

**Health Information Technology Policy Committee
Final
Summary of the September 14, 2011, Meeting**

KEY TOPICS

1. Call to Order

Judy Sparrow, Office of the National Coordinator (ONC), welcomed participants to the 27th meeting of the Health Information Technology Policy Committee (HITPC). She reminded the group that this was a Federal Advisory Committee meeting being conducted with the opportunity for public comment, and that a transcript would be made available on the ONC Web site. She asked the Committee members to introduce themselves, and then turned the meeting over to National Coordinator for Health Information Technology Farzad Mostashari.

2. Opening Remarks

Mostashari began his opening remarks by reminding the group that this meeting was being held during National Health IT Week, and that for the first time, there has been a Presidential proclamation acknowledging the importance of health IT and its place in having the kind of health care delivery envisioned by the ONC. Two days prior to this meeting, the Office launched the consumer eHealth component of ONC's activities. The ONC recognized and brought together national leaders who are making it easier for people who want to get their own health information to do so. Mostashari reported that Leon Rodriguez, the new Director of the Office of Civil Rights, has stated that this is the patients' right and is a key step towards giving patients the tools to become more empowered and more engaged consumers of health care.

The ONC also announced a Notice of Proposed Rulemaking that clarifies Health Insurance Portability and Accountability Act (HIPAA) language and mirrors the administration's position is that patients should have a right to their own information from laboratories as well from providers and health plans. In addition, the Million Hearts Campaign was launched during the week of this HITPC meeting—heart disease, cardiovascular disease, heart attacks, and strokes comprise the largest portion of avoidable deaths in this country. The Campaign links ONC and HITPC efforts to a much broader public and private commitment to focus on cardiovascular disease.

Mostashari commented that it is remarkable that in a short time since the launch of the health IT incentive payments, a fundamental change is coming to the delivery of health care in a way that is thoughtful and that takes into account the kind of care this group envisions while not solely focusing on the technology. He also took a moment to recognize ONC's Judy Sparrow, who has announced her retirement after a lengthy career in the government. Sparrow has been instrumental in supporting ONC's efforts, particularly with regard to the HITPC and HIT Standards Committees. Sparrow thanked Mostashari and the Committee members, applauding them for conducting their work and characterizing their efforts as a lesson on how the government and private sector can work together in a meaningful way. Mary Jo Deering has agreed to take over for Sparrow during the transition to a permanent replacement.

3. State HIE Program Update

ONC's Claudia Williams provided an update on the experiences and challenges facing the State Health Information Exchange (HIE) Program. The program is driven by the objective of getting supporting providers (small providers, large providers, and hospitals) to achieve the meaningful use objectives, specifically the exchange objectives. Priorities include focusing on lab exchange, care summary exchange, supporting pharmacies participating in e-prescribing, and public health reporting. In the last year, efforts have centered on working with states to get concrete, tangible implementation plans tied to these objectives.

Williams' presentation focused on care summary exchange, which includes hospitals sending discharge summaries and the requirement for sharing care summaries. In meaningful use Stage 1, many different methods could be used to achieve simple sharing of a care summary or collective transition—the next step is a requirement that this be done through the electronic exchange of information. Currently, very few systems support the capacity for two physicians being able to send each other information about a patient as that patient transitions to have a test, get a referral, etc. In many cases there is an aggregation of hospital data that can be queried by a physician, but no real way for two physicians to share information as a patient moves through the health care system.

Williams explained that the types of strategies to address this challenge vary depending on existing capacity. For example, the State of Rhode Island is working with its policy infrastructure and opting consent approach to enable physicians using electronic health records (EHRs) who send a care summary to another physician for a patient transition such that another copy of that message can be sent through a consent filter to populate the repository the physicians query. Another strategy involves states working with local health information organizations to examine how they can more rapidly build the capacity for achieving some of the basic meaningful use requirements in areas where trust is already developing and where there is a business case (in many instances, states are directly funding or supporting those local efforts).

Part of the challenge lies with the fact that communities have their own preferences and ideas as to where they want to go—finding ways to build a pathway to achieve both meaningful use exchange requirements while meeting the community's needs requires careful planning and implementation. Defining the qualification criteria from privacy and security as well as from interoperability perspectives is needed (e.g., what are the basic standards that need to be developed, what are the baseline policy requirements for different qualified entities, how is they will share information, etc.?). The ONC is trying to support those efforts while learning from their experiences so that this information can be fed into the governance work.

Hunt Blair, Department of Vermont Health Access, discussed progress in the State of Vermont in terms of HIE and Health Information Technology for Economic and Clinical Health Act (HITECH) program implementation as well as tying that work into statewide efforts related to health reform and health care transformation. He noted the importance of recognizing that this work in essence “levels the information exchange playing field” by putting doctors, hospitals, insurers, and individuals all on an equal footing. This runs against the typical hierarchy of the

health care business model—HIE is, by its very nature, disruptive to the ecosystem, but in a creative way.

