HIT Policy Committee
FINAL
Summary of the July 9, 2013 Virtual Meeting

ATTENDANCE

Members present:

- David Bates
- Christine Bechtel
- Arthur Davidson
- Connie White Delaney
- Paul Egerman
- Judith Faulkner
- Scott Gottlieb
- Gayle Harrell
- David Lansky
- Deven McGraw
- Farzad Mostashari
- Marc Probst
- Joshua Sharfstein

Members absent:

- Madhulika Agarwal
- Neil Calman
- Patrick Conway
- Thomas Greig
- Charles Kennedy
- Frank Nemec
- Alicia Staley
- Latanya Sweeney
- Robert Tagalicod
- Paul Tang

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 50th meeting of the Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with an opportunity 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 and Review of the Agenda

Chairperson Farzad Mostashari, National Coordinator, noted his fourth anniversary at ONC. Many complex issues have been encountered. It is important to recognize milestones and trends and adapt policies as needed. Four years ago, 90 percent of medical records were on paper. Considerable progress in

adoption and digitization has been made. Articles published today in *Health Affairs* summarize this progress. To date, the benefits of HIT have been somewhat uneven. They must accrue to all. Care coordination and patient engagement are the current challenges.

He asked for a motion to approve the meeting minutes. A motion was made and seconded. A voice vote for approval of the summary as circulated with the meeting materials was unanimous.

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

Data Update

Robert Anthony, CMS, presented slides summarizing the most recent information on registration and attestation. Approximately 79 percent of all eligible hospitals have received an EHR incentive payment for either MU or AIU. About 8 out of 10 eligible hospitals have made a financial commitment to an EHR. Approximately 56 percent of Medicare EPs are meaningful users of EHRs. Approximately 63 percent of all Medicaid EPs have received an EHR incentive payment; 11 percent of Medicaid EPs are meaningful users. Over 53 percent of Medicare and Medicaid EPs have made a financial commitment to an EHR. Over 297,000 Medicare and Medicaid EPs have received an EHR incentive payment. At the end of May 2013, 195,337 Medicare EPs had attested, 195,124 successfully. 3,046 EHs had attested, all successfully. 5,720 Medicaid EPs had attested (2012 only). Regarding Medicare, most thresholds were greatly exceeded, but every threshold had some providers on the borderline. Drug formulary, immunization registries, and patient list were the most frequently selected menu objectives for EPs, compared to advance directives, clinical lab test results, and drug formulary for hospitals. Transition of care summary and patient reminders were the least frequently selected menu objectives by EPs, compared to transition of care and reportable lab results for hospitals. There was little difference among specialties in performance, but they differed in exclusions and deferrals. Performance on core objectives over the 90-day period was comparable from 2011 through 2013.

With regard to non-returning Medicare providers on which a number of articles are being published, approximately 10,000 Medicare EPs who attested in 2011 did not return for the 2012 program year. CMS surveyed non-returners. 17 percent changed to another practice. 28 percent did not meet the deadline. 50 percent attributed their non-return to multiple factors. Of those citing multiple factors, one-third of providers indicated each of the following: missing deadline, requirements too complicated, too time consuming, and waiting for Stage 2 information. The majority of non-returners indicated that they intended to become users again in the future. CMS is using this information to develop and target resources (www.cms.gov/EHRIncentivePrograms). Medicaid 90-day core objective performance was compared with Medicare in 2012. Although Medicare performance is somewhat higher on most objectives, both types of providers greatly exceeded thresholds. For the complete report visit http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html

Christine Bechtel wondered why providers had problems with providing clinical summaries to patients. Anthony speculated that they had failed to adopt it into their workflows.

