Meeting Notes

Health Information Technology Advisory Committee (HITAC)

January 15, 2020, 9:30 a.m. – 3:00 p.m. ET

IN PERSON

Executive Summary

The HITAC reviewed the agenda for the meeting and approved the October 16, 2019, meeting minutes. **Lauren Richie** presented the HITAC 2020 Work Plan, detailing the list health IT topics that ONC and HITAC will consider that address the 21st Century Cures Act priority target areas of Interoperability, Privacy and Security, and Patient Access to Information, and members of the HITAC suggested additional issues of importance. **Carolyn Petersen** and **Aaron Miri** presented the Fiscal Year 2019 (FY19) HITAC Annual Report draft, and members of the HITAC offered feedback. **Dr. Thomas Mason** and **Alix Goss** gave a presentation on the intersection of clinical and administrative data standards, and a discussion and the announcement of a new task force followed the presentation. **Seth Pazinski** and **Peter Karras** presented the newly released 2020-2025 Federal Health IT Strategic Plan and asked members to review the document in advance of the February HITAC meeting, as the period for public comment ends on March 18, 2020. The ONC Chief Privacy Officer, **Kathryn Marchesini**, gave an update on ONC's efforts to improve patient privacy, and she included a brief overview of Categories of Regulated Actors for Electronic Health Information Privacy Purposes, individual's HIPAA Right of Access to electronic health information, and a snapshot of industry self-regulatory approaches. Lastly, following a presentation by **Dr. Al Taylor**, HITAC members discussed integrating and using received data, and members offered suggestions for the committee to address in the coming year. There were several public comments, including one public comment submitted over the telephone and multiple comments submitted in the chat via Adobe Connect.

Agenda

9:30 a.m.	**Call to Order/Roll Call**
9:35 a.m.	**Welcome Remarks**
9:40 a.m.	**Review of Agenda and Approval of October 16, 2019 Meeting Minutes**
9:45 a.m.	**HITAC 2020 Work Plan Review**
10:05 a.m.	**HITAC Annual Report Draft Review**
10:50 a.m.	**Break**
11:05 a.m.	**Intersection of Clinical and Administrative Data Standards Discussion and Next Steps**
11:30 a.m.	**Public Comment**
11:45 a.m.	**Lunch**
1:00 p.m.	**2020-2025 Federal Health IT Strategic Plan Overview**
1:30 p.m.	**Chief Privacy Officer Update**
2:10 p.m.	**Integrating and Using Received Data Discussion and Next Steps**
2:45 p.m.	**Public Comment**
3:00 p.m.	**Closing Remarks and Adjourn**

Roll Call

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair (by phone)
Michael Adcock, Adcock Advisory Group

Christina Caraballo, Audacious Inquiry
Cynthia A. Fisher, PatientRightsAdvocate.org
Valerie Grey, New York eHealth Collaborative
Anil Jain, IBM Watson Health
Jim Jirjis, Clinical Services Group of Hospital Corporation of America (HCA)
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare
Clement McDonald, National Library of Medicine
Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver, Baptist Health
Terrence O'Malley, Massachusetts General Hospital
James Pantelas, Individual
Raj Ratwani, MedStar Health
Steve L. Ready, Norton Healthcare
Abby Sears, OCHIN
Alexis Snyder, Individual
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem Blue Cross Blue Shield
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Tina Esposito, Advocate Aurora Health
Terry Adirim, Federal Representative, Department of Defense
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)

FEDERAL REPRESENTATIVES

Adi V. Gundlapalli, Centers for Disease Control and Prevention (CDC)
Jonathan Nebeker, Department of Veterans Health Affairs
Ram Sriram, National Institute of Standards and Technology (by phone)

ONC STAFF

Donald Rucker, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator
Elise Sweeney Anthony, Executive Director, Office of Policy
Kathryn Marchesini, Chief Privacy Officer
Thomas Mason, Chief Medical Officer
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Seth Pazinski, Division Director, Strategic Planning and Coordination
Avinash Shanbhag, Director, Office of Technology (by phone)
Al Taylor, Office of Technology
Peter Karras, Lead, Federal Health IT Strategic Plan

