The Office of the National Coordinator for Health Information Technology

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

March 18, 2020, 10:00 a.m. – 1:00 p.m. ET

VIRTUAL

EXECUTIVE SUMMARY

Donald Rucker and **Steve Posnack** welcomed members of the HITAC and noted that they would be hearing presentations on two final rules. **Carolyn Petersen** announced that the Fiscal Year 2019 (FY19) Annual Report was transmitted to the the National Coordinator and the Annual Report Workgroup would reconvene in May. The HITAC approved the February 19, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.

Denise St. Clair presented an overview of the CMS Interoperability and Patient Access Final Rule (CMS Final Rule) and noted that their goal was to get one step closer to their ideal state of interoperability in the healthcare system. Following the presentation, HITAC members submitted comments.

Elise Anthony gave an overview of ONC's 21st Century Cures Act Final Rule (ONC Final Rule) and 2015 Cures Updates. **Beth Myers** provided a high-level overview of ONC's approach for the updates made to the 2015 Edition Certification Criteria.

Robert Anthony, Avinash Shanbhag, and **Michael Lipinski** presented ONC's 21st Century Cures Act Final Rule Conditions of Certification Provisions. **Michael Lipinski** presented ONC's 21st Century Cures Act Final Rule Information Blocking Provisions.

Beth Myers presented ONC's 21st Century Cures Act Final Health IT for the Care Continuum Provisions. There was a short window for general discussion on all of the presentations and several members submitted comments and questions. **Carolyn Petersen** asked HITAC members to send comments, questions, or topics of interest to her or **Robert Wah** by the end of Friday, March 27 with regard to the COVID-19 pandemic. A special meeting of the HITAC to address potential COVID-19 responses would be scheduled as soon as possible.

There were several public comments, including two public comments submitted over the telephone and multiple comments submitted in the chat feature of Adobe.

AGENDA

10:00 a.m.	Call to Order/Roll Call
10:05 a.m.	Welcome Remarks
10:15 a.m.	Review of Agenda and Approval of February Meeting Minutes
10:20 a.m.	Overview of CMS Interoperability and Patient Access Final Rule
10:50 a.m.	Overview of ONC 21st Century Cures Act Final Rule & 2015 Edition Cures Updates
11:05 a.m.	ONC 21st Century Cures Act Final Rule Conditions of Certification Provisions
11:35 a.m.	BREAK
11:50 a.m.	ONC 21st Century Cures Act Final Rule Information Blocking Provisions
12:30 p.m.	ONC 21st Century Cures Act Final Health IT for the Care Continuum Provisions
12:45 p.m.	Public Comment
01:00 p.m.	Closing Remarks and Adjourn

ROLL CALL

Carolyn Petersen, Individual, Co-Chair
Robert Wah, Individual, Co-Chair
Michael Adcock, Magnolia Health
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
Ken 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
Abby Sears, OCHIN
Alexis Snyder, Individual
Sasha TerMaat, Epic
Denise Webb, Individual

MEMBERS NOT IN ATTENDANCE

Amy Abernethy, Food and Drug Administration (FDA)
Tina Esposito, Advocate Aurora Health
Steve Ready, Norton Healthcare
Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.

FEDERAL REPRESENTATIVES

James Ellzy, Defense Health Agency, Department of Defense
Laura Conn (on behalf of Adi V. Gundlapalli), Centers for Disease Control and Prevention (CDC)
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services (CMS)
Denise St. Clair, Centers for Medicare and Medicaid Services (CMS), Health Informatics Office
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Donald Rucker, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator
Elise Anthony, Executive Director, Office of Policy
Beth Myers, Deputy Director, Office of Policy
Robert Anthony, Division Director, Certification and Testing
Avinash Shanbhag, Acting Executive Director, Office of Technology
Ryan Argentieri, Deputy Director of Technology
Michael Lipinski, Division Director, Regulatory Affairs
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

WELCOME REMARKS

Donald Rucker welcomed members to the virtual meeting of the HITAC, and he emphasized the importance of the work ONC has been doing now, during the time of a pandemic, and will be doing in the future with interoperability and other modern technologies. He thanked ONC, the HITAC, and the public for all of the extraordinary comments and feedback that helped them to formulate the rules. He noted that there is a good balance between the interests of the public, providers, and the EHR vendor community and those who might enter the app economy in the future. The ONC Final Rule is over 1,200 pages, and he estimated that about 1,100 of those are comprised of work done as a result of all the comments, responses, and feedback ONC received.