Jennifer King, ONC, reported on papers co-authored by her and other ONC staff and published July 9, 2913 in Health Affairs. Adoption and use of EHRs were analyzed based on data from the most recent NCHS National Ambulatory Medical Care Survey of physicians and the American Hospital Association's survey of hospitals. Both surveys reportedly had response rates of more than 60 percent. King emphasized that basic EHR adoption is not the same as meaningful use. Among office based physicians, reported adoption of "any" EHR system increased from 51 percent in 2010 to 72 percent in 2012. Over that period, adoption of a basic system increased from 25 percent to 40 percent. Although adoption varied by practice

characteristics, such as size, ownership, specialty, and age of physician, as well as by area characteristics, increase in use from 2010 was consistent for all categories. More than half of physicians who had a computerized capability reported using it although some functions were used less than others. EHR adoption by hospitals increased from 9 percent in 2008 to 44 percent in 2012. The greatest relative increase was among those hospitals with previous low adoption (small, rural, for-profit, or non-teaching), indicating somewhat of a catch-up trend. Adoption of capabilities varied considerably, with patient engagement, care coordination, and public health measures lagging.

Members made no comments. They asked no questions.

Non Targeted Query Virtual Hearing Report Out

Deven McGraw, Chair, Privacy and Security Tiger Team, reported on the June 24, 2013 hearing on non-targeted query. No recommendations were presented for committee action. The purpose of the hearing was to understand what policies are being deployed to ensure that a non-targeted query for a patient record is appropriate, legal, and authorized. Such policies may include limitations on who can conduct the query, the purposes for which a query can be conducted, geographic or other limits and parameters intended to help assure proper access, and demonstrate that the requester is authorized to access a patient's records. The tigers were interested in limitations placed on access to the record via query. Examples include, but are not limited to, partial access to the record, geographic limits and purpose, such as limiting queries to those for direct treatment. Some HIEs may have inherent limitations, based on factors such as geography in the case of a regional HIE. The scope of non-targeted queries involves use of an aggregator, such as a record locator service, data element access service, or health information exchange. Although the tigers focused on use cases involving direct treatment relationships, they were interested in hearing about how non-targeted queries are used for other purposes.

She showed the lists of eight panelists and the questions they were asked. The tigers are scheduled to meet July 10, 2013 to talk about the hearing. Recommendations will likely be presented at the August HITPC meeting.

Discussion

None

Quality Measures Workgroup Recommendations on Data Intermediaries

Chairperson Helen Burstin introduced Marc Probst, who leads the Data Intermediaries Tiger Team (DITT). The DITT was charged to specify the role and functions of intermediaries in e-measure reporting and feedback, including their role in measurement calculation, submission, data transformation, data governance, and bi-directional communications with providers and end users, and to explore the current and desired future state of intermediaries. The team was asked to consider which attributes of an intermediary are required to satisfy future state needs. The team formulated recommendations related to: privacy and security; data quality; CEHRT standards alignment; and organization type and characteristics. Probst presented the following recommendations:

> Accept EHR data for clinical quality measure calculation – Short term: DI will be certified to 2014 CEHRT and function as Certified EHR Modules. Will accept a Quality Reporting Document Architecture Category I (patient level data) consistent with ONC Standards and Certification Criteria for MU2 and will not add innovative measures to MU. Long term: For the sake of encouraging consistent implementation and calculation of MU CQMs, DI will accept quality data that conform to future standards (e.g. QRDA). To allow multi-source data capture, DI will also accept proprietary data reporting formats. Data intermediaries may have proprietary

formats for transfer of multisource data for innovation path measures, but those formats will not be required for EHR certification

Ensure quality of data transferred and stored – Short term: Require import and export testing for certification as in MU2. Long term: Intermediaries attest that the data they report to HHS truthfully describe clinical care and are faithful to data received from providers. The attestations as above in addition to federal regulators or representatives will be responsible for random and periodic audits of intermediaries to prove compliance with entity data management plan and maintenance of data quality.

Execute patient and provider attribution logic – Short term: Intermediaries attribute patients to providers as specified in 2014 EHR Incentive Program CQM specification. Long term: Intermediaries may develop proprietary attribution logic but must disclose the attribution method employed to providers and federal stakeholders and attribution logic will be transparent to public.

