs that have federal and state components and other types of variation lie in differences that are solely rooted in areas where states have independent policy authority (e.g., privacy, liability, etc.). The workgroup recommended:

- CMS should include HIE requirements in all programs including state waivers and future advanced payment demonstrations, and require coordination as much as possible with the state HIT coordinators
- CDC should continue and increase its work to harmonize the variability across states in the standards utilized for public health reporting to enhance use of HIE
- HHS should create model language available for inclusion in state-level programs (e.g., Medicaid MCO contracts, state employee health plans, etc.) to encourage HIE activities
- HHS should identify and encourage any opportunities for reducing state-level variation in privacy and liability policies related to HIE activities

Infrastructure recommendations consisted of the following:

- CMS should repurpose existing data and business infrastructure to facilitate market development of HIE capabilities including: apply open data principles to provider databases (NPES, MU, NPI) to make data available to market for provider directory creation; build on credentialing of patients and providers to support validation needs for HIE activities (e.g., provisioning patients with Direct addresses); and enable patient access to immunization information contained in public health immunization registries
- HHS should align FDA programs with the meaningful use framework, such as device interoperability (facility and home), structured product labeling standards, and event reporting standards

The presentation slides also outlined all of the above sets of recommendations in somewhat greater detail.

Discussion

Tang announced that the workgroup's recommendations are for the purpose of comments on the RFI; they do not constitute recommendations of policy. He declared that their comments were comprehensive and well thought-out.

Harrell noted that they had left out mental health providers in their consideration of ineligibles. Tripathi acknowledged the oversight and agreed to add mental health to both the ineligibility and the state categories.

Robert Tagalicod concurred with the recommendations and said that a CMS committee is working on payment policies. He offered to report back.

Probst referred to slide 4 and said that since the benefits of information exchange are enormous, additional payment incentives should not be necessary. Faulkner talked about patient access to immunization data and said that vendors must facilitate the use of numerous state-specific registries. Universal standards would be helpful. In response to a question about retail clinics, someone said that they may be EPs. Faulkner complained that faxes continue to be used in EDs. She pointed out that state insurance exchanges present a unique opportunity to encourage exchange. Someone responded that CMS is moving exchanges to a front burner. Mostashari asked Sharfstein to report on the marketplace and insurance exchange in Maryland. Sharfstein said that the HIE provider directory will be available for use by consumers. Tripathi talked about using the HIE and Medicaid enrollment process to issue direct addresses to patients. Sharfstein reported that the Maryland hospital rate commission is aligning payments. The HIEs are compiling reports for hospitals to submit. Readmission requirements for payments are driving an increase in exchange. Regarding access to immunization registries, he pointed out that alignment with EHRs is very difficult. A single standard would help.

Mostashari asked for more information on leveraging the infrastructure for credentialing. Tripathi responded that the recommendation pertained to patient enrollment and validation for Medicare and Medicaid as well as provider enrollment in these programs. The recommendation also referred to collecting providers' addresses with attestation.

Christine Bechtel asked whether anyone is thinking about a Blue Button for Medicaid recipients. Tagalicod indicated that CMS staff is thinking about it. He offered to report back on the status of their thinking. Bechtel suggested that something about Blue Button be included in the comments. She went on to ask about making it easy for providers to upload what they need, saying that that issue should be included in the comments. Mostashari replied that ONC staff is doing a lot around technical aspects of exchange. There are numerous use cases. The RFI focuses on the policy, standards, and business case for the sharing of information. It should not be unprofitable to share data. People in Louisiana are working on access to Blue Button for Medicaid recipients.

Tang announced that the time allocated for discussion had ended.

Art Davidson said that he agreed with Sharfstein about the burden of requiring access to immunization registries. Although he agreed in principle that patients should have access to their information, it would place a considerable burden on public health agencies. Tripathi referred him to the appendix slides which explained that the recommendation is for patient access via tethered portals. In response to another question about labs and safe harbor, Tripathi again referred to the appendix and the detailed recommendation to review lab requirements. He assured the members that the intent is to reduce the burden on labs.

David Bates announced his support for Bechtel's comments. He declared that the dominant players in the market require a regulatory approach.