In Vermont, health reform is this main HIE use case as HIT has been embedded in health reform from the outset. The state looks to HIT and HIE to enable the kind of communication and linkages between the various components and elements of the health care system that are all too frequently not as tightly integrated and knit together as they should be. Blair described a series of core design principles. For example, all Vermonters should have their own blueprint for health—a primary care medical home, and all of those medical homes are connected through community health teams that provide linkages not just for subpopulations and specialized groups but also for all the general population. These community health teams connect primary care with the rest of the health care and social services system with the goal that “fragmentation of care should be a never event.”

Blair explained that integration and “systemness” have been key design principles in Vermont health reform, with a focus on building a fully integrated technical infrastructure. Components of this model include advanced primary care medical homes, community health teams, and targeted services for complex cases that are all linked with a combination of the exchange and a Web-based clinical data repository. To help integrate this within the state, Vermont is drawing on leveraging and re-using its IT artifacts. For example, the state is standing up its core enterprise resources to include both a master persons index and a state provider directory. Blair emphasized that in Vermont, it is not a matter of simply connecting eligible hospitals and eligible providers, but also connecting long-term care, mental health, home health, and human service providers. One of the state’s innovative programs involves expanding community health teams to include staff located at public, nonprofit, and housing sites where they are able to help coordinate care and are instrumental for keeping people at home longer and having much better transitions when they go into the hospital or rehabilitation.

Vermont is a state with a multi-payer claims database and has partnered with the University of Vermont on an informatics platform that brings together both claims data and clinical data for analyzing the blueprint and for modeling the future global budget and single system enterprises. Blair concluded his remarks by noting that this work represents an opportunity to drive alignment—not just the quality measures and quality metrics—but how the key data elements are recorded in EHRs.

Discussion

- Paul Eggerman asked about how Vermont’s work is being funded, other than through ONC grants. Hunt Blair explained that in 2008, the Vermont State Legislature passed an HIT assessment bill that involves a fee on top of all major medical claims. Vermont uses data in its multi-payer claims database for the previous year, generates a report, and on a quarterly basis invoices all carriers that have more than 200 covered lives in the state utilizing that resource. That revenue has reached approximately \$3 million per year to support the infrastructure. Vermont also has a long-range plan that includes instituting fees for providers utilizing the system, but the policy decision was made early in the process to build out the infrastructure and demonstrate the value on the front end first.

- David Lansky asked if the Committee should be considering ways to leverage the leadership efforts of places like Vermont and the development of uniform policies. He also asked if there is a teaching site where information is available and can be used to take advantage of the work being done in areas such as Vermont. Blair agreed that there is an opportunity for the HITPC to weigh in on the role of government to provide policies that set a framework. He commented that data liquidity is required to make the rate of increasing health care costs more manageable. The move from volume- to value-based payment cannot be made without the information infrastructure, and a true information infrastructure cannot be put in place without an agreement about the boundaries of how that happens.
- Claudia Williams suggested that there a number of areas where the HITPC could provide input on these issues. Thought should be given at a policy level regarding how these efforts intersect with health care transformation work at state and national levels. Ongoing state-level efforts should be examined to expose and reveal the issues, challenges, and opportunities that exist. Williams suggested that the Committee could consider how HITECH provides a roadmap for and interacts with these activities. She noted that not every state is going to use its governmental powers in the same way, but there are some generalizeable opportunities and challenges that can be useful to consider.
- Gayle Harrell noted that critical issues include: (1) funding, which is critical to these efforts (states do not have money to do this, and the grants will run out very soon); (2) governance (who are the decision makers, is this a state entity, is this a public/private corporation, and who is making the basic governance decisions?); and privacy and security (how are those decisions made in the privacy and security framework that has been established, and are there clear policies or requirements on privacy and security?).
- With regard to governance, Blair explained that in 2009, Vermont passed legislation very closely modeled on the HITECH Act placing responsibility for policy governance inside state government and operational governance with Vermont Information Technology Leaders, Inc. (VITL), the private, non-profit organization that operates the state's HIE network. In terms of the privacy and security framework, Vermont adopted privacy and security policies developed as state policies by VITL. Vermont is in the process of reviewing and revising the consent policy. Blair commented that there is a good, proven structure in place that has resulted in an effective framework and division of labor between the state and VITL.

4. Review of the Agenda

HITPC Vice Chair Paul Tang reviewed the remaining agenda items for the meeting and congratulated Judy Sparrow for her more than 20 years of dedicated service to the government. He noted that all of the tremendous gains associated with the HITPC and HIT Standards Committee (HITSC) and their various workgroups could not have occurred without her efforts and contributions to the ONC.

Action Item #1: Minutes from the August 3, 2011, HITPC meeting were approved by consensus.