Calculate meaningful e-clinical quality measures from EHR data that providers use for MU credit – Short term: Providers will only receive credit for measures that are part of the EHR Incentive Program. Long term: There will be a minimal set of standardized quality measures that approximate the core measures for the EHR Incentive Program that all DIs will be certified to import data elements for, calculate and report to HHS via QRDA cat III (or appropriate data standard). Long term: Intermediaries will be encouraged to develop proprietary measures and providers will receive credit for reporting on intermediary-developed measures via standard reporting document (e.g. QRDA cat III). Long term: Require some review of proprietary and innovative measures that is less extensive than current requirements for national endorsement. Long Term: Limit innovative measures to those that conform to the following criteria: Specification expressed in unambiguous logic that conforms to Quality Data Model or future standard for eCQM and uses standardized value sets and logic consistent with others measures in the EHR Incentive Program; measures are outcomes focused, or if a process measure is developed and tested, it must be submitted as part of a "suite" of measures which includes process measures that have close proximity to a desired outcome measure; address one or more NQS domains that are high priority or have gaps in EHR Incentive program (e.g. care coordination, patient engagement, etc.); innovative measures should use multi-source data (claims, patient reported outcomes, financial, etc.); providers that participate in MU and use core and innovative measures will receive credit for quality reporting across multiple programs as appropriate (PQRS, MU, VBM, etc).

Report to public – Short term: No reporting of MU eCQM scores to the public. Long term: Public report requirements will mimic the reporting required by HHS for MU. Innovative measure data should eventually be visible to the public.

Report to HHS – Short term: Consistent with current certification criteria, intermediaries that are certified HIT modules will report on MU2 measures via QRDA Category 3 aggregate reports. Long Term: Requirement for reporting to HHS for innovative measures should mimic those for the legacy MU measures.

Report data to providers – Short term: Intermediaries will be expected to create reports on performance scores to providers. Long term: Intermediaries will be required to create reports on performance scores, benchmarking and data quality (e.g. rates of data errors) to providers.

Discussion

Probst said that the function of intermediaries is to increase efficiency and safety. Mostashari said that they may help with benchmarking and quality improvement. They can add to rigor in measurement. Some

quality measures are only meaningful when they use data aggregated across providers. Their role is related to the topic presented by McGraw.

Bechtel asked who can be an intermediary. Probst responded that any organization that meets the criteria may be an intermediary. The team did not reach consensus on scale and size.

Someone inquired about security and privacy. Probst indicated that the slide on that topic had somehow disappeared. Privacy and security would be left to providers who must meet specific obligations.

Paul Egerman asked whether a payor could be a data intermediary. Probst repeated that the recommendation contained no restrictions on organization type. Egerman opined that a payor in that role would raise privacy and security concerns. McGraw referred to the policy on business associates.

Mostashari declared that privacy and security recommendations are needed. He told Probst to ask the Privacy and Security Tiger Team to review the recommendations on the missing slide and then present the results at the next meeting. He went on to ask about governance and trust: What about business practices and intermediaries that impose limits on providers sharing of information? Probst acknowledged that the team had not discussed the topic. Burstin suggested that business practices would be related to who the intermediaries are. Mostashari announced that he would prefer to defer action on the recommendations until the August meeting.

Bechtel wanted information on the relationship between the Stage 3 RFC responses and the recommendations. She reminded them that her idea expressed months ago was to create a way to open up innovation in measure development to an individual provider. But the data intermediaries are different from individual providers in that they aggregate data. Burstin reminded Bechtel that the tigers were instructed to consider intermediaries. Some of the roles listed in the recommendations could be performed by individual providers. Bechtel asked about an individual provider who does not aggregate. Jesse James, ONC, reported that individuals were out of scope for the recommendations. The charge to the DITT grew out of a hearing on quality measures. Bechtel asked how the intermediary would support innovation in measure development. James responded that the hearing yielded information from actors in the field that they were already creating measures from various sources. They have learned by measuring quality improvement and they want these measures to be available to more providers. The QMWG had discussed a platform for measures; one issue is how to credit the results of the measurement. Most likely the ACO Workgroup will deal with the individual provider and measure innovation. Bechtel went on to talk about today's types of measures benefiting funders not consumers. Providers might be more likely to develop measures that consumers find useful. She questioned the extent to which intermediaries would have any incentive to develop novel measures. Burstin referred to a tool kit and Bechtel recommended that the recommendations expand on the tool kit idea.