Tang summarized the points to be added to the Information Exchange Workgroup's recommendation: mental health; insurance exchange infrastructures; standard for direct patient access to immunization registries; and Blue Button for Medicaid. He asked about additional items. Bates reiterated that large players not wanting to be involved in the exchange is an issue. Many of the recommendations are aimed at changing the incentive structure to bring in that large player. Someone noted that the recommendations or comments on the RFI should be specific to certain policies and regulations. Tang asked the members for their opinions on patient access to immunization registries. Mostashari informed Faulkner that state laws regulate the registries. She repeated her concern about the burden on vendors. Harrell announced her concern about the expense for states. She said that she agreed with Davidson. The HITPC cannot mandate policy for states. Patient access to registries should not be included in the comments. Sharfstein said that as a representative of a state health department the value would be enormous. It would be easier for patients to access the state registry than to obtain the information from providers and would make school enrollment easier. Also, the information would be readily available at immunization clinics. Davidson, in

discounting the latter argument, pointed out that providers have direct access to the registries from the immunization clinics. In any case, the Stage 3 recommendation is for immunization data to flow back into the EHRs.

Tang ruled that they agreed with inclusion of a single standard. They did not agree to include direct access to patients. But they did agree to include direct access with an asterisk and elaboration on the concern with burdening the state health departments. He called for a vote on acceptance of the recommendations from the Information Exchange Workgroup. No opposition or abstentions were heard.

Action item #2: The recommended comments from the Information Exchange Workgroup to the ONC-CMS RFI were accepted with several additions as described above.

Privacy and Security Tiger Team Recommendations

Tang noted that the presentation at the March meeting had covered one of the three scenarios in great detail. He urged McGraw to respect the time allocation.

McGraw, Chairperson, Privacy and Security Tiger Team, presented the team's recommendations on query and response. By way of background, she repeated from previous meetings that query and response actions among different providers occur regularly in health care. The question is: What new challenges and questions are raised when automating this process? HIPAA and other laws regulate when most health care providers are permitted to disclose identifiable protected health information (PHI), including in response to a query or request. The rules permit, but do not require providers to release PHI in a range of circumstances. The goal of the recommendations is to reduce potential real or perceived barriers, such as through clarification regarding provider liability for responding to a query, to enable them to respond to external queries consistent with their professional ethical obligations and the law.

She went through three scenarios. The first was targeted query for direct treatment, which is controlled by HIPAA. In this situation the data holder (provider B): needs some reasonable assurance as to the identity of the entity requesting the data; needs some reasonable assurance that the querying entity has, or is establishing, a direct treatment relationship with the patient; makes a decision about whether to release data, and if so, what data, consistent with law; and if responding, needs to send back data for the right patient, needs to properly address the request, and needs to send the information securely. The requester (provider A): needs to present identity credentials; must demonstrate (in some way) the treatment relationship; and must send patient identifying information in a secure manner to enable the data holder to locate the record. Reasonable reliance could be based upon: use of DIRECT certificate; membership in a network that the data holder trusts; or the requester is known to data holder (such as through a pre-existing relationship). She went on to show a series of slides that delineated the questions (and answers) considered by the tigers in formulating the recommendations. The recommendations for scenario 1 are that the previous recommendations on patient-matching should be implemented:

- A standardized format for data matching fields is needed and HITSC should propose such standard formats. EHRs should be tested and certified for interoperability regarding standard data fields. HITSC should develop recommendations on missing data and consider the benefits of a USPS validation or normalization.
- Health care organizations/entities should evaluate the effectiveness of their matching strategies to internally improve matching accuracy.
- Matching accuracy should be enforced through governance. HIEs should be required to establish programs that ensure matching accuracy by participants and how to respond if incorrectly matched.
- ONC should establish a program(s) to develop and disseminate best practices in improving data capture and matching accuracy.

- Increase patient access to their health information and establish audit trails to track where information has been accessed. Set simple process for reporting corrections to their information.
- Data holders should respond to queries consistent with their professional and legal obligations. (Note that even acknowledgement of the existence of a record is PHI.)
- Data holders have a duty to respond to queries in a timely manner by either providing: some or all of the requested content and a standardized response indicating the content requested is not available or cannot be exchanged (DURSA).
- The data holder should log both the query from an outside organization and the response, regardless of its content. The requester also should log the query. This information (query and response logs) should be available to the patient upon request.