5. ONC Initiatives

Jodi Daniel of ONC provided Committee members with an update on certain ongoing ONC activities, including the Federal Health IT Strategic Plan for 2011-2015, the Consumer e-Health Program launch, and ONC work in the areas of data integrity and fraud detection/prevention. She reminded the group that a draft of the Strategic Plan was released in March for public comment. The Plan includes the following five goals:

- Achieve adoption and information exchange through meaningful use of HIT
- Improve care, improve population health, and reduce health care costs through the use of HIT
- Inspire confidence and trust in HIT
- Empower individuals with HIT to improve their health and the health care system
- Achieve rapid learning and technological advancement.

Daniel noted that the final Strategic Plan was released earlier during the week this HITPC meeting was held. Although the majority of the Plan remained intact from the March draft, there were some changes. She reviewed these changes, which were in the areas of privacy/consent management, pace of change and timing for Stage 2 meaningful use, usability of EHR products, outreach and education to providers and consumers, and other areas (e.g., barriers to adoption and HIE, further harmonization of standards, inclusion of providers not eligible for incentive payments, accessibility). In an effort to make the Strategic Plan more current and interactive, the ONC anticipates using its Web site and social media to obtain input in real time.

Daniel noted that earlier in the week, the ONC held a Consumer e-Health Summit (an archive of the Summit is available online) to commemorate the launch of the first federal consumer e-Health program. The goal of the Summit was to focus on consumer empowerment, and on patients getting access to their information as a tool for empowerment. ONC announced a program that involves having entities pledge to empower consumers using HIT as well as a pledge for data holders and a pledge for non-data holders. To date, 40 organizations have pledged to empower consumers using HIT, and this initiative remains open. Additional information is available on the ONC Web site.

Daniel then discussed strategies to support consumer engagement via HIT in the areas of: (1) access (improving electronic, secure access to health information); (2) action (stimulating the development of innovative tools and applications to help individuals take action with the information); and (3) attitude (shifting attitudes about how to improve care through consumer empowerment).

Committee members were asked to provide input in the areas of data integrity and fraud detection and prevention. ONC's goal in these areas is twofold: (1) consider the implications of HIT on data integrity and fraud detection and prevention, and identify where HIT activities can help address concerns; and (2) identify any areas of priority for ONC activity. Daniel explained

that since 2005, the ONC has periodically conducted research, for example the Office published the 2007 *Report on Recommended Requirements for Enhancing Data Quality in Electronic Health Records*. This report included recommendations for certification criteria and included general categories such as audit/access logs, identity proofing/authentication, document integrity and authorship/legal record keeping, administrative/billing, and “auditor” access to records. Daniel noted that the issue of data integrity and fraud prevention may present an opportunity to form a workgroup to examine whether there are areas that should be prioritized and determine what issues fall within the scope of the HITPC. She also suggested that the Certification and Adoption Workgroup could review the recommendations from the 2007 report and work with ONC staff to identify ongoing/past activities, identify any recommendations that should be considered by the HITPC/HITSC, and identify any priorities.

Discussion

- Paul Egerman suggested that consumer access to data could play a strong role in this area—if consumers have access to their clinical data, they can serve as an additional monitor for data integrity/fraud prevention. Daniel agreed and added that the ONC is working on a project to help patients who identify something wrong with their health data to raise the issue with their health care provider or provider organization. , .
- Gayle Harrell emphasized the importance of addressing fraud. She noted that at least 10 percent of the \$23 billion spent each year in Florida on Medicaid can be attributed to fraud, duplications, and coding issues.
- Neil Calman commented that ONC’s efforts represent a proactive move to give people access to information, which may conflict with federal and state-level regulations that restrict access in certain situations. Daniel explained that currently, some states allow patients to get direct access to their lab data from labs. A proposed rule would allow patients to access their lab data in any state.
- Joy Pritts of ONC clarified that the Notice of Proposed Rulemaking includes a section on how it is anticipated that this would interact with state law. She further explained that the regulation here is somewhat complicated because there was a carve out in HIPAA that gave people right of access to their health information from all health care providers, except for directly from laboratories. The Clinical Laboratory Improvement Amendments (CLIA) removes those limitations and the privacy rule itself includes that right of access. Deven McGraw added that Congress had declared that HIPAA would pre-empt any state law that was deemed to be less protective, commenting that it is uncertain and arguably not permitted for a regulation by itself to be able to pre-empt a state law.
- Marc Probst asked whether there was any ongoing effort to examine the new payment mechanisms for health care, which could have a tremendous impact on fraud, and whether this effort (if it exists) could be used as a reference to the Certification and Adoption Workgroup. Daniel commented that the Office of the Inspector General and the Centers for Medicare and Medicaid Services are the lead entities for health-related anti-fraud activities.

These groups could be tapped to provide insight to the Committee and Certification and Adoption Workgroup.

6. Privacy and Security Tiger Team Update/Recommendations

Privacy and Security Tiger Team Co-Chair Paul Egerman began this presentation by listing the Tiger Team members and explaining that in July, public input was sought on proposed changes to the current regulations overseeing research on human subjects, often referred to as the Common Rule. An Advanced Notice of Proposed Rulemaking (ANPRM) was published in July—the comment period for the ANPRM expires on late October.