Egerman referred to the recommendations on reports, which he interpreted as saying intermediaries would not generate quality reports. Other members interpreted the recommendations differently. Comments were made about the importance of understanding the feedback. Probst interpreted the recommendation as saying to constrain the development to the standards, not the measures themselves. James stated that Probst was correct in terms of constraining to the standards. Someone noted a tension between standards and innovation. Bechtel located the RFC document and wanted to know to which question the reported responses referred. James did not have the RFC in hand and it was difficult for participants to hear him. He repeated that the responders were opposed to removing constraints. Bechtel declared that the organizations with which she works interpreted the question differently. She urged the members not to put much stock in the reported responses. Mostashari talked about the difficulty of re-tooling the quality measures that were designed for a paper system. Egerman observed that quality measures that do not use EHR data are the problem. According to Mostashari, many gaps in quality measures could be filled by de nova measures. He cautioned against a false dichotomy between constraint and innovation. Burstin

located an old slide and reported that 25 comments recommended consistency. Egerman observed that the recommendations would primarily benefit the intermediaries.

Doug Fridsma observed the emphasis on reporting: What about calculation and metadata? Probst wondered whether Fridsma had missed the presentation of the calculation recommendations. Fridsma continued, saying that current standards limit the development of quality measures based on more sophisticated statistical analysis. Standards are not sufficiently robust. Novel measures may drive the development of standards. David Lansky pointed out that this being the 50th meeting of the committee, the members need to rearticulate the policy framework. IT capability is separate from the purposes for which it is used. The committee has tended to blend the two. The development of measures for providers' use is separate from CMS recognition of those measures for purposes of payment. These two tracks should be considered separately along with standards and governance decisions in each track. Probst said that the D ITT focused on requirements for the meaningful use program. Lansky said that the meaningful use program itself is ambiguous. The process measures are not of high public value and they are not reported to the public. Burstin mentioned a distinction between reporting and quality improvement. Bechtel said that the recommendations should refer to the problems to which they are directed. Innovation is a different challenge. Mostashari told Probst to focus on more stringent requirements for accountability and payment. Burstin talked about the possibility of staging standards.

Judy Faulkner asked how to ask a question. Mostashari repeated that the procedure for asking questions is to send an e-mail saying that one wishes to ask a question.

Mostashari brought up patient reported outcomes, saying that EHRs are not the best way to collect this data: Did the DITT discuss the role of intermediary in collecting patient responses? Probst indicated that non-standardized data could go directly to an intermediary; no recommendation was made on the topic. When asked, Bechtel agreed that the topic was an important one. Patient responses should be collected at the portal and go to another location. Lansky noted that individual patient reported data belongs with an intermediary. But probability sample survey data do not require this kind of intermediary.

Mostashari asked Probst to present a consolidated set of recommendations in August for committee action.

Information Exchange Workgroup (IEWG) Update

Chairperson Micky Tripathi, IEWG, reported that the workgroup was working on three Stage 3 issues: query for patient record; provider directory; and data portability. In addition to the consideration of responses on those topics to the RFC, the workgroup considered whether any market developments or lessons learned would necessitate amendment of the list. The members agreed that: query for the patient record is high priority for Stage 3; provider directory to support query as well as directed exchange is required for Stage 2; and data portability is required to meet the growing need for cross-vendor data migration. He showed slides and presented recommendations on query and provider directory:

> HITPC recommends that EHR systems have the ability to electronically query external EHR systems for patient medical records and that EHR systems have the ability to electronically respond to electronic queries for patient medical records from external EHR systems. HITPC recommends that the following principles be used for establishing requirements and standards for query-based exchange: continuity -- build on Stage 1 and 2 approaches and infrastructure for directed exchange where possible, and allow use of organized HIE infrastructures where applicable and available; simplification -- **s**et a goal of having query and response happen in a single (or minimal) set of transactions; generalization -- accommodate flexibility in use cases, workflows, installed base capabilities, and legal or policy considerations; and transactions.