McGraw went on to scenario 2 – targeted query for direct treatment, controlled by stronger privacy laws in addition to HIPAA, and read the recommendations:

- Data holders and requesters must comply with the laws or policies that apply to each. In some cases requesters must obtain the patient’s consent/authorization prior to a query; in some cases the data holder must have the patient’s consent/authorization prior to releasing PHI.
- The form of consent must comply with applicable law, i.e., the requester must have a form that satisfies their legal requirements (if applicable), and data holders must have the form that satisfies their legal requirements (if applicable). These forms may not be the same.
- As a best practice and to assist providers in complying with applicable law and policies, parties to a query/response should have a technical way to communicate applicable consent/authorization needs or requirements, and maintain a record of such transactions. For example, data holders may need to communicate with a querying entity that a particular patient authorization is required before data can be shared; the data holder (and in some cases the requester) may need or want to record the communication and the authorization. As another example, data holders sharing data subject to 42 CFR Part 2 (substance abuse treatment regulations) may need to communicate restrictions on “re-disclosure.”
- The HITSC should give further thought to technical methods for giving providers the capacity to meet their needs re: complying with applicable patient authorization requirements or policies. This may be an area where “one size fits all” is neither possible nor desirable given current technologies. Entities may also choose to use a service to meet their needs in this area.

She moved to scenario 3 and explained that providers frequently raise concerns about the impact of more stringent privacy protections on patient care and workflows; at the same time, patient advocates worry that failure to protect this information would create barriers for patients seeking confidential care for sensitive conditions. Technical methods should facilitate compliance with existing sensitive health data laws and policies but without adding so much complexity that providers and others involved in facilitating health data exchange leave sensitive data out of exchange altogether.

Scenario 3 was more challenging for the tigers since it is a non-targeted query for direct treatment purposes. It assumes a patient’s previous providers are not specifically known and is an initial query to find the locations of a patient’s record(s). This situation may require use of an aggregator service (such as a record locator, data element access service, master patient or health information exchange) to find possible sources of record. The tigers considered whether patients should have meaningful choice on whether or not they are included in an aggregator service that permits queries from external providers. Although the tigers agreed that the answer is yes, they were unable to move to a recommendation. She said that they sought the committee’s help with this question: Should querying entities be required to limit

queries (e.g. by geography, list of providers, etc.)? She asked whether the team should continue to debate this question insofar as to date very little time had been available for such a discussion.

Discussion

Mostashari announced that he was pleased with the recommendations. He asked about the determination of the existence of a treatment relationship. What about an artifact? Egerman indicated that it referred to a known relationship. McGraw talked about capability to confirm. She referred to a difference in words rather than a different concept.

Faulkner referred to slide 17 and said that the rules for exchange of sensitive data originated in the paper world. She wondered how to help with compliance. The separate environment for sharing mental health information is a problem when vendors have integrated systems. She wondered about sharing medication information, noting that some drugs are used for both mental health and other conditions. Vendors need to understand how to separate these data. McGraw talked about the issue of what the law specifically says. Some state laws have exceptions for medications. Guidance on the interpretation of these state laws is frequently lacking. The issue is a persistent one. Some states are adopting federal laws. She wondered what more the team can say. Faulkner (who is a member of the Tiger Team) then referred to slide 11, asking about situations in which data holders do not have control. Egerman explained that the slide referred to automated response. Faulkner suggested that the phrase be clarified to refer to providers that do not have the capability to automate their rules. Egerman agreed.

Following another clarification, Mostashari suggested incorporating the concept of meaningful choice in a situation in which a network participation agreement has an all or nothing clause.

Harrell acknowledged her participation in team meetings. She exclaimed that mental health is not the only condition requiring special treatment of information. The PCAST report and data segmentation should be addressed. Egerman interrupted to say that the recommendations under discussion have nothing to do with segmentation. Harrell responded that although they may not apply to the discussion, policy is nevertheless needed. Vendors are having huge problems dealing with sensitive data. States will not change their laws without federal direction. Egerman noted that it is difficult for vendors to find out what states laws actually are.