Tiger Team Chair Deven McGraw explained that the Common Rule was designed to address clinical trials and focuses primarily on protecting human subjects from physical risks, as opposed to informational risks. However, the Common Rule does cover research that is using information that is identifiable. The framework of the Common Rule is based on two foundational requirements: (1) independent review of research by an Institutional Review Board (IRB), and (2) informed consent of the research subject when there is more than minimal risk.

McGraw discussed the role of IRBs, which are composed of five members of various backgrounds, including one member not affiliated with the institution. IRBs review and approve all research activity, require documentation of informed consent or may waive the requirement for informed consent, and conduct continuing reviews of the research (not less than once per year). If research falls into a list of categories that involve no more than minimal risk, then it can be reviewed by a single IRB member as opposed to the entire IRB (a process known as expedited review). There are categories of research that are exempt from required IRB review—one of these categories is research that involves study of pre-existing data that is initially collected for purposes other than research (e.g., treatment data from EHRs), provided the investigator is receiving the information in a way that does not directly or indirectly identify the subjects. When the research is not exempt from IRB review, for the most part it also requires the informed consent of the subjects. However, an IRB can waive requirements for consent that might otherwise apply under certain conditions (e.g., when the research involves minimal risk a waiver would not adversely affect the rights of the subjects).

The Common Rule currently does not require researchers to adopt any security measures. However, some researchers that are covered entities may also be covered by the HIPAA Security Rule, and disclosure of a limited data set to researchers may require a data use agreement, which requires the researchers to agree to safeguard the data.

McGraw explained that HIPAA does not apply to research across the board, but does apply to certain covered entities and business associates of covered entities when they conduct research (ONCs programs are aimed at providers and hospitals—entities typically covered under HIPAA). Again, HIPAA also only covers protected health information, so the information needs to be identifiable. As a result, some entities may be subject to both HIPAA and the Common Rule. This has led to considerable frustration on the part of the research community in terms of perceived conflicts and a lack of clarity between how those rules can be read together to create a consistent set of obligations. Research is distinguished from “health care operations,” which

includes quality assessment and improvement activities, as long as the “primary purpose” of such activities is not to “obtain generalizable knowledge.”

HIPAA requires authorization in most cases if research is using fully identifiable data. A covered entity can release protected health information for research purposes if it receives documentation that an IRB or “Privacy Board” has approved a waiver of the requirement. Covered entities may use and disclose a limited data set for research purposes (stripped of names and other identifiers). De-identified data is not largely subject to regulation by HIPAA.

McGraw then explained that the ANPRM focuses on changes to the Common Rule and also expresses a desire to harmonize and streamline different research rules (in particular the Common Rule and HIPAA). The Privacy and Security Tiger Team focused on the provisions with a direct impact on ONC programs—the rules surrounding the secondary uses of health information initially collected for another purpose (e.g., for treatment). The ANPRM proposes to expand the scope of the Common Rule to any institution that receives federal research funds, even if the particular research project in question is not supported with federal funding. It also continues to exempt research on existing data from IRB review (potentially even if identifiable); however, it recommends that a study be registered through filing a “brief form” with an institutional office.

With regard to informed consent for the use of pre-existing data originally collected for non-research (e.g., treatment) purposes, the ANPRM reiterates the existing rule that consent is required only if the researchers obtain information that identifies the subjects. Thus, no consent is required for research using a limited data set or de-identified information. The ANPRM is seeking comment on whether consent should be required here, and if so, what type of consent. The ANPRM also proposes, for the first time, that researchers be required to adopt baseline security measures that vary with the identifiability of the data. Essentially, the HIPAA standards should apply in cases of individually identifiable information being used. In the case of a limited data set or de-identified information, the security requirements are lessened somewhat, they focus in particular on commitments not to re-identify.

Egerman then shifted the presentation to a discussion of the Tiger Team’s recommendations, which are focused in the following two areas: (1) what secondary uses of EHR data should be considered to be “research?” and (2) application of the full complement of Fair Information Practices (not just consent, and not just security. He emphasized that the ANPRM retains the exemption from IRB approval for the secondary uses of clinical data for research but does require general consent when the data is identifiable. The use of EHR systems creates new technological opportunities to improve the treatment of patients and to evaluate the quality, safety, and effectiveness of that care. There is concern that the potential treatment of such activities as “research” could limit these types of activities. Clarifying the definition of “research” could help remove real or perceived obstacles. Current rules (both the Common Rule and HIPAA) define “research” as “activities designed to develop or contribute to “generalizable knowledge.” Egerman commented that characterizing research as any evaluative activity that is intended to contribute to “generalizable knowledge” may no longer serve the interests of either patients or providers.