Requirements for transactions were listed on the presentation slides under querying systems' abilities; responding systems' abilities; transaction details; authorization; and patient-matching.

Discussion

Mostashari asked Tripathi whether the committee should consider the transaction details listed on the presentation slides in acting on the recommendations. Tripathi responded that they were an important part of the recommendations. Terry Cullen asked whether the recommendations are doable in terms of standards development. Tripathi replied in the affirmative. The HITSC is working on standards. Cullen said that she is aware of that work through her employment at VA. FIRE has yet to be implemented anywhere. The market may not embrace the standard. Mostashari noted that the recommendation was to not specify any specific standards. McGraw reported that the recommendations are consistent with adopted privacy and security recommendation. Mostashari expressed concern that the HITPC would include a recommendation on standards, which are the purview of the HITSC. Tripathi explained that the workgroup members thought there is too much variation in the market. He said that he understood about the distinction in the HITPC and HITSC purviews. McGraw referred to query response, saying that there is policy in the response; communicating that the patient has a record with that provider does disclose some information. Claudia Williams, ONC, asked whether variation in policy and workflow makes uniform standards difficult. Tripathi responded that that was the point being made in the recommendation. Mostashari referred to HIEs, saying that in Stage 2 EHR-mediated exchange, he wanted providers to be able to select their means of exchange: Would the recommended requirement bind providers to one vendor or mechanism of exchange? Tripathi indicated that was not the intent. Certified technology would provide a floor. The recommendation does not attempt to break new ground in that area.

Mostashari called for the vote on the query recommendations. Robertson asked for a voice vote. Votes in favor were heard. No votes in opposition were heard. Mostashari declared the query recommendations approved. He asked Tripathi to take the standards question back to the workgroup.

> **Action item #2: The recommendations of the Information Exchange Workgroup on query for patient record were approved unanimously.**

Tripathi presented the recommendations on provider directories. He emphasized that the new recommendations reflect feedback from previous HITPC recommendations on directories as well as IEWG observations on current and expected market trends.

> HITPC recommends that EHR systems have the ability to query external provider directories (PD) to discover and consume addressing and security credential information to support directed and query exchange and that EHR systems have the ability to expose a provider directory containing EPs and EHs addressing and security credential information to queries from external systems to support directed and query exchange. HITPC recommends that the following guidelines be used for establishing standards for provider directories: scope -- standards must address PD transactions (query and response) as well as minimum acceptable PD content to enable directed and query exchange; continuity -- build on Stage 1 and 2 approaches and infrastructure for directed exchange where possible and allow use of organized HIE or cross-entity PD infrastructures where applicable and available (i.e., remain agnostic to architecture and implementation approaches); simplification -- **s**et goal of having a query and response happen in a single (or minimal) set of transactions.

The recommendations included a long list of transaction requirements and details, which Tripathi read.

Discussion

Egerman asked for a description of the external entities that maintain directories. Are there privacy and security issues? Tripathi explained that the directory provider could be another entity, HISP, HIE, provider, or any number of other kinds of organization. The market would decide. The privacy and security issues are the same as with certification. Egerman pointed out that the directory information applies to providers. Tripathi indicated that the organizations that develop directories would determine the trust fabric.

Gayle Harrell inquired about authentication of providers. Who would be responsible for assuring that the information on the providers' licensures, board certifications and so forth is accurate? Tripathi replied that the recommendations do not include requirements for listings in directories. Each owner would determine the type and quality of information listed. The workgroup did not set accuracy thresholds for a directory.

Fridsma reported that last year the HITSC looked at directories and found many different ways to compile directories. Most of the information does not require authentication, only that there are end points. In looking for other industry-wide directories, not many good examples were identified. Typically, search and microdata are used. The requirements are burdensome. Tripathi commented that authentication is likely taken care of in other ways. He repeated that the workgroup did not have recommendations on specific requirements for authentication. Fridsma talked about finding the end points, or falling back to LDAP. Authentication of credentials should not be required. Although some information could be sensitive, if the information is simply how to contact a provider, authentication is not necessary. Mostashari told Egerman that the lack of directories hinders information exchange.