Terry Cullen observed that the problem is how to implement these policies electronically. The VA is working on segmentation. McGraw repeated that the scenarios define the boundaries of the recommendations. The tigers did not discuss segmentation. Other organizations are working on testing and piloting standards for segmentation. In response to a question about the meaning of the word “technical” on slide 19, McGraw said that it refers to exchanging the consent and authorization as stated.

Mostashari asked Faulkner about the Cleveland Clinic’s use of Epic. She indicated that although it is technically feasible to communicate the consent, systems cannot determine when a higher level of consent would be required. It might be possible for a provider to mark the information that requires higher consent. Mostashari talked about a demonstration at the HIMSS conference by the VA and SAMHSA on a method for differentiating levels of consent. Egerman said that a provider could choose to get consent for everything.

Cullen asked whether the vagueness of the statement on slide 9 was intentional. Regarding slide 13 and data matching, she said that VA staff members were concerned about the rework that would be required to go back to collect additional information from patients. McGraw reminded her that the recommendation was made in February 2011 and requires standards that have not yet been developed. The vagueness is intentional. Someone said that the standards for a header in C-CDA for Stage 2 may be applicable.

Calman inquired about the reference to a direct treatment relationship on slide 9. McGraw explained that it applies to a situation in advance of an appointed visit. Calman indicated that he concurred about the anticipated relationship.

Tang asked whether members agreed that the Tiger Team should continue to work on scenario 3. There appeared to be agreement. He asked for approval of the recommendations through slide 22. No one voiced opposition or abstention.

Action item #3: The recommendations on privacy and security for query scenarios 1 and 2 (through slide 22) were accepted.

Public Comment

Given that the meeting was running behind schedule, Tang asked about postponing all public comments until the final item on the agenda. Robertson rejected the request.

Darrell Roberts, American Nurses Association, wrote his master's thesis on HIPAA. He observed that it is unlikely that CommonWell will go away. Therefore, ONC should open a discussion with the CommonWell vendors and nonaffiliated vendors.

Carol Bickford, American Nurses Association, requested that ONC explore publication of an HIE IP directory.

Meaningful Use Workgroup: Draft Recommendations for Meaningful Use Stage 3

Tang made the presentation in his role as chairperson of the Meaningful Use Workgroup. He reminded the members that Stage 3 is to focus on improved outcomes. He reviewed the principles used in Stages 1 and 2 and several new principles for Stage 3. His slides also summarized the application of what was learned in Stage 1. As related in a previous meeting, the workgroup divided into two subgroups to discuss consolidation of measures and an alternative path to meaningful use called deeming. Both are intended to reduce reporting burden and the latter would attempt to reward good behavior.

Bechtel described the consolidation recommendations. The 43 objectives proposed in the Stage 3 RFC were consolidated to 25 objectives. The workgroup has yet to consider the feedback from the RFC and to update the criteria. All criteria will be included in certification. The focus will be on using data. Consolidation would give credit for objectives that should be standard practice once past Stages 1 and 2. Consolidation is based on: advanced within the concept of another objective; duplicative concepts for which the objective becomes certification only; and demonstrated use and trust that performance will continue.

She went on to show slides that depicted which objectives were consolidated, including those designated for certification only. Eighteen objectives were moved to certification only. She explained that work remained to be done.

Moving to deeming, Tang described the assumptions used. A provider cannot reliably achieve good performance (or significantly improve) without effective use of HIT. Therefore, in order to promote innovation, reduce burden, and reward good performance, high performers (or significant improvers) would be deemed in satisfaction of a subset of meaningful use objectives *as an optional pathway* to qualifying for meaningful use. He showed an example on a slide in which high (top 30th percentile) or improved performance (20 percent reduction of gap between last year's performance and top quartile) could be demonstrated by selecting two objectives from a list of patient safety items and two from the care coordination list. For disparities, the provider would have to stratify all four selected population reports by disparity variables. Objectives recommended for deeming were: CDS; eRx, formulary, generic subs; reminders; electronic notes; test tracking; clinical summary; patient education; and reconcile problems, meds, and allergies. VLT and secure messaging are candidates pending results from Stage 2.