Egerman and McGraw then presented the Privacy and Security Tiger Team’s two draft recommendations in the area of secondary uses of EHR data as follows:

1. The use of a provider entities’ EHR data for treatment purposes or to evaluate the safety, quality and effectiveness of prevention and treatment activities should not require consent or IRB approval or registration. Such activities should not be considered “research” but instead should qualify as treatment and operations if conducted by, or on behalf of (such as by a business associate), a provider entity.
 - a. This exemption should apply even if the results are intended to, or end up being, publicized or more widely shared (i.e., contribute to generalizable knowledge).
 - b. We expect provider entities to maintain proper oversight over, and be accountable for the conduct of, these activities.
 - c. Consent should not be required to access EHR data for these purposes, even if the data does not qualify as either a limited data set or de-identified data; however, provider entities should always use the minimum necessary amount of data to accomplish these activities (including removing patient identifiers prior to analysis for quality, safety and effectiveness when it is not necessary to identify individual patients).
 - d. Examples of activities the Tiger Team agrees should be covered by this recommendation (not intended to be an exhaustive list):
 - Using EHR data to improve care provided to patients.
 - Identifying patterns of adverse events to detect patient safety issues.
 - Evaluation of interventions designed to improve compliance with existing standards of care and outcomes.
 - Monitoring individual clinicians and professional staff for adherence to existing standards of care and existing treatment protocols.
 - Outreach efforts intended to increase patient compliance with existing standards.

2. Consistent with the Tiger Team’s previous recommendations, the previous exemption should apply only when the provider entity (or OHCA) retains oversight and control over decisions regarding when their identifiable EHR data is used for quality, safety and effectiveness evaluations.
 - a. This recommendation is based on previous Tiger Team/Policy Committee recommendations that recognize that patients place their trust in their health care providers with respect to stewardship of their health information. Consequently, when the provider entity (or the OHCA) that the patient trusts no longer has control over decisions regarding access to patient identifiable data (such as in certain centralized HIO arrangements), the patient should have meaningful choices regarding whether or not his or her identifiable information is part of such an arrangement.
 - b. This exemption should be interpreted to allow provider entities (or OHCA) to collaborate and share identifiable information for treatment purposes or to conduct quality, safety and effectiveness assessments, as long as the entities remain in control over decisions regarding how their EHR identifiable data is to be accessed, used and disclosed.

- c. Entities should follow the full complement of fair information practices in using identifiable data for these purposes, including (but not limited to) being transparent with patients about how their data is used for treatment and quality, safety and effectiveness evaluation purposes, using only the minimum amount of data needed to accomplish the particular activity, and protecting the data with security measures that are commensurate with the risks to privacy).

In differentiating between the ANPRM approach and the Tiger Team's recommendations, Egerman explained that the ANPRM seeks to reduce obstacles to use of clinical data for evaluative purposes by continuing to exempt it from IRB approval, but: (1) such quality, safety and effectiveness evaluations are still considered to be "research;" (2) such research must be registered (via a brief summary) with the institution; (3) general consent would be required if the data involved is identifiable (not a limited data set or de-identified); and (4) no other institutional obligations are put into place beyond compliance with appropriate provisions of the Security Rule. The Tiger Team recommends not creating real or perceived obstacles to quality, safety, and effectiveness evaluations that contribute to a learning health care system by calling such activities research, as long as they provider entity (or OHCA) maintains decision-making control over identifiable information accessed for such evaluations. No consent should be required even if the data are identifiable, and provider entities remain accountable to their patients and the public for activities performed using data under their stewardship.

Under current regulatory definitions (and the ANPRM), activities with data are research if they are intended to contribute to "generalizable knowledge." This distinction will no longer hold in a learning healthcare system. However, is provider entity accountability enough to protect individuals from inappropriate uses of their health information? There may be a more effective way to draw the line between research and operations, to ensure widespread accountability.

The Tiger Team also made a third draft recommendation, focusing on the application of Fair Information Practices, as follows:

3. Researcher entities should be required to adopt policies and/or best practices that follow the full complement of fair information practices, regardless of whether or not a patient's consent is required to be obtained.
 - Examples:
 - Limit the amount of information collected to what is necessary.
 - Limit the number of people who have access to those performing the research.
 - Adopt and adhere to specific retention policies with respect to the data.
 - As another example of fair information practices, researchers should be required to adopt security protections consistent with the privacy risks associated with inappropriate exposure of the data. The Tiger Team applauds the ANPRM for recommending researchers be required to adopt security protections.

Discussion

- David Lansky noted that there are some critical challenges facing these efforts. For example, the manner in which the data will be used for public recognition and payment programs. Not

only is the information in the EHR going to be used to generate quality measurement data subject to some of these secondary uses, but many of the newer measures the HITPC is interested in require linkages between systems. Even re-admission rates requires capturing data not only from the primary institution but from some other attachment system as well (e.g., claims data or an HIO). He suggested that it is not enough to fix the Common Rule and HIPPA issues that are on the table for this discussion—there is a need to look forward to the applications of data that are on the horizon with ACOs and other structures. One question that needs to be addressed is whether or not use of data for public reporting and quality measurement is in the “research bucket” or in the “operations bucket.”