Then, he turned the presentation over to **Steve Posnack**, the Deputy National Coordinator. He noted that the ONC Final Rule was released and a colleague from CMS would also give an update on the CMS Interoperability and Patient Access Final Rule, which would comprise the largest part of the agenda today. He emphasized the need to make the most effective use of all members' time and to keep them doing all the valiant healthcare work for the country, and he thanked healthcare workers fighting COVID-19.

REVIEW OF AGENDA AND APPROVAL OF FEBRUARY MEETING MINUTES

Robert Wah welcomed everyone and noted that the bulk of their time would be spent on the Final Rules.

Carolyn Petersen announced that the Fiscal Year 2019 (FY19) Annual Report was transmitted to the National Coordinator and the Annual Report Workgroup would reconvene in May.

She reviewed the agenda for the meeting and invited members to examine the minutes from the February 19, 2020, meeting of the HITAC. There were no comments or corrections, so she called for a vote.

The HITAC approved the February 19, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.

Robert Wah thanked the FY19 Annual Report workgroup co-chairs, **Carolyn Petersen** and **Aaron Miri**, for their efforts. Then, he introduced **Denise St. Clair,** who would be presenting the overview of the CMS Interoperability and Patient Access Final Rule.

OVERVIEW OF CMS INTEROPERABILITY AND PATIENT ACCESS FINAL RULE

Denise St. Clair, Policy Analyst in the Health Informatics Office at the Centers for Medicare and Medicaid Services (CMS), presented an overview of the CMS Interoperability and Patient Access Final Rule (CMS Final Rule). She stated that their goal with the CMS Final Rule was to get one step closer to their ideal state of interoperability in the healthcare system. In this system, they will have an interoperable healthcare data exchange that will enable coordinated care, improve health outcomes and reduce cost, improve the experience for patients, provide additional tools for providers to do their best work with less burden, and ensure payers are able to facilitate efficient and coordinated care.

Ultimately, she noted that everything they are doing falls into a vision for their road map, which is built on a strong foundation of privacy and security working through three main buckets of work.

- Patient access: empowering patients by giving them access to their health information so they can make the best informed decisions about their care, all while keeping that information safe and secure.
- Connect healthcare through data exchange: driving to value-based care by promoting seamless data exchange across the care continuum.
- Technology and standards: promoting the use of the latest technology and standards to drive innovation and data exchange in healthcare.

Then, she gave an overview of the timeline related to the CMS Final Rule and when its policies will become applicable. The timeline presented was from January 2019 through April 2022. She noted that the CMS Final Rule was published on CMS's website on March 9, 2020 and will be published in the Federal Register shortly; six months after it has been published there, hospitals will be required to send patient event notifications regarding admission, discharge, and transfer. She emphasized that this will greatly support care coordination and ensure that patients can get timely follow up when their care team is aware of an event in the hospital. In late 2020, two policies will become applicable. She stated that these are the public reporting of clinician or hospital data blocking and providers without digital contact information in the National Plan and Provider Enumeration System (NPPES); in both cases, violators of these policies will see their names publicly reported on CMS's websites. She noted that they want a seamless data exchange to occur, and one key piece of that puzzle is making sure people know how to contact each other in a secure digital manner.

On January 1, 2021, the application programming interface (API) policies will go into effect. According to the Patient Access API policy, patient health care claims and clinical information will be made available through standards-based APIs for Medicare Advantage, Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS), Medicaid and CHIP managed care, and Qualified Health Plans (QHPs) on the federally facilitated exchanges (FFEs). She noted that this is a Fast Healthcare Interoperability Resources (FHIR) R4 API, and it will need to meet the interoperability technical standards that were finalized in the ONC 21st Century Cures Act Final Rule.

She explained that all of this data would be available, so, if a patient finds a health app they like and want to use, they may authorize that app to ping their payer to access their data. In this way, the patients would be able to obtain data that is useful, valuable, and understandable to them. She emphasized that privacy and security was a top priority in the development of these policies. She gave more details on the options and provisions added to the CMS Final Rule that were based on the feedback received from the stakeholder community, including the HITAC.

The second API policy, which is the provider directory API, would require that payers make certain information about their provider networks available via a public-facing, digital API that would be available through a public-facing, digital endpoint on their payers' website. In this way, that API is easily accessible to third-party applications. She noted that the API needs to meet the interoperability technical standards finalized by HHS in the ONC 21st Century Cures Act Rule, but it would not include the security protocols related to authentication and authorization because it is publicly accessible data. She stated that they would need to make provider directory information available via the API no later than 30 calendar days after an update is received or new information is received by a payer.