Welcome Remarks

Dr. Donald Rucker welcomed members to Washington, D.C., and thanked them for their hard work throughout the past year. He acknowledged that everyone contributed an extraordinary amount of work within a compressed time frame over the past year and stated that he hoped the schedule would be more balanced in the upcoming year. He noted the overall progression of health information technology (health IT), especially the increase in new computing technologies, and he emphasized the importance of ensuring that the federal government is synced in their use of health IT. He announced the release of the 2020-2025 Federal Health IT Strategic Plan, which will serve as an outline for the priority topics. He thanked **Carolyn Petersen** and **Robert Wah** for agreeing to continue in their roles as co-chairs and congratulated the following members on being re-appointed: **Leslie Lenert**, **John Kansky**, **Raj Ratwani**, **Brett Oliver**, and **Denise Webb**. **Denni McColm** stepped down from the HITAC, and he thanked her for her service. Additionally, he welcomed the following new members to the HITAC: **James Pantelas**, **Abby Sears**, and **Alexis Snyder**. Also, he welcomed **Jim Jirjis** to his first in-person meeting, as he was appointed to the HITAC recently. **Dr. Rucker** briefly described the membership structure of the HITAC, as a reminder for the public. He stated that 2,000 public comments have been received on the Final Rule on the 21st Century Cures Act, and they will be considered in an effort to meet the needs of the American public. He explained that ONC is focused on two major topic areas, policy, including the writing of rules, and technology. He thanked **Jon White**, the prior deputy National Coordinator at ONC, for his work.

Following **Dr. Rucker's** remarks, **Steve Posnack,** who replaced **Jon White**, thanked the HITAC members for their dedication to a productive new year. **Elise Sweeny Anthony** thanked HITAC members for their great work in 2019 and explained that the HITAC co-chairs, along with ONC's leadership and 25 federal organizations, were involved in the creation of the HITAC 2020 work plan, which is based upon the 2019 HITAC annual report. **Carolyn Petersen** thanked the members for their attendance and their contributions last year. **Robert Wah** thanked the HITAC for their great work and thanked everyone, including public members, committees, and subcommittees, for the substantial amount of work that has been completed on the proposed rule. Also, he acknowledged the ongoing support from ONC and **Dr. Donald Rucker**.

Review of Agenda and Approval of October 16, 2019, Meeting Minutes

Members reviewed the agenda for the previous meeting. The HITAC approved the October 16, 2019, meeting minutes by voice vote. No members opposed. Two (2) members abstained (names not given)**.**

Lauren Richie invited committee members to disclose any outside activity with ONC, and the following was stated:

- **Christina Caraballo** is working on a small white paper for ONC on social determinants of health (SDOH).
- **Steven Lane** worked with the electronic health record (EHR) reporting program contractor as a consultant and the ONC group on the technical expert panel on provider data integration. Through his roles with Carequality and the Sequoia Project, he is exposed to the work on the Trusted Exchange Framework and Common Agreement (TEFCA).
- **Ken Kawamoto** has worked on consulting, honoraria, sponsored research, or sponsored travel on health IT within the past three years with McKesson, Premier, Vanderbilt University, Ready to Implant (RTI) Surgical, Hitachi, Kaiser, Klesis, University of Washington, Association of American Medical Colleges (AAMC), University of California San Francisco, Mayo, and ONC. He is also an unpaid board member of Health Level 7 (HL7) and is in the process of developing health IT tools that may be commercialized.
- **John Kansky** serves on the board of the Sequoia Project.

- **Raj Ratwani** is a part of MedStar Health, recipient of the ONC Leading Edge Acceleration Projects (LEAP) Award.
- **Clem McDonald** is a reviewer for a grant project at Boston Children's Hospital.
- **Jonathan Nebeker** frequently coordinates with ONC as a part of his federal role.

HITAC 2020 Work Plan Review

Lauren Richie gave an overview of the process of the creation of the 2020 work plan for HITAC and reviewed the priority target areas of the 21st Century Cures Act: Interoperability, Privacy and Security, and Patient Access to Information. She presented a list of topic areas suggested by HITAC members to be addressed in 2020, including a list of priorities and the creation of two new task forces. She presented the timelines for the tasks that will be prioritized in 2020. Also, she presented the activities that will begin immediately and they include the following: finalizing the FY19 HITAC Annual Report; beginning the EHR Reporting Program Task Force; and, discussing the 2020-2025 Federal Health IT Strategic Plan. Finally, she invited members to offer input on additional tasks or initiatives that the committee should be aware of and/or work on.