- Lansky also pointed to the need to clarify whether registries are operations or research. Ideally registries would be considered as operations, but if the regulatory process deems that the registries are “research,” then IRB approval mechanism that would apply to address the patient consent issues should be simplified. McGraw agreed that the issues raised by Lansky require additional clarity moving forward.
- Paul Tang asked for clarification regarding when secondary uses of clinical data for research may be exempt from IRB approval. McGraw explained that there are requirements in the Common Rule on IRBs and there are institutional policies with respect to the role that IRBs play in managing data use within their institution. If something is exempt from IRB approval, it is not that the IRB is given the authority to exempt it, it is that the rule does not require IRB approval for that to take place.
- Tang also asked about repurposing of data. If a business associate gets access to identifiable information through a legitimate means, can that business associate go on and repurpose it if it creates de-identified aggregate information? McGraw explained that the Tiger Team made the assumption that business associates would only be acting pursuant to some strict confining authority from covered entities with respect to identifiable data.
- Arthur Davidson discussed provider entity accountability and asked if some structure is needed to allow organizations to work together at a quality improvement or population perspective level. Is it enough to say they are covered entities and they are going to act responsibly? McGraw agreed that this is an issue, noting that the Tiger Team’s letter accompanying its recommendations includes language suggesting that additional work may be needed in this area in terms of oversight over the organizations to ensure that the public is comfortable with these activities. Madhulika Agarwal argued for leaving this area more open, which may put more of a burden on providers and institutions, but defining this issue more concretely may lead to additional barriers and challenges.
- Judy Faulkner pointed out that research will continue to be viewed differently as technology continues advancing. In response to her question regarding re-identifying data, McGraw explained that if a researcher is getting de-identified data from an institution, there should be at a minimum a commitment from the researcher not to re-identify that data. If the researcher sees something in the data that could improve patient care, the researcher should approach the covered entity. She clarified that there is no obstacle to the use of identifiable data for the purpose of treatment (i.e., a physician taking care of a patient).

- Robert Tagalicod asked about noncompliance and whether the ANPRM would address this issue. He also noted the challenges associated the need to provide de-identified data in rural areas where practices have discrete numbers of practices with discrete numbers of patients. Tagalicod also noted the challenges associated with creating harmonization between covered and non-covered entities.
- Lansky discussed the need for rulemakers to consider that EHR data will likely exist in a variety of platforms and media, which will have implications for how providers capture data from patients and send data to patients. He noted that many registries have difficulty capturing patient-reported data because the institution feels that it is too difficult to go through the consent process to obtain the data from the patient. He emphasized the need to remove barriers from obtaining patient-reported data.
- Neil Calman noted that at present, 76 percent of all medical journals require IRB approval before they will publish an article. This represents another barrier to generalizable knowledge and obtaining information. Egerman added that there are many avenues for researchers to publish their findings outside of medical journals—making information available on a Web site, for example, could contribute to generalizable knowledge.
- One Committee member asked if the environment is ready for comprehensive legislation indicating that everyone who touches data should be held accountable. Egerman indicated that the Tiger Team’s third recommendation is similar, indicating that research entities must follow Fair Information Practices.
- Gayle Harrell noted that with an additional month of time to respond to the ANPRM, the next Tiger Team meeting could focus on secondary uses of information, particularly in the context of business entities/associates and what patients expect will happen with their information. McGraw indicated that the letter accompanying the Tiger Team’s recommendations will include comments related to business associates. The Tiger Team will also consider a work schedule that will allow the Team to address some of the other issues raised during this discussion with respect to de-identified data use either by covered entities or their business associates.
- McGraw summarized that the discussion has indicated the need for some changes to the Tiger Team’s letter, but not to the recommendations. A draft of the revised letter will be circulated prior to the next HITPC meeting for comment will be revised and brought back to the Committee for consideration at its next meeting.

Action Item #2: The Privacy and Security Tiger Team will revise its letter and circulate a draft to Committee members prior to the next HITPC meeting.

Action Item #3: The Committee accepted the Privacy and Security Tiger Team’s recommendations by consensus.

7. Query Health

Richard Elmore of ONC presented on Query Health, recently launched initiative to develop standards and services for distributed population queries. Guidance from and linkage to the HITPC will be crucial to the success of this effort. Elmore presented the vision of Query Health as follows: “Enable a learning health system to understand population measures of health, performance, disease, and quality, while respecting patient privacy, to improve patient and population health and reduce costs.”

The nation is reaching a critical mass of deployed EHRs with greater standardization of information in support of HIE and quality measure reporting. There is an opportunity to improve community understanding of population health, performance, and quality through:

- Enabling proactive patient care in the community
- Delivering insights for local and regional quality improvement
- Facilitating consistently applied performance measures and payment strategies for the community (hospital, practice, health exchange, state, payer, etc.) based on aggregated, de-identified data
- Identifying treatments that are most effective for the community.