Next, she described the payer to payer data exchange policy, which will become applicable on January 1, 2022. This policy requires all payers to have a system in place to exchange data, especially the United States Core Data for Interoperability (USCDI) clinical data, which they maintain and incorporate that data into a patient's record. She explained if a current patient wants their previous payer to send data to their current payer, up to five years after disenrollment, they may request their payer to send the data forward. Then, the payer would receive and incorporate that data into their record. Ultimately, the goal of this policy is to help the patient create their cumulative health record with their current payer.

The last policy she described will become applicable in April 2022, and it will improve benefits coordination for dually eligible individuals. She explained that moving from the monthly exchange of data to a daily exchange would help patients get the right services at the right time and avoid some of the duplications that occur if their dual-eligible status is not immediately known, which could lead to additional rework, extra paperwork, or delays in patients getting access to services. She stated that this would significantly improve the experience for patients.

She concluded her presentation by referencing a website where CMS has provided more information. It is https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

Discussion:

- **Sasha TerMaat** inquired about the alignment on the USCDI standard for clinical data. She noted that it is great to see the use of the same standards and technical formats with FHIR in those two areas, but she was surprised to see the difference in timelines between ONC's regulation and CMS's regulation. She voiced her concern that the CMS timelines are adopting the newer version of FHIR in the additional resources that are part of USCDI. She worried that this could place a burden on those participants, and she asked for more background on why the timelines are not aligned between the two programs.
    - **Denise St. Clair** explained that, with the use of the USCDI in the CMS Final Rule, they are looking at the payer population and the data that the payers already maintain. The resources that are necessary to be able to share this data via an FHIR R4 API are currently available as links on the site for the US Core IG. That provides the tools people will need to be able to prepare the data and to share the data in R4 for the purposes of implementing the API.
- **Valerie Grey** noted that she was disappointed that the CMS Final Rule excluded a requirement for health plans to connect to trusted exchange networks. She asked Denise to talk more about why that was removed from the CMS Final Rule.
    - **Denise St. Clair** responded that they received a good number of comments on this topic. Their commenters wanted to see a mature Trusted Exchange Framework and Common Agreement (TEFCA) in place to be able to facilitate that trusted exchange network. The work on TEFCA is ongoing, and they wanted to finish that prior to CMS requiring the payers to be on a trusted exchange network. They felt that the criteria proposed could be best accommodated by TEFCA. She stated that they were afraid there would be too few trusted exchange networks that currently met the criteria in the current landscape, and it was too soon to require it.
- **Jim Jirjis** inquired if there is a consideration on adjusting the timelines of implementation in a compassionate way, so that they do not inadvertently pull people away from important pandemic work.
    - **Denise St. Clair** noted that it is a unique situation. They are thinking about all of the real and important work on which everyone is focusing, and the timelines are under consideration right now. They are assessing the situation and looking for feedback.
- **Denise Webb** asked if CMS is applying the ONC Final Rule to payers, in which payers are not defined

as actors in information blocking. If they are aligning the CMS Final Rule with the ONC Final Rule in this area, she inquired if there would be any enforcement for payers.

  - **Denise St. Clair** affirmed that ONC does not list payers as an actor under the information blocking provisions, but, though CMS strongly supports all the information blocking work that ONC has done, it is not something CMS is applying to payers either. They are not focusing as much on information blocking, and she noted that CMS only has one information blocking provision in the CMS Final Rule, which is related to promoting the interoperability programs and the eligible clinicians and hospitals who are taking part in those programs. She stated that they support it in terms of the spirit of their work and of HIPAA, with regard to patients' rights to their own data, but not in terms of the letter of the law.