Discussion:

- **Ken Kawamoto** suggested that the topic of privacy and security, which was emphasized in the annual report, is an issue of high concern, especially from healthcare providers. He and several other members emphasized that it should be addressed by the HITAC.
- **Terrence O'Malley** stated that metadata is involved in many critical activities for data exchange and, therefore, it is important to develop standards regarding it.
- **Steven Lane** seconded the suggestion of the area of patient privacy and of data as it leaves the protection of HIPAA.
- **Christina Caraballo** stated that patient access is a topic that needs to be addressed further and suggested that a patient-focused Qualified Health Information Network (QHIN) be evaluated by the HITAC.
    - **Cynthia Fisher** noted that, according to market research conducted across the country, patients have reported an increase in distrust of the medical system, and this stems from a lack of access to medical records. She stated that it is difficult for patients to gain access to all of their medical data, especially those from specialists or providers other than a primary care physician. She noted that the extensive use of a computer in the exam room also leads patients to distrust their providers, as they are not aware of what is being entered into the system during their visit or what they will see on their medical bills. She noted that price transparency would help build patients' trust in the medical system, and this would include standards about how prices should be calculated
    - **Robert Wah** described a new organization funded by The Rockefeller Foundation, called the Commons Project, which seeks to be a non-profit organization that sits between the public and private sectors and aims to address topics that each sector could not individually. For example, the Commons Project has developed an Android app that acts as a proxy for users and pulls all of their medical records information onto their mobile devices. This will give Android users similar mobile health capablilities as those on iOS. He disclosed that he was invited to be a board member of the Commons Project.
- **Jonathan Nebeker** noted that the HITAC should address approaches to certification of EHRs by ONC.
- **Raj Ratwani** identified the area of patient safety as requiring a broader framework, which would include certification, proactive safety surveillance, and the use of audit log data.

- **Sheryl Turney** suggested that all-payer claims databases (APCD) should have standards regarding how data are collected and should be more transparent regarding how data are collected and shared.
- **Abby Sears** suggested that the HITAC discuss how social service record locators should be embedded in the data standards.
- **Lauren Richie** stated that many of the topics suggested by HITAC members are areas that have been discussed within the last year.
- **Robert Wah** reminded members that the 21st Century Cures Act created a list of prescribed activities for the committee, but the ONC has tried to ensure that the HITAC can expand upon that list. He invited members to submit ideas for topic areas they would like the HITAC to consider to the co-chairs.

HITAC Annual Report Draft Review

Carolyn Petersen reviewed the overarching membership of the Annual Report Workgroup and gave a summary of its scope. She presented the next steps for the development of the FY19 report and reminded HITAC members to submit written comments on the draft by January 21, 2020. She summarized the activities and accomplishments of the workgroup from the past year, and she noted that they have taken a tiered approach to recommendations made to the HITAC and future opportunities.

Aaron Miri thanked ONC staff for their work on the report. Then, he summarized the recommended HITAC activities. He reviewed the outline for the FY19 Annual Report, and he highlighted items of note in each section of the draft report.

As part of a process to refine the draft, **Carolyn Petersen** invited members to give their feedback.

Discussion:

- **Denise Webb** suggested that the time frame to address the effectiveness of current patient matching methods and EHR-related patient safety events be changed to reflect that they are immediate opportunities. Also, she noted that, in the report, there is an immediate activity to create more social determinants of health (SDOH), and there is a long-term activity to create standards regarding SDOH. She suggested that the time frames for these two activities should match one another.
- **Steven Lane** inquired if patient-generated health data (PGHD) included both manually entered data as well as automatically generated device data. When **Carolyn Petersen** stated that PGHD does include both types of data, he suggested that this be clarified within the draft.
- **Ken Kawamoto** noted that some recommendations within the annual report draft are not reflected in the scheduled work of the HITAC for 2020, and he suggested that these recommendations be followed up on now and not be included, again, as recommendations for the next annual report. Additionally, he emphasized that patient privacy and security should be addressed, and he stated that it needs to be clear to patients what specific type of data will be shared when they are offering consent.
    - He noted that the area of research consent complicates the area of patient consent.
    - He emphasized the need for transparency with patients in disclosing what and how data are being shared.
- In response to a question from **Steve Posnack**, **Ken Kawamoto** emphasized the importance of limiting the amount of a patient's medical data that is shared with an outside party, as the entire record is not often needed, but rather a small subset of data.