Elmore commented that the challenges include the high transaction and “plumbing” costs associated with variation in clinical concept coding (even within organizations), the lack of query standards, and the lack of understanding best business practices. There is also a centralizing tendency that moves data further away from the source, increases personal health information exposure, and limits responsiveness to patient consent preference. Another challenge is that the work done to date, with a few exceptions, has been limited to larger health systems (with large IT and/or research budgets).

The goal is to improve the community understanding of patient population health to be able to ask a question, whether it is to a small physician’s office or a larger hospital, and obtain an aggregate result back. Questions could focus on disease outbreaks, prevention activities, research, quality measures, etc. With regard to scope and approach, Elmore explained that Query Health is being structured in a way that is similar to the Direct Project. It is a public-private partnership project focusing on the standards and services related to distributed population queries. The concept is to have an open, democratic, community-driven consensus-based process. There is a critical linkage with the HITPC and Privacy and Security Tiger Team to provide the guidance needed to drive this project.

Elmore reviewed a series of user stories to demonstrate how to adjust queries with simple, secure use cases to establish the standards and protocols for patient data that is going to be queried against, the query and case definition, and then getting the results back to the requestor of the information.

The organization has a voting group of committed members, the Query Health Implementation Group. There are three workgroups (Clinical Workgroup, Technical Workgroup, and Business Workgroup). In terms of timeline, Query Health is at the requirements and specification stage (the next steps are approaching consensus, and undergoing pilots). Query Health was designed with goals alignment with the S&U Framework, as an open government initiative that is engaging a wide variety of stakeholders. Query Health is also aligned with meaningful use and various standards, as well as with one of ONC's major strategies, the digital infrastructure for a learning health system.

Elmore described the Summer Concert Series, a presentation by the practitioners that have working on distributor queries that highlights the importance of this project. Through this event, a number of challenges were identified, including best practices for data use/sharing, sustainability, auditability, etc.

It is hoped that the HITPC and Privacy and Security Tiger Team will provide Query Health with policy guidance and will monitor Query Health's progress. It is anticipated that the first activity with which Query Health will be looking for such guidance is in the policy sandbox and to ensure that the project is safe, cautious, and conservative for the purposes of starting that initial pilot work. The initial set of policy sandbox ideas has been modeled after previous S&I Framework initiatives in consultation with ONC policy and privacy and S&I Framework leaders and their staff. The concept is that query requests and responses will be implemented in the pilot to use the least identifiable form of health data necessary in the aggregate within the following guidelines: (1) a disclosing entity should have its queries and results under their control (manual or automated); (2) the data being exchanged will be mock or test data, aggregated de-identified data sets or aggregated limited data sets, each with data use agreements; and (3) for other than regulated/permitted use purposes, cells with less than five observations in a cell shall be blurred by methods that reduce the accuracy of the information provided.

Discussion

- Larry Wolf asked how Query Health relates to other activities focused on quality measure initiatives. Elmore indicated that this issue has been raised during the Summer Concert Series as well as in Query Health's Technical Workgroup. In the next few months, it is expected that decisions will be made as to which standards will be applied. Query Health will be leveraging other ongoing initiatives moving forward. Wolf suggested minimizing the diversity of requirements generated for systems to handle queries and result sets.
- In response to a question about information exchange, Elmore commented that the assumption is that the information behind an organization's firewall is identifiable. Only in an instance of a public health permitted use would identifiable data be outside the firewall.
- Farzad Mostashari noted that Query Health's strategy has significant architectural and certification implications in the near future. Getting in front of those and considering them early on will be critical. Clarity about the potential timeframe is needed, as it affects work in areas such as quality measurement. The business case for this effort also requires careful consideration.

- Gayle Harrell noted that there is a tremendous upside to Query Health, but there is also a significant potential for abuse that may frighten the public. She asked about the role of the HITPC in terms of providing input as this project moves forward. Deven McGraw noted that Query Health will be discussed at the next Privacy and Security Tiger Team meeting. Elmore added that the HITPC and Privacy and Security Tiger Team will be relied on to provide significant input for guiding the future of Query Health. He noted that with the exception of public health, where it is already allowed by law today to send some identifiable information, Query Health will be dealing with aggregated information and will not be exposing individual's information. The project itself will be trying to drive towards enabling a non-centrally planned use of technology that is under the control of those responsible for the data.
- Arthur Davidson discussed the burden faced by organizations trying to participate in these important population-based efforts to analyze and move towards the learning healthcare system. He asked if there has been a discussion at the ONC level regarding the leadership role that either the ONC or the HITPC might play in harmonizing these various data models. Elmore noted that Query Health's Technical Workgroup is examining these data models with the vision of some harmonization of standards.
- It is expected that, from the point of view of keeping it simple for an initial pilot implementation, the pilot will probably create a focus around the clinical record, whether that be an EHR or more of an HIE.