- **Clem McDonald** noted that there are regulatory and legal constraints around COVID-19 tests, and he wondered if some regulations around the intense concern about individual privacy might be relaxed a bit so that they could find out what is going on to stop people from getting sick.
  - **Denise St. Clair** stated that it is beyond the scope, but she will mention it to leadership.
- **Steven Lane** asked her to say more about the interface between the ONC rules and how CMS promoting interoperability will help to prevent information blocking. Specifically, he inquired how this affects requirements on providers to release information included in the USCDI.
  - **Denise St. Clair** responded that the intersection of the ONC Final Rule and the Promoting Inoperability Program category in terms of USCDI, specifically the requirements for 2015, will require USCDI to be made available to patients from providers, beginning when EHR requirements start. She stated that 24 months after the publication of the Final Rule in the Federal Register, providers would need to be able to share the USCDI data with patients via patient access requirements under the promoting interoperability programs using certified EHR technology. She noted that there is the requirement of EHRs to have the capability to make the data available versus in the CMS Final Rule, where they are requiring payers -who already maintain this data- to prepare the data and make them available for sharing via an API following the minimum data set of the USCDI. The data elements included in the USCDI is the base minimum of data to share. She asked colleagues from ONC if they wanted to elaborate further.
  - **Steven Lane** responded that she mentioned that USCDI would be required 24 months after publication, but he was under the impression it was a shorter timeline. They are looking at 6 months after publication of USCDI 2020 for all electronic health information. He asked for this matter to be clarified over the course of today's discussion.
  - **Beth Myers**, from ONC, stated that, it is 24 months, and added that they can talk more about it in the next presentation.
- **Les Lenert** reinforced Clem's statement about the urgency of looking at privacy laws and the confusing morass of state and federal privacy regulations that may inhibit the effect of clinical information during this outbreak. He noted that this is off subject but hoped they would take it back to their leadership. He emphasized that they need to move forward on how to restructure privacy so that there can be frictionless information flow about test results and their clinical meaning across responders, particularly, with the move to new testing strategies and telehealth for screening, drive-through facilities for specimen collection, and new laboratories bringing up capacity at an unprecedented rate.
- **Cynthia Fisher** congratulated ONC and CMS for this herculean effort on the release of the rules. She voiced her agreement with Clem and Les about moving faster on COVID-19 response efforts. She asked about a way that the HITAC could come together, as they have been working so closely with ONC and CMS, to look at delivering work as an industry much faster than the 24 months for all electronic health information.
- **Elise Anthony** clarified one of the points that was mentioned earlier. She noted that, on the ONC side, six months after the effective date of the ONC Final Rule is when some information would be required, and this would be the type of data that is included in the USCDI. She noted that this does not mean the USCDI standards, itself, but the type of data that are covered by the USCDI. And then, after 24 months, it would be the full EHI. She noted that they will discuss this more as they go through the information

blocking section. She reiterated that six months after the publication date is when they would be required to move some information. Then, after 24 months, they would be required to move the full spectrum of what is defined as the EHI.

- **Arien Malec** asked if there is time on the agenda to discuss the COVID-19 response and the role of health information technology (HIT) and information discovery of disease surveillance. He recognized the importance of the Final Rule, but he urged the co-chairs to restructure the agenda to leave more time for this discussion. Also, he suggested that they consider putting together a special committee meeting to address the role of health information technology and the COVID-19 response.
    - **Carolyn Petersen** responded that she and Robert would contact ONC during the scheduled break period to work on this issue.

OVERVIEW OF ONC 21ST CENTURY CURES ACT FINAL RULE & 2015 EDITION CURES UPDATES

Elise Anthony noted that, due to time constraints, she would give a slightly shortened overview of ONC's 21st Century Cures Act Final Rule (ONC Final Rule). She noted that, while they make every effort to be sure that the presentations are accurate, it is important to note that it is not a legal document. She directed them to their website at https://www.healthit.gov/curesrule/ where they have a number of different materials. Not only do they have their upcoming webinar dates, but she mentioned that the next one will be held on March 19, 2020 at 2:00 p.m. ET. She informed them that there are fact sheets and other helpful resources on the website, including a complaint process attached to the information blocking section and an overall feedback system that ONC has related to certification program complaints or concerns. She provided the disclaimer that this presentation was developed at taxpayer expense.

Before she began the presentation, she thanked the community, from patients, doctors, hospitals, developers, and the public, for the broad array of feedback they received while developing the ONC Final Rule. She gave a brief of overview of how feedback was received, evaluated, and incorporated.

She presented the list of groups served and purposes the ONC Final Rule is meant to achieve, including:

- Patients: Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy
- Doctors and Hospitals: Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation
- Patients, Doctors, and Hospitals: Improving Patient Safety
- Health IT Developers: Minimizing API Development and Maintenance Costs, Protecting Intellectual Property
- American Public: Maximizing Innovation, Transparency in Health Care

She gave an overview of the history that led to the information blocking provision. In a 2015 report to Congress, ONC provided a definition of information blocking, an analysis of the extent to which the practice exists in the industry, and recommendations to address the issue. ONC continued to engage with stakeholders and provided ongoing technical assistance to Congress. In December 2016, the 21st Century Cures Act was signed into law. It included a definition of information blocking and provisions for addressing information blocking. She noted that there are two main sections: the conditions of certification, which relate to the health IT developers who are certified under their program, and the information blocking provision, which is broader. She mentioned that there are other provisions, and, later, **Beth Myers** would cover the care continuum support that is included in the rule, particularly, around supporting pediatric settings.