He went on to talk about other considerations, such as to offer both absolute threshold (e.g., > 70th percentile) and significant improvement (e.g., reduce gap between last year's performance and full performance by 20 percent) options for deeming. Another possibility is to propose that the performance reporting period be six months instead of one year to give providers a chance to deem, yet still have time to resort to functional objectives qualification if they are not meeting deeming thresholds. Specialists may have fewer options for deeming as determined by the available NQF quality measures. If they are not able to report on at least four performance measures, then they may not be eligible for the deeming pathway.

Discussion

Tang (in his role as vice chairperson of the HITPC) asked for comments on continuing with consolidation and deeming. George Hripcsak, Co-Chair, Meaningful Use Workgroup, commented on the value of this approach.

Harrell gave her approval and asked about the use of PQRS measures for deeming. Tang acknowledged that he had not considered their inclusion. He preferred to first deem meaningful use, followed by PQRS. Bechtel pointed out that all of the measures on the list are PQRS measures as well. Someone said that not all PQRS measures are meaningful use measures. Several members appeared to agree that PQRS inclusion should be considered in deeming.

Christopher Boone referred to his experience with the American Heart Association and wondered about the technical assistance available to providers in working with patient registries. As part of the reconciliation act, there was a reference to PQRS and deeming of reporting to professional registries. Reporting to registries is an optional (menu) item for meaningful use. Would participation in a registry be deemable for some of the functional measures? Tang said that the example fell under consolidation. Bechtel said that it may be useful to look at the comments made on PQRS and registries. Tagalicon acknowledged that the alignment of all quality programs should be the goal. PQRS may be good starting point. Kate Goodrich, CMS, is working on this integration. Tagalicon offered to forward Goodrich's slides to Tang.

Probst asked about deeming being skewed toward one type of provider over another. Tang responded that the group tried to follow national priorities.

Cullen pointed out that improvement cannot be shown on new measures in the same year in which they are introduced. To demonstrate improvement requires measurement at a minimum of two points in time. Tang admitted overlooking that consideration. Calman asked about expanding the list on slide 18, pointing out that this is an opportunity to broaden the scope of meaningful use and to get specialists to think about the application of tools. Tang responded that he had tried to take that into account. But deeming uses outcome measures and there are a limited number for specialists. Calman opined that specialists could innovate even without approved measures. Bechtel reported that innovation was discussed at length in both subgroups. There may be opportunity to establish a third pathway for quality measurement: A provider could create a measure and report on its logic and application. Tang reminded the members that the innovation pathway was in the RFC for core CQMs. A provider that selected the innovation path would be expected to describe the rationale, reliability and validity considerations, the range of values, and so forth, of the innovative measure. Candidate measures are in the pipeline and NQF is working on filling the gaps.

Mostashari agreed that it makes sense to have outcome measures deemed. But the process-outcome dichotomy may not be appropriate because some process measures are close to outcomes. While sending a discharge summary is a process measure, closing the referral loop is closer to an outcome and could be deemed. He gave another example with patient experience. Tang agreed, saying that the measures in the examples are candidates for deeming. Mostashari went on to say that the deemed measures should be tied to the functional measures for communication purposes.

Faulkner asked for more attention to pediatrics and childhood obesity. Harrell said to ask the specialty societies to suggest their deeming measures.

David Lansky declared that he concurred with involving the specialty societies in nominating deemed measures. They could be invited to propose subsets of measures for deeming based on some requirements that CMS would devise. Vendors must be encouraged to be more flexible in allowing for the design of and reporting on measures. Standards for measures that specialists may come up with are needed so that they can be used more widely.

Mostashari pointed out that CAHPS data reside outside of the meaningful use reporting system. The idea of deeming performance in one reporting system to another may potentially apply in other areas, for instance, the ACO reporting system. How broadly should this be considered? Tang acknowledged that he had not thought about outside systems. Mostashari referred to expectations about program integrity and prohibitions about meaningful use funds duplicating other funding programs. Bechtel urged ONC to explore the use of CAHPS data and to support mapping of the data to Stage 3 objectives.