8. Centers for Medicare and Medicaid Update on Meaningful Use

Robert Tagalicod of CMS opened this presentation by noting that there has been a positive uptake in the Medicare and Medicaid incentive program, and that CMS and OSC are working much more closely together to ensure greater coordination around the Regional Extension Centers (RECs), Beacon Communities, and CMS regional offices. CMS is also working with the Health Resources and Services Administration and other groups to get a better sense of what affects the large number of government healthcare reform activities, particularly in terms of the effects on industry and stakeholders, and how it impacts the trend in meaningful use.

Robert Anthony of CMS reminded the Committee that at its last meeting, CMS presented on attestation information; this presentation will focus on registration and payment. At the October HITPC meeting, CMS will present an update on attestation. Anthony reported that for the month of August, slightly more than 13,000 active registrations occurred—roughly a 30 percent increase compared to July (which in itself was an increase over June). As of the end August, there are more than 90,000 people actively registered for the program, including all eligible professionals and hospitals, both Medicare and Medicaid.

With regard to Medicare incentive payments that were made as of August, CMS paid more than 1,000 eligible professionals in the month of August. These are people who have actively attested, have gone through the registration and the attestation process, and they have been paid. This figure is almost double that for July (which was nearly double that of June). Anthony

provided specialty-specific information, noting that internal medicine and family practice make up the largest proportion of Medicare eligible professionals, followed by cardiology, podiatry, nephrology, gastroenterology, urology, etc.

In terms of Medicaid, Anthony reported that there are 23 states currently open for the Medicaid incentive program. Almost 1,300 eligible professionals were paid in the month of August, an increase of 23 percent over July (which again, was an increase over June). It is encouraging that almost \$150 million in payments were made for Medicaid incentives within the month of August. This is slightly less than half of the total year to date payment. The overwhelming majority of these payments were made to physicians, followed by nurse practitioners, acute care hospitals, dentists, nurse-certified midwives, etc. Anthony noted that in certain provider categories such as dentists, CMS had heard very early on that there may be some significant barriers to meaningful use, and yet at a very early stage of meaningful use there is a significant portion of dentists who are able to successfully meet meaningful use and attest.

Anthony summarized that August was the first month during which the program as a whole surpassed the \$500 million mark of incentive payments paid out, which was twice as much as was paid out in July. It is not unreasonable to think that the \$1 billion dollar mark will be reached fairly soon, with many more providers expected to come into the program.

Discussion

- Paul Egerman asked if there were any projections for fiscal year 2012. Anthony indicated that there are no solid projections, and fiscal year 2012 will depend largely on what happens through the rest of 2011. Egerman commented that it is difficult to judge these encouraging numbers without some sense of what is expected in 2012. He asked if the numbers to date indicate that the program is on track, ahead, or behind. Tagalicod suggested that CMS may be in a better position to advise the Committee when data for the full year are collected and available.
- Neil Calman asked about the variables being collected on those who are qualifying and receiving payment. Anthony indicated that the type of information CMS has is primarily what exists in its provider enrollment system. There are some indications of specialty, and of subspecialty in some cases. CMS does not measure practice size. Because the program includes ONC's certified health product list, CMS is able to determine what products people are using, and will be examining these data. It is hoped to also break down the data by Zip code to obtain a sense of where providers practice (e.g., rural, urban).
- Calman commented that it is critically important to identify if there is additional information that could be used to identify gaps and who is qualifying by practice size or any other type of variables. It also may be possible to match this database against other available databases to obtain additional information about the people that are successfully attesting. Anthony agreed on the importance of finding this information when it is available, and noted that CMS is conducting surveys to help identify areas where additional education may be needed.

- Calman noted that in general, younger providers are more adept at using computers—it would be interesting to know whether this holds true in the CMS data and whether the group of providers who will likely retire using paper-based systems are being left out. Anthony noted that the CMS does have some data on this issue through some selective surveys indicating that older physicians will not be interested in the program. The penalties will likely start close to or after the time that they retire.
- Tagalicod commented that CMS and ONC are sharing data, and there has been a great deal of data collected on those providers participating in the RECs (e.g., geography, practice size, vendor), and CMS will begin examining this information. It is estimated that approximately 100,000 providers have signed up with the RECs.
- Gayle Harrell also voiced the need for any information on participating providers and asked that the Committee receive any detailed information that CMS has already collected. She asked about the effectiveness of the RECs and what percentage of participating providers are also participating in the RECs. Harrell also asked about the overall nationwide percentage of eligible providers who are participating in the program. Anthony noted that the total number of eligible professionals is roughly 500,000, so slightly less than 20 percent of them have registered at this point. The total number of eligible hospitals is estimated at 5,000, so slightly less than half of eligible hospitals are registered. Harrell commented that it would be useful to collect information on providers by state—Anthony indicated that this should be possible.

9. Public Comment

No members of the public provided comment.

SUMMARY OF ACTION ITEMS

Action Item #1: Minutes from the August 3, 2011, HITPC meeting were approved by consensus.

Action Item #2: The Privacy and Security Tiger Team will revise its letter and circulate a draft to Committee members prior to the next HITPC meeting.

Action Item #3: The Committee accepted the Privacy and Security Tiger Team's recommendations by consensus.