She presented the overall path to the ONC Final Rule. Following the enactment of the Cures Act, ONC continuously met with stakeholders. ONC listened to and reviewed complaints of information blocking. She thanked ONC staff for all of the work they did during this part of the process. She stated that ONC consulted with federal agencies, including the HHS OIG and OCR, and the Federal Trade Commission (FTC). After release of the ONC proposed rule on March 4, 2019, ONC received over 2,000 comment submissions. She noted that ONC met with stakeholders and consulted with federal agencies. Finally, ONC's final rule was released on March 9, 2020.

Beth Myers described some of the updates made to the 2015 Edition Rule in terms of the criteria that are required. She highlighted specific items that the HITAC has been interested in and commented on. She gave a high-level overview of ONC's approach for the updates that they made to the 2015 Edition Certification Criteria, and she reminded HITAC members that these would be updates to the 2015 edition, rather than an entirely new edition of technology, despite some concerns and a lot of discussion about whether it should be a new edition or whether there should be some other pathway that allowed for it to be differentiated in order to avoid confusion.

Next, she described the way they determined the scope for the process. She noted that, historically, an entirely new edition has been captured and implemented across the industry as an entirely new product, and that is both on the developer side and the provider expectation side. Because of that, essentially, it creates an artificial crunch on an update cycle. They were concerned that there would be issues with delays, with significant burdens on development teams, and further burdens on providers in being able to mitigate that cost within their potential system needs and enterprise needs. Because of these considerations, she stated that they determined that they did not meet the bar for a full, new edition change but, rather, they determined that it should consist of updates to the existing criteria.

She highlighted key updates to the 2015 Edition Certification Criteria and directed members to the presentation slides for more detailed lists of the updates, which were categorized under time-limited and removed criteria, revised criteria, and new criteria. She detailed the thought processes behind these items and the effects of their implementation. These updates included:

- Time-Limited and Removed Criteria
    - Drug formulary/Drug List Checks
    - Patient-Specific Education
    - Secure Messaging
    - Problem List, Medication List, Med Allergy List
    - Smoking Status
    - Common Clinical Data Set summary record –create & receive criteria (replaced with USCDI)
    - API (replaced with Standardized API criterion)
    - Data Export (replaced with EHI export criterion)
- Revised Criteria
    - Interoperability criteria (C-CDA, VDT, etc.)
        - Updated with USCDI
        - Updated with C-CDA Companion Guide
    - ASTM criteria
    - Security tags send & receive criteria

  - Electronic Prescribing (aligned with CMS)
  - CQM – report criterion (aligned with CMS)
- New Criteria
  - Electronic Health Information (EHI) export
  - Standardized API for patient and population services
  - Privacy and Security Attestation Criteria

With regard to the new criteria, she emphasized the work they did to ensure alignment, because the HITAC, as well as the public emphasized that alignment was essential for the specific definitions of the types of data sets that they referenced. She reminded HITAC members that **Michael Lipinski** would address that definition later during the information blocking presentation. She noted that the criteria are specifically aligned to the information blocking definition of electronic health information.

Beth Myers noted that the United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set (CCDS) definition 24 months after publication of the ONC Final Rule. She pointed out that the 24-month timeline is the end of the update cycle. Essentially, health IT developers can begin doing that update immediately, and, they need to update their certified health IT to support the USCDI for all certification criteria affected by this change within 24 months after the publication of the ONC Final Rule. Also, she mentioned that, specifically with the USCDI, they tried to constrain the updates to that data set itself. It is based on the CCDS. They have adopted the following new required data classes and data elements: provenance, clinical notes, pediatric vital signs, and address/email/phone number. She pointed out that the address, email, and phone number data elements were the items identified for patient matching to support patient matching use cases.

ONC 21ST CENTURY CURES ACT FINAL RULE CONDITIONS OF CERTIFICATION PROVISIONS

Robert Anthony introduced himself as the Director of our Certification and Testing Division, which oversees the certification program at ONC, and he noted that he would be joined by **Avinash Shanbhag**, Acting Executive Director of ONC's Office of Technology, and also **Michael Lipinski**, Director of ONC's Federal Policy and Regulatory Affairs Division. He noted that they would present a short summary on the conditions and maintenance of certifications bucket.