    - An exchange followed in which they both discussed patient access to data, patient control over which data are confidential, and what patients might believe should or should not be shared with third-party vendors. They agreed that the landscape is complicated by the number of factors at play and the fact that this close control by patients requires that they have comprehensive access to their records, which is not currently available.
    - They discussed the liability on both the sender and receiver of data, as well as the burden on the receiver to filter through the entire record and find the pieces of data relevant to their role.
    - **Alexis Snyder** noted that there are a great number of patients who lack awareness of what they agree or consent to share during the sign-off process, and there needs to be more stringency around this process.
    - **Steve Posnack, Alexis Snyder, Cynthia Fisher, and Terry O'Malley** discussed the complex landscape of issues surrounding patient consent, patient control over the privacy and security of their data, and the possible need for a consent task force.
- **Les Lenert** suggested that the approved recommendation documents from each task force should be referenced within the report to increase transparency and readability of the document.
    - **Denise Webb** suggested the addition of a traceability matrix in the appendix of the report. This would offer a place to list the task forces and associated recommendations. Also, she suggested that the recommendations within the report be numbered for easier traceability.
- **Clem McDonald** stated that the flow of externally produced data should be regulated in a way that the data must be reviewed when it is received.
    - **Arien Malec** emphasized the need to segment patient data so that only what is necessary in the situation is released. The patient should be in control of the scope of the data and not the health system.
    - **Jim Jirjis** lent support for the sub-segmentation of information and noted that it is an issue of liability.
- **Andrew Truscott** suggested that, in the area of patient access in the report, a 2019 report from the Information Blocking Task Force regarding approaches to price transparency be added. Additionally, he suggested that the topic of app vendors that avoid conforming to certified health IT, create situations in which patient information might be mishandled, be addressed immediately.
    - **Christiana Caraballo** noted that a patient-facing QHIN would create a governance model for third-party apps and allow patients to choose a reliable app to handle their data.
- **Ram Sriram** raised the question of how to best serve patients who do not have access to an online health portal, due to a lack of access to technology or an understanding of how to access the portal. These patients would not able to control their health data.

Intersection of Clinical and Administrative Data Standards Discussion and Next Steps

Carolyn Petersen welcomed **Dr. Thomas Mason,** Chief Medical Officer at ONC, and **Alix Goss**, Co-chair of the Standards Subcommittee for the National Committee on Vital and Health Statistics (NCVHS), and she thanked them for their willingness to present to the HITAC.

CHALLENGE: SEPARATE CLINICAL AND ADMINISTRATIVE DATA STANDARDS

Dr. Thomas Mason began by noting that, in order to inform their work, ONC partnered with CMS and other key stakeholders and went through a series of listening sessions to gather feedback. He gave an overview of the feedback they received from practicing physicians on clinical and administrative data standards. He

noted that many administrative data standards, like those regarding prior authorizations, have not been widely adopted by healthcare centers. The progression of payment in the healthcare system from a fee-for-service system to a value-based care system leads to a need for clinical and administrative data standards that align with this shift. He described this lack of harmonization as leading to burdens within the healthcare system, which ultimately impact patient safety and the quality of care that is delivered. He announced the creation of a new task force. Its vision is to "support the convergence of clinical and administrative data to improve data interoperability to support clinical care, reduce burden and improve efficiency – furthering implementation of 'record once and reuse.'" The overarching initial charge is to produce information and considerations related to the merging of clinical and administrative data, its transport structures, rules and protections, for electronic prior authorizations to support work underway, or yet to be initiated, to achieve the vision.

STANDARDS RULEMAKING AUTHORITIES SEPARATED ACROSS PROGRAMS

Alix Goss gave a brief overview of the background on standards for rulemaking authorities separated across programs and described the role of NCVHS and their responsibilities directly related to the Health Insurance Portability and Accountability Act (HIPAA). She explained that the Division of National Standards (DNS) oversees the creation of the regulatory framework necessary to fulfill HIPAA, while EHR and certification standards fall under the scope of ONC. Also, she mentioned that some new standards, like HL7, are being proposed for adoption under various authorities. Pharmacy standards are adopted by a variety of different organizations, including the Drug Enforcement Agency (DEA), Medicare, and the National Council for Prescription Drug Programs (NCPDP). Other pharmacy standards are adopted under HIPAA (i.e., NCPDP D.0) and impact all covered entities. These are written by the Division of National Standards at CMS.