Mostashari called for the vote and asked Robertson to call the roll. McGraw, Faulkner, Davidson, Probst, Lansky, Harrell, Bechtel, and Terry Cullen (for Agarwal?) voted yes to approve the recommendations. Egerman voted no. There were no abstentions. (A number of members may have exited the call prior to the vote.) Mostashari told Tripathi to follow-up with Egerman on his objections.

> **Action item #3: The Information Exchange Workgroup's recommendations on provider directories were approved by a vote of 8 to 1.**

ONC Updates

Jodi Daniel, ONC, talked about the HIT Patient Safety Action and Surveillance Plan, which was released July 2, 2013. ONC staff developed the plan on behalf of HHS and with collaboration from other HHS agencies. Staff considered input from the HITPC as well as public comments on an earlier draft of the plan (December 2012). HIT is playing an ever-larger role in the delivery of care to patients, and this trend has significant implications for patient safety. HIT presents new opportunities to make care safer by, e.g., preventing medical errors, enhancing clinical decision-making, and enabling a learning health care system. These benefits are widely acknowledged; achieving them remains a top priority for ONC and HHS and is at the core of their regulatory and programmatic efforts. However, the rapid deployment of HIT in already complex health care delivery systems may lead to unintended consequences and new risks of harm. The IOM found little published evidence quantifying the magnitude of risks associated with HIT. More research is needed on the types and severity of HIT-related risks and hazards. HHS officials wish to guide nationwide efforts towards fully achieving the benefits of HIT (including its potential to make care safer) while minimizing unintended consequences and new risks of harm.

Moving to surveillance of certified EHR Technology, she told them that ONC issued guidance on July 2, 2013. In 2014, ONC-ACBs will be expected to perform live surveillance of: safety-related capabilities and developers' complaint processes. ONC-ACBs will be encouraged to make surveillance results public. On July 2, 2013, ONC issued guidance to its Authorized Certification Bodies (ONC-ACBs) explaining their responsibilities for conducting live surveillance of certified EHR technology (CEHRT). For 2014,

surveillance will include a heavy focus on HIT safety. ONC-ACBs will perform live surveillance of certain safety-related capabilities (CPOE, drug-drug and drug-allergy interaction checking, and medication reconciliation). The results will provide insight into how these capabilities perform in actual clinical environments in which they are used, and will help staff understand and mitigate the risks associated with these capabilities. ONC-ACBs will also examine developers' processes for receiving and responding to user complaints related to the safety of developers' HIT products. ONC is strongly encouraging ONC-ACBs to make the results of their surveillance publicly available. This will promote transparency and provide users and customers with better comparative information when selecting HIT products and services.

Daniel went on to report approval of a 1-year contract with option year with the Joint Commission to conduct near-term analysis, support early detection and mitigation of serious events and hazards, and make recommendations on the role of external oversight bodies in ensuring HIT patient safety. Also, ONC and ASPE awarded a patient-centered outcomes research (PCOR) strategic opportunities contract to NORC to explore standards, policies and services required to establish PCOR infrastructure. Documents will be posted for public input. For new resources, visit http://www.healthit.gov/policy-researchers-implementers/resources. A Congressional report on HIT adoption is available at: http://www.healthit.gov/sites/default/files/rtc_adoption_of_healthit_and_relatedefforts.pdf

Doug Fridsma, ONC, showed a slide with updated operating metrics. Query health will be re-launched on July 16, 2013 to assist users with getting access to data. The capability is relevant to topics of today's call. Structured data capture is progressing. ONC is working with the EU and US memorandum on the establishment of a common set of standards to support innovation. For more information, visit http://wiki.siframework.org/

Public Comment

There was no public comment.

Mostashari thanked Robertson for her support of the FACAs. Michelle Nelson will coordinate the FACAs activities until Robertson's replacement is hired. Robertson thanked the members for their work.

SUMMARY OF ACTION ITEMS

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

Action item #2: The recommendations of the Information Exchange Workgroup on query for patient record were approved unanimously.

Action item #3: The Information Exchange Workgroup's recommendations on provider directories were approved by a vote of 8 to 1.

Meeting Materials

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