Tagalicod informed them that CMS has been asked to do the prepayment audits. He will report back on the operational effects. A member talked about expanding the options by involving the specialty boards. Boone also advocated for involving specialty societies and gaining a better understanding of specialty registries. Davidson asked about incorporating patient reported outcomes in registries. Mostashari urged greater boldness with consolidation and deeming while taking into account the protection of program integrity.

Mostashari observed that heads were nodding in agreement. Tang declared that he understood the sense of the committee was to proceed with consolidation and deeming with increased boldness. No objections were heard.

Action item #4: The general approaches of consolidation and deeming measures for Stage 3 were approved.

Clinical Documentation Hearing Report Out with Recommendations

Tang reported on behalf of the Meaningful Use Workgroup and the Certification and Adoption Workgroup. Based in part on testimony provided at a public hearing several months ago and summarized by ONC staff, the Meaningful Use and the Certification and Adoption Workgroups met jointly and formulated the following recommendations on clinical documentation:

- Move clinical documentation menu item to core in Stage 3
- Do not proscribe or prohibit method of clinical documentation. Guide appropriate use through education and policies
- Help reader assess accuracy and find relevant changes by making the originating source of sections of clinical documents transparent analogous to "track changes" in MS Word™. Default view of documents in the medical record and those transmitted to other EHRs is a "clean copy" (i.e. not showing tracked changes). The reader can easily click a button and view the tracked-changes version.
- To improve accuracy, to improve patient engagement, and to guard against fraud, EHRs should have the functionality to provide progress notes as part of MU objective for View, Download, and Transmit (VDT)
- Further innovation and research required to collect and meaningfully display information (possibly using graphical views), rather than just text
- Increase education about E&M coding criteria; better yet, as payment reform emphasizes outcome over transactions, seek to change E&M coding criteria to reduce over-reliance on specific language in clinical documentation

- Propose that HITSC review what standards are needed to ensure that CEHRT maintains legal medical record content for disclosure purposes (e.g. what was accessed during the encounter and what gets printed out as the legal medical record?)

Discussion

Larry Wolf, Co-Chair, Certification and Adoption Workgroup, responded to Egerman's question about clinical documentation being restricted to ambulatory progress notes, saying that documentation was used more broadly to include both EH and EP. Text could be created within a separate system and brought over into the EHR. Egerman pointed out that the recommendation about tracked changes did not quite apply. He suggested formulating a recommendation that the HITSC establish standards to bring in information from consultative reports. The track changes should relate only to progress notes, not to text that comes from other sources. Debate ensued about the management of text. Faulkner advised that large vendors be consulted on the feasibility of the track changes recommendations. Tang responded that representatives of several vendors participated in the discussion leading to the recommendations. They indicated that development of such a function is underway.

A member talked about the difference between mistakes and fraud and cautioned about the use of the latter word. Standards for things like "record reviewed" are needed. Tang said that Congress mandated the examination of fraud. He agreed that mistakes are different from fraud.

Mostashari talked about the overuse and inappropriate use of productivity tools sometimes creating problems with accuracy, both on the clinical side as well as the billing side. Providers need some kind of guidance or a code of conduct. Tang indicated that the group had not discussed guidance on appropriate documentation. Presentations at the documentation hearing indicated that people do not want to have proscriptions. A discussion commenced about up-coding and codes of conduct. Medical necessity governs the code level. Calman mentioned an "anti-certification" requirement: that EHRs cannot contain a counter function to encourage up-coding.

Tang asked for opinions on the track changes recommendation. Egerman announced that he agreed provided the recommendation is limited to progress notes entered directly and does not include information imported into the EHR from other sources. For example, a radiologist's final report could be entered without showing any earlier changes in that report. Tang indicated that that was the implication. No disagreement was voiced.

Tang asked for opinions on the inclusion of progress notes in the VDT recommendation. Cullen reported that the VA initiated open notes prospectively in January following extensive provider education. Some problems were reported with the use of words such as obesity. To do open notes retrospectively would introduce many difficulties. Mostashari said that EHRs should have that functionality. This is not a recommendation for Stage 3; it is a recommendation for certification. Tang corrected him, referring to the text of the draft recommendation on a core measure. Mostashari asked Tang to hold off on recommendations for Stage 3. Bechtel and Tang agreed to comply.