PRIOR AUTHORIZATION

Dr. Thomas Mason and **Alix Goss** defined and described prior authorization in detail, and gave an overview of prior authorization transactions under HIPAA. They described the current standard transactions for prior authorization through both HIPAA and Medicare Part D. They discussed the methods of exchange for electronic prior authorizations and noted that portals, phone, fax, and mail are the methods primarily used by providers. The presenters posed a list of questions for the newly formed task force to review. Also, they laid out the specific charges of the new task force. **Lauren Richie** invited HITAC members to reach out if they are interested in joining the new task force. She mentioned that meetings are expected to begin within the next month and more details about the scope, charge, and schedule of the task force will be established as soon as possible.

Discussion:

- **Arien Malec** questioned the charge of the newly proposed task force and inquired if CMS has the authority to name different standards for the same transaction set. He emphasized the urgent need for coordination of where standards get done from a policy perspective and requested that some of these policy considerations be part of the formal charge for the task force. He mentioned the urgent need to coordinate where standards are created, as there are a variety of different organizations involved, as discussed in the presentation.
- **Cynthia Fisher** highlighted the need for a digital process for prior authorization to improve the interaction between a patient and provider. Also, she noted the delays in care that can result while waiting for prior authorization, which supports the need for the creation of the newly formed task force.

- **Cynthia Fisher** suggested that the electronic explanation of benefits (EOB) be available to the patient at the time of care after the digital prior authorization has occurred, allowing the patient to know the price prior to the time of care.
- **Dr. Thomas Mason** suggested that a standard be created to include the delivery of the clinical, administrative, and financial information to patients.
- **Alexis Snyder** emphasized the need to include patients in the prior authorization process.
- **Clem McDonald** stated that there can often be a delay in prior authorizations as the required data is not available to the physician. He noted the lack of patient access to their prior authorization numbers, as well as the disconnect between the provider, insurer, and patient were discussed as burdens that fall on patients as a result of the current prior authorization process.
- **Alexis Snyder** requested more information on the concept of the "record once and reuse" process.
    - **Dr. Thomas Mason** explained that the process utilizes data in a patient file that has already been collected and uses it for a variety of purposes, rather than needing to gather and record the same data sets multiple times. The process also emphasizes seamless data transmission between providers, insurers, and patients.
- **Les Lenert** suggested that, generally, prior authorization may not benefit all parties (patients, providers, and insurers) and that there is often a shift in where the burden lies, but there is not an elimination of a burden.
    - **Cynthia Fisher** suggested that a physician, especially in highly specialized fields, may often have the most educated response on whether or not a treatment is medically necessary, rather than the insurers. She suggested looking at whether there are any existing studies that show the cost of the whole prior authorization system, and to determine when it is the right time to say, "Where can we eliminate it and allow for efficiencies, and allow for more patient/physician time?"
- **Ken Kawamoto** suggested that data that are most often properly encoded, like medications, be addressed first, in an effort to make significant progress.
- **Alexis Snyder** noted that it is often administrative staff within a medical center who fill out and submit prior authorization paperwork. If these staff members are undereducated or not thoroughly trained on the prior authorization process, it can result in delays for the patient. She suggested that reminders are present within the EHR regarding when prior authorizations expire, so patients can ensure that there will be no delays in renewing the prior authorization.
- **Les Lenert** stated that there is a need for a standard for analysis of data at the insurer, allowing for transparency about the process.

Public Comment

There were no public comments.

2020-2025 Federal Health IT Strategic Plan Overview

Seth Pazinski, Director of the Division of Strategic Planning and Coordination at ONC, and **Peter Karras**, Lead of the Federal Health IT Strategic Plan at ONC, presented an overview of the 2020-2025 Federal Health IT Strategic Plan. It was released on January 15, 2020, and they explained that the draft plan would be open for a 60-day public comment period, ending March 18, 2020. HITAC members will have an opportunity to provide feedback to ONC on the plan at the HITAC meeting on February 19, 2020. **Seth Pazinski** discussed the reason for an updated plan and the sources of input for the plan: collaboration with federal agencies, feedback from the HITAC (especially in the FY18 annual report), and comments from the public. He stated that the aims of the strategic plan are as follows: ensure that individuals have access to their electronic

health information to enable them to manage their health and shop for care; create new business models made possible through the use of APIs that benefit individuals and providers; establish data sharing practices that are in use by the healthcare industry; and, serve as an operational tool to manage federal activity and collaboration through Plan implementation and continual assessments.
Additionally, he laid out the framework of the strategic plan and four goals. He presented the proposed outcomes of the plan, as well as the timeline, in which, he stated that the final Federal Health IT Strategic Plan is scheduled to be published in the summer of 2020. He explained that the plan was created with the intention that all members of the health care space, including patients, be able to understand it. As a result, the plan is not text-intensive and is comprised of only 28 pages.