He noted that Congress required through the 21st Century Cures Act (the Cures Act) that they establish this concept of conditions and maintenance of certification for the certification program and, specifically, enjoined them to look at particular areas that had to be covered, including information blocking, assurances, communications, application programming, real world testing, attestations, and future electronic health record (EHR) reporting criteria submission. He noted that he would cover each of these on information blocking assurances except the EHR reporting criteria, which also is required by the Cures Act. He noted that they have deferred to future rulemaking in that case. The Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s). Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

The first condition of certification he covered was information blocking, though, he noted it will also be covered in a later presentation that day. That presentation will describe how information blocking covers health care providers, health IT developers of certified health IT, health information exchanges (HIEs), and health information networks (HINs). He described the specific condition of certification that applies to health IT developers and actions that are taken specific to their certified health IT module. He noted that it simply prohibits any health IT developer who has a health IT product that is certified under their program from taking any kind of action that will constitute information blocking overall.

The second condition of certification is the condition for assurance. He stated that under this condition, a health IT developer must do the following:

1. Provide assurances that it will not take any action that constitutes information blocking, or any other action that may inhibit the appropriate exchange, access, and use of electronic health information
2. Ensure full compliance and unrestricted implementation of certification criteria capabilities
3. Not take any action to interfere with a user's ability to access or use certified capabilities
4. Disclose and attest whether a health IT product presented for certification stores clinical information
5. Certify a health IT product which electronically stores clinical information to the §§170.315(b)(10) criteria

The next condition he described was the electronic health information (EHI) export criterion. In response to comments on this criterion and for the proposed information blocking policies, they have adopted a focused definition of EHI. Also, he noted that they defined the scope of data that needs to be exported to EHI, that can be stored at the time of certification by the product, of which the Health IT Module is a part. He reminded HITAC members that, in shorthand, this is the B10 criteria, in which, if your certified module is a part, stores electronic health information. Then, you have to certify within 36 months to the EHI export criteria. He directed them to the slides for an overview on the general requirements, and he noted that there are two case areas by which you have to certify. One is for single patients' electronic health information export and the other is for patient population, in general. This allows for the two scenarios that were discussed in the Final Rule. It allows patients to fully access and move their health information across systems. It also allows providers to be able to move entire EHI for entire patient populations and migrate between products.

Michael Lipinski started off with a caveat that they should not read into it that an attorney was asked to talk about this condition of certification. It was more so that he worked closely with other staff on this condition. He reminded members of the six areas called out in the Cures Act, which were listed on the slides, and he presented more information on each of them. He stated that they had to balance what Congress gave them, in terms of prohibitions and restrictions, with the rights and interests of health IT developers. They created unqualified protections for certain communications, and he directed HITAC members to make a note of them on the presentation slides before giving a brief overview. Then, they created a separate category called permitted restrictions and prohibitions. He stated that those would be areas where developers would be allowed to apply restrictions.

He noted that the statutes provide for a broad definition of what is meant by "communications," so this means that they include written and verbal communications. Also, they include visual communications in the ONC Final Rule, which also covers screenshots and video. He gave an overview of these kinds of communications, and he directed members to the slides for the specifics on permitted prohibitions and

restrictions on developer employees and contractors, non-user-facing aspects of health IT, and intellectual property.

Finally, he explained the maintenance of certification with regard to communications. He noted that they received many comments on maintenance fees, including from the HITAC, which asked for more time to amend contracts. They agreed there would be additional time necessary and felt that the notification piece would be a substantial mitigating factor in terms of when the contracts were amended. They will notify all customers annually starting in 2020 that any communication or contract/agreement provision that violates the Communication Condition of Certification will not be enforced by the health IT developer. Also, he stated that they will notify all customers annually up to and until the health IT developer amends the contract or agreement to remove or void any contractual provisions that violate the Condition of Certification. He reminded the HITAC that there is HIPAA rulemaking in the works, and, if that comes to fruition, they would expect changes to be made regarding this condition and certification at that time.

Avinash Shanbhag provided more details about API conditional certification. ONC has established API Conditions of Certification to address the use of certified API technology and the healthcare ecosystem, in which certified API technology will be deployed, including health IT developers' business practice. He stated that the API conditions of certification apply to practices associated only with API-focused certification criteria, which they defined as certified API technology, and do not, generally, apply to other software interfaces. He referenced the scope of electronic health information and key definitions, as presented on the slides.