Members shared their experiences with consumers and open notes. Tang clarified that the recommendation did not differentiate between EH and EP. Faulkner wondered about the extent to which having open notes distracts providers from providing the best care. McGraw pointed out that HIPAA allows withholding of information thought to be harmful to the patient.

Tang asked for opinions on the legal medical record recommendation. Calman talked about three components: what the record contains, what was available at any point in time, and what was accessed at specific times.

Tang indicated that the workgroups would continue to deliberate on the documentation recommendations, including Mostashari's suggestion about a code of conduct.

Long-Term Care Coordination

Evelyn Gallego, ONC, talked about the lack of current and proposed standards for transitions of care (ToC) and exchange of care plans for Stage 2 and Stage 3 and described the efforts behind evolving standards for ToC and care plans and their expected level of maturity for 2013. She reminded the members that comments on this topic had been solicited in the Stage 3 RFC and summarized by staff at the February 6 HITPC meeting. She went on to consider in turn each of three main gaps. The first is the lack of care plan definitions, relationships, and the ability of the C-CDA to represent needed care plan content. The concept of care plan and its component parts are ambiguously defined in meaningful use and thereby impact the ability for interoperable exchange. Current standards do not support the requirements to exchange a care plan. The C-CDA focuses on problem-specific goals, instructions, and care team. Other components, particularly health concerns, interventions, and the patient's overarching goals, are omitted. There is no standard for codifying all of the care team members. There is no standard on conveying when and how each section of a plan was last reconciled for a given patient. There is no standard to convey the many-to-many relationships among the components of the care plan.

She moved to the second gap: EP and EH information needs and responsibilities for ToC. Hospitals must be responsible for providing information to LTPAC (and other) providers. The Massachusetts IMPACT project, a recipient of one of the ONC challenge grants, identified the needs of the receivers of patients during ToC. Forty-six organizations were surveyed to identify data elements needed for ToC and exchange. Researchers started with the CCD, the part of the consolidated CDA which has data elements. An additional 150 elements were identified specific to ToC needs. Staff came up with a new dataset of 483 data elements, many of which can be mapped to CDA templates with applied constraints, leaving approximately 30 percent of necessary data elements with no appropriate templates.

A third gap is standards maturity and adoptability. A number of efforts are underway to address the insufficient standards for transitions of care and care plans. They include the following: ONC S&I ToC, esMD, and LCC WGs; HL7 Patient Care Workgroup; IHE Patient Care Coordination Technical Committee; and AHIMA LTPAC HIT Collaborative. She went into great detail about the S&I LCC and the five transition data sets being tested and fielded by IMPACT. (For information, go to the LCC Wiki Site: <http://wiki.siframework.org/Longitudinal+Coordination+of+Care>)

Q&A

In terms of readiness for Stage 3, the standards will be balloted in August through September, and assuming their acceptance, the standards gaps will be closed. Calman pointed out that EHRs have yet to develop the mechanisms for capturing all of this information. Gallego said that the standards build on the C-CDA and they are consistent with what was done with paper records. Tang exclaimed that in this case standards will be ahead of practice. Providers do not currently know how to query patients to obtain some of this information. Gallego said that staff is working toward the care plan use case and once there is agreement on these components, definitions will be considered. In some, but not all, settings, patients are involved in setting care plan goals. Although the standards will be available, ONC cannot proscribe the provider's process for involving the patient. The provider associations will be involved.

In response to a question from Davidson, Gallego said that there is no content for the 30 percent of elements not in the C-CDA template. Mostashari asked that the HITPC not try to re-do the work of the LCC group. He offered to send more information on the IMPACT project to the members. He asked the members to consider the most essential information to transmit to control readmissions.

Tang asked about the incorporation of these functionalities in professional education systems. Gallego emphasized that help is needed in that regard.

Public Comment

None

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the March 2013 HITPC meeting was approved.

Action item #2: The recommended comments from the Information Exchange Workgroup to the ONC-CMS RFI were accepted with several additions as described above.

Action item #3: The recommendations on privacy and security for query scenarios 1 and 2 (through slide 22) were accepted.

Action item #3: The general approaches of consolidation and deeming measures for stage 3 were approved.

Meeting Materials

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