NUTS AND BOLTS OF THE PLAN

Peter Karras reviewed the structure and components of the plan, including the vision, mission, and principles for Federal Health IT. He explained that the Federal Health IT principles are utilized as a guideline for decision making. He reviewed challenging areas in healthcare. Then, he presented the desirable opportunities in a digital health system. He described the four goals of the plan, all of which have multiple objectives, and they are as follows: 1) promote health and wellness, 2) enhance the delivery and experience of care, 3) build a secure, data-driven ecosystem to accelerate research and innovation, and 4) connect healthcare and health data through an interoperable health IT infrastructure. He presented questions for HITAC members to consider while reading the draft plan.

Discussion:

- Based on a clarifying question from **Aaron Miri**, it was noted that there is a reference to public health as a stakeholder, particularly in the section of the plan around promoting health and wellness
- **Abby Sears** suggested that medical-grade networks should be addressed in the plan if it is not already. She also questioned whether there was collaboration with the National Institutes of Health (NIH) in regards to research standards.
    - It was noted that Teresa Zayas Caban serves as ONC's liaison to NIH, in addition to collaboration with the Agency for Healthcare Research and Quality (AHRQ) and the National Science Foundation (NFS). Outcomes from these collaborative conversations were included in the build a secure, data-driven ecosystem to accelerate research and innovation section of the plan.
- **Anil Jain** suggested aligning workforce training and medical education within the progression toward digital health. He also suggested including clinical care burden on providers as a result of increased technology, and ideas on how to address it. Finally, he highlighted that there are problems with patient access and usability of technology; even when it is available, it might not be usable in the way it is needed.
- **Raj Ratwani** noted his appreciation for the incorporation of safety (both use and utilizing it for improvement) as a focus in the plan. He also questioned how the execution of the goals will be prioritized over the course of the five years.
    - **Seth Pazinski** commented that each federal agency is working to advance different aspects of the plan, providing opportunities for collaboration and coordination from ONC. Some initial areas of focus that ONC will be coordinating with federal partners include Cures, TEFCA, and the U.S. Core Data for Interoperability (USCDI) expansion.

Chief Privacy Officer Update

Kathryn Marchesini introduced herself as the Chief Privacy Officer at ONC and described her role. She

described the three groups that make up the healthcare information privacy arena, including HIPAA Covered Entities, HIPAA Business Associates, and Non-HIPAA Covered Entities. Then, she discussed the operationalization of the HIPAA Right of Access to Electronic Health Information and cited the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act and 2016 Cures Act as steps to fulfill right of access to EHR. She explained that Congress is determining whether or not federal legislation is warranted regarding secondary use of data, as this is a problem that is broader than just the healthcare field. She reviewed the work of ONC on addressing this area, including two reports to Congress and educational materials for patients. Then, she presented Model Privacy Note (MPN), which was created by ONC, as a resource and guideline for developers to convey information about security practices to patients. She clarified that the MPN does not mandate specific policies, but, rather, it is a voluntary resource that will benefit patients. Also, she presented and elaborated on a self-regulation process through which health companies are encouraged to adhere to a code of conduct, guidelines, and set of principles regarding health information. She noted that both the MPN and the self-regulation process aim to address concerns that patients have regarding the sharing of personal information.

Discussion:

- **Ken Kawamoto** questioned whether any agency, including ONC, provides guidance on whether the current approaches to providing open access to data to fast healthcare interoperability resources (FHIR) are HIPAA compliant.
    - **Kathryn Marchesini** suggested that further guidance on this issue be sought from the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).
- A document created by the Health IT Policy Committee and Health IT Standards Committee's joint Application Programming Interface (API) Task Force described where HIPAA applies, and **Aaron Miri** suggested that this document be updated, or a new document of that nature be created.
    - **Kathryn Marchesini** stated that a more recent piece of educational material is available called Key Privacy and Security Considerations for Healthcare Programming Interfaces APIs. Also, she noted that there is a recently created resource for mobile health app developers that explains federal laws that are applicable to apps.
- **Aaron Miri** suggested that a new task force be created that is focused on privacy and security, particularly related to third-party access.
- **Arien Malec** suggested that basic concepts, including how a covered entity is defined under HIPAA and guidance that has been given by the OCR on the role of patient access, particularly readily available forms, be reviewed with the committee.
- **John Kansky** stated that regulation of consumer for-profit companies that have access to health information is necessary, just as the creation of the EHR lead to the need for HIPAA.
- **James Pantelas** noted that the creation of disease-specific data repositories is an area of concern with regard to whether or not it follows HIPAA.
- **Andy Truscott** stated that the committee should refrain from discussing the practicality of HIPAA, as the conversation is occurring elsewhere, but rather look at how standards can support the enforcement of the policies.
- **Cynthia Fisher** emphasized the urgent need for health information to be accessible to patients, their caregivers, and their families. Also, she suggested that modern technology decreases the amount of privacy throughout society as a whole. She stated that this lack of privacy, due to systems like Bluetooth and tracking technology, means that patients should have access to their own data, as attempting to completely protect the health information is futile.

Integrating and Using Received Data Discussion and Next Steps

Al Taylor, clinical informaticist in the Standards Division of the Office of Technology at ONC, discussed a priority item for the HITAC in 2020, which is the integration and use of received data. He presented the immediate goals and offered the HITAC a list of discussion topics and questions. He invited members of the HITAC to discuss and share feedback. Also, he presented a number of areas, which had already been identified by the HITAC, as possible chances for integrating external data. He asked the HITAC for reasonable outcomes that members hope to achieve within the coming year.

Discussion:

- **Jim Jirjis** suggested that various implementations of the same data standards, based on different interpretations, is an area that warrants the focus of the HITAC.
- **Arien Malec** stated that framing data as "inside data" and "outside data" is problematic and reframing it as "patient's data" would be a positive change that would give a patient better access to their data.
- **Steven Lane** identified the mapping of discrete laboratory result data in a way that allows it to be shared between systems as a challenge that ONC should consider addressing.
- Additionally, **Steven Lane** identified large data volume as another concern that can be overwhelming to a provider, especially patient-generated data that is downloaded to a health system.
    - **Carolyn Petersen** suggested that a conversation should occur between providers and patients that addresses external data and what data will be used in what way. She stated that ONC should encourage these conversations, so there is a common understanding by both parties.
    - **Steven Lane, Carolyn Petersen, Denise Webb** discussed smart technology, especially tracker watches, and some members questioned whether there are standards to which the technology must conform. **Denise Webb** suggested that the area of provider integration of patient-generated data from an unregulated device be explored.
- **Steven Lane** identified the definition of the legal medical record as a challenge, as the outside data used for a medical decision should be a part of the record, and there is a need for a process to achieve the complete record.
- **Clem McDonald** discussed his opinions of the amount of data that should be collected, saved, and reviewed. He emphasized that it is important to determine the amount of usable patient data collected to best serve the patient without overwhelming a provider and compromising patient safety. He opined that collection should be done very carefully to make sure it is done correctly, appropriately, and with the right balance so that the provider gets enough information, but patient privacy is not compromised.
    - **James Pantelas** stated that he holds an opposing opinion, coming from the lung cancer world, he believes that collecting as much patient data as possible is preferred as it can all be meaningful, and it is simple to store. He noted that studies of lung cancer showed the positive outcomes of collecting large amounts of patient data. He emphasized the importance of collecting meaningful data.
    - **Alexis Snyder** discussed the importance of maintaining accuracy and addressed the various instances in which accuracy can be compromised. She noted that allowing patients access to review their entire medical record prior to it being shared would help increase accuracy, as the patient would be able to catch and address any inaccuracies.
- **Steve Posnack** suggested that ONC consult with the OCR or another legal body to create a statement about the standard of practice regarding data interoperability.

Public Comment

Marni Jameson Carey, Association of Independent Doctors: Marni introduced herself as the Executive Director of the Association of Independent Doctors and stated that she would be sharing concerns on behalf of independent doctors' regarding health IT areas. She discussed the need to decrease the amount of time spent by a provider entering patient data during a visit, as it decreases the quality of care the patient is receiving. She stated that independent doctors are limited in their interoperability among EHR systems as there is confusion about the most appropriate EHR system for the provider to purchase, as well as the risk involved in the purchase. She stated that the lack of access to interoperability drives independent doctors to move into employment models, which negatively impacts the healthcare system. She agreed that allowing patients better access to health information is a necessary change to achieve a less burdensome health care system. She noted that price transparency is also important, as it allows patients to choose lower-cost, higher-value care, which is often offered by independent doctors. She requested that the committee work toward a reformed health IT system that has a larger emphasis on serving patients and providers, and less of an emphasis on health systems, insurers, and IT companies.