He stated that the API conditions are meant to complement the technical capabilities specified for APIs in the ONC Final Rule and seek to minimize the special effort necessary to use API technology. Specifically, these API conditions apply to the developer practices associated with the three previously finalized API functional criteria finalized in the 2015 edition certification and the new FHIR released full based API read-only criteria for single and population services that have been finalized in this Cures rule. He stated that is also worth noting that the scope of EHI is limited to the data elements specified in the USCDI.

He presented a high-level description of the three conditions of certification associated with API. They are as follows:

- Transparency: This condition clarifies the publication requirements on certified API developers for their business and technical documentation necessary to interact with their certified API technology.
- Fees: This condition sets criteria for allowable fees, and boundaries for the fees certified API developers would be permitted to charge for the use of the certified API technology, and to whom those fees could be charged. He noted that there are three categories of fees that are permitted to be charged by certified API developers and provided more information on these.
- Openness and Pro-Competitive: These conditions set business requirements that certified API developers will have to comply with for their certified API technology to promote an open and competitive marketplace.

Then, he stated that they have also structured the API maintenance of certification requirements, which are the ongoing certification requirements that are to be met by the certified API developers and their certified API technology. He reminded the HITAC that this set of requirements are only specific to the new standards-based API, and they are the verification of the authenticy of the app developer or user of the app, application

registration, and service base URL publication. Certified API developers are required to publish service-based URLs for all its customers of certified API technology that can be used by patients to access their electronic health information. He noted that, as mentioned by his colleagues Beth and Denise, all of the timelines for rolling out the API conditions of certifications will be aligned.

Robert Anthony presented a high-level overview of the topic of real-world testing of the conditions of certification. A health IT developer with certified Health IT Module(s) must successfully test the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed. He noted that the ongoing maintenance condition is something that will allow developers to verify the extent to which their certified health IT modules deployed in a production environment demonstrate conformance with the full scope of whatever certification criteria they have to comply with, within those particular workflows or architectures.

He explained that they put some parameters around what things have to be part of that testing and walked them through some examples listed on the slides. Developers must submit their real-world testing plan to the ONC-ACB by a date that enables the ONC-ACB to publish the plan on the CHPL no later than December 15th of each calendar year. Then, they must submit real-world testing results to the ONC-ACB by a date that enables the ONCACB to publish the results on the CHPL, no later than March 15th of each calendar year. He provided more detail on what real-world testing plans should also include.

He noted that, essentially, it all comes down to how a developer's module is certified and how they are employing a number of different measures related to the real-world application of that technology as a whole. He explained that they are creating a way for the information to be made publicly available, including both the plan and the results from the developer. He distinguished that these testing plans are not necessarily per individual module, but, rather, they are per developer, per applicable criteria, and per setting of care or applicable workflow. So, he noted that it is possible, especially for vendors that have a large number of health IT modules, to be able to bundle some of those together to relieve the burden on them to submit.

He stated that there are things that are dependent within this condition on some of those criteria within the real-world testing plan. So, overall, there will be some requirements to both update certified health IT modules as applicable and also roll out to customers things like the USCDI, updates to the newest standards for CCDA, and electronic prescribing, for example. There are some other privacy and security things that also dependent, and this is all on the developer's side.

He emphasized that the standards version advancement process is an important concept for moving health IT forward more nimbly. The standards version advancement process allows developers to choose among the versions of standards and implementation specifications listed in regulation or National Coordinator (NC)-approved newer version updates for any or all standards applicable to criteria subject to real-world testing requirements. This flexibility to choose among NC-approved versions of standards and implementation specifications will be available both when developers seek initial certification or to maintain certification of a health IT module. Then, he gave some information on how it will work for a developer to take advantage of this flexibility and referred to more information in the presentation slides. He noted that they will be releasing more information in weeks to come, and it will be a process by which people will be able to nominate potential standards for advancements. Then, they will consider them, gather information and then, ultimately, the National Coordinator will decide on approving specific standards for advancement and adoption moving forward.

Due to time constraints and pending topics of discussion, **Lauren Richie** noted that **Robert Wah** and **Carolyn Petersen** would be adjusting the agenda.

Robert Anthony gave an overview of final criteria – attestation. He noted that this is a very simple concept, under which, a health IT developer is attesting to meeting the previous conditions of certification. He stated that the first window will not open until n April 1, 2021 but, essentially, there will be attestations submitted every six months. There will be a 30-day window for health IT developers to submit those attestations to having met those conditions of certification. He reminded the HITAC that this is a requirement of the Cures Act. ONC will enforce this through the direct review process that is already in use for overall ONC surveillance.