QUESTIONS AND COMMENTS RECEIVED VIA ADOBE CONNECT

Thompson Boyd: Annual Report Comments - Provider Experiences regarding PGHD: suggest methods of improving the efficiency Provider Workflows in the discussion of PGHD and SDOH with the Patient. Time with the patient is limited. Having tools, such as AI, in the background may highlight the more important aspects for discussion during the Patient visit with the Provider. It is hard to ask the Provider to do more. Need to use tools to increase the "value" and the efficiency of the visit.

Thompson Boyd: Annual Report (Privacy and Security): Patients need the ability to "change their mind" regarding consent and regarding authorization. This means, the electronic record needs to be able to accommodate the patient's wishes.

Thompson Boyd: Annual Report (Privacy): Please continue to work on Data Segmentation for Privacy (DS4P). As stated during the JASON Report Discussions, the Patient should not be surprised to see that their data is in a location of their surprise. Patients need to know where their data is and be able to communicate their wishes who sees which parts of their data.

Patrice Kuppe: Prior Authorization they are discussing is related to medical benefits, not the drug benefit. The drug benefit uses NCPDP prior authorization transactions and has high adoption rates.

Thompson Boyd: Allowing the Patients to know their financial obligation, before the procedure or before prescribing a medication is beneficial and may promote patient engagement? We need to take the financial/cost "surprise factor" out of the patient experience.

Thompson Boyd: Federal Strategic Plan, Slide 7: Promote Health and Wellness. Would add the notion of Population, or Population Health.

Thompson Boyd: Federal Strategic Plan, Slide 7: Connect Healthcare and Health Data Thought an Interoperable Health IT Infrastructure: Would at the notion of using Standard.

Thompson Boyd: Federal Strategic Plan, Slide 11: The Vision Statement is supposed to be about the "future". Where do we want to be? The current Vision Statement is more aligned with a Mission Statement. Consider as a Vision Statement: A better health system delivering higher quality care, at reduced costs,

through the use of Health IT and by Engaging Critical Stakeholders.

Thompson Boyd: Federal Strategic Plan, Slide 16: Need to add the notion of improving Provider Workflows and Usability.

Thompson Boyd: Federal Strategic Plan, Slide 17: Healthcare Data. Please look at the work generated from the ONC's Standards and Interoperability Framework's Query Health Initiative.

Thompson Boyd: Federal Strategic Plan: would more clearly state need of delivery of Broadband Access to remote communities, and Precision Medicine (genomics).

Thompson Boyd: Above: Precision Medicine.

Thompson Boyd: Would add the notion of the Health IT Workforce. Need more Health IT Professionals to implement the Federal Health IT Strategic Plan.

Thompson Boyd: Privacy Slide 6: should be "Sell" Whom we sell your data to"

Thompson Boyd: Privacy Presentation: may wish to bring up the health of students - FERPA. How FERPA intersects with HIPAA.

Thompson Boyd: Received Data Presentation, Slide 3: Two sources of important data: data from the Provider's Regional HIE, data from the regional/state(s) wide PDMP. These data need to be clearly integrated into the Providers EMR, aligned with Provider Workflow. For example, in Washington State, the PDMP is linked into the HIE Data which is readable by Providers, caring for Patients; there is no need to login separately into the PDMP, since PDMP Data feeds into the Provider's EMR. This was a presentation at the ONC Annual Meeting in 2019.

Rita Torkzadeh: Perhaps there should be more focus on defining and capturing metadata for different data types that identifies provenance and any modifications?

Thompson Boyd: Agree: data provenance is critical. The ONC's HIT Standards Committee had a Task Force on Data Provenance a few years ago, this was very productive.

Closing Remarks and Adjourn

Co-Chairs, **Carolyn Petersen** and **Robert Wah**, thanked members for their thoughtful participation and feedback. They reminded members to submit comments regarding the draft of the FY19 Annual Report by January 21, 2020, as it will be voted on at the next HITAC meeting.

The next HITAC meeting is scheduled for February 19, 2020.

Lauren Richie asked members to reach out to if they are interested in joining the Intersection of Clinical and Administrative Data task force.

The meeting was adjourned at 3:00 p.m. ET.