He concluded by reviewing the timeline for the process and noted that it will be a cascading process. It will happen over the next six, 18, 24, and 36 months, and it is not something that happens all at once.

Robert Wah explained that the co-chair's plan would be to hold off on the discussion in order to get a sense of where they are in terms of health information technology and COVID-19. He noted that they would take a small break in between the next presentation and the final presentation to start soliciting some of those priorities. Then, they would circle back with a plan of how to incorporate those priorities into either a task force or another special meeting of the HITAC regarding COVID-19. He noted that they must respect the scheduled public comment period, and, after it, they could continue the discussion of the presentations and/or discuss their COVID-19 response priorities.

ONC 21ST CENTURY CURES ACT FINAL RULE INFORMATION BLOCKING PROVISIONS

Michael Lipinski presented on the information blocking provision. He gave an overview of what they were asked to do by Congress, and noted that they focused on this throughout the entire rulemaking process and with the ONC Final Rule.

Then, he presented a checklist from the slides that listed all of the ways in which an individual or entity could be an information blocker. This list included the following items:

- Actor regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception

He gave an overview of information related to timelines and noted that they finalized that all actors subject to the information blocking provision, including developers, health information networks, and providers, would not have to comply with information blocking until six months past the publication date of the rule. The other key point that he noted from the slides is that the Office of the Inspector General has not yet issued their civil monetary penalties rule, and it is still under review. Until they finalize that, they have indicated that there would be no enforcement before the six months. Then, they will exercise discretion if they were to, for example, issue the rule another six months after that. He explained that the in-between time, they would exercise discretion as to enforcement.

He noted that, in October 2019, the administration issued two executive orders, 13.89.1 and 13.89.2, focusing on enforcement actions. They cited that in the rule, and he stated that they have always encouraged self-disclosure and we continue to do that whether it's related to the program or related to information blocking. Once that executive order is fully implemented, there may be an opportunity for advisory opinions, as well related to information blocking.

Then, he gave a summary of the four actors identified by Congress that would be regulated in the Final Rule. They are health care providers, health IT developers of certified health IT, health information networks (HINs), and health information exchanges (HIEs). Of these actors, he focused on HINs and HIEs, definitions for them, and the four ways in which they changed. He noted that many comments were submitted in this area, and he described several specific pieces of feedback and how they tried to evaluate and accommodate them. They focused on alignment with HIPAA. He detailed the ways in which they narrowed their focus to the entities that are covered and how this related to information blocking.

He noted that ONC received many comments about their proposed definition of EHI being overly broad. He covered changes and clarifications from the ONC Final Rule. One of these focused on the definition of electronic PHI (ePHI) included in a designated record set (DRS). This definition does not expressly include or exclude price information. To the extent that ePHI includes price information and is included in a DRS, it would be considered EHI. He stated that many of the actors that are going to be covered under the information blocking provision have familiarity with information that ePHI found a designated data record set; they are already collecting it, maintaining it, and making it available. So, therefore, he stated that they think it is practical and operational in that respect. They considered how it would work with the definition that they finalized, and they decided that it is not expressly included or excluded. If it is in the designated record set then, it would be considered EHI, and that, he noted, is the bottom line.

He presented the definition of what is meant by "interfere with" or "interference"; they mean to prevent, materially discourage, or otherwise inhibit. He highlighted three key examples in the presentation, which included the following:

- Publication of "FHIR service base URLs" (sometimes also referred to as "FHIR endpoints") - A FHIR service base URL cannot be withheld by an actor as it (just like many other technical interfaces) is necessary to enable the access, exchange, and use of EHI.
- Delays – An actor's practice of slowing or delaying access, exchange, or use of EHI could constitute an interference and implicate the information blocking provision.
- Costs for Electronic Access by Patients/Individuals - An actor's practice of charging an individual, their personal representative, or another person or entity designated by the individual for electronic access to the individual's EHI would be inherently suspect under an information blocking review.

Then, he presented what the definition is not and noted that "interfere with" or "interference" means to prevent, materially discourage, or otherwise inhibit.

- Business Associate Agreements (BAAs) – Actors are not required to violate BAAs or associated service level agreements. However, a BAA or its associated service level agreements must not be used in a discriminatory manner by an actor to forbid or limit disclosures that otherwise would be permitted by the Privacy Rule.

- Educate Patients about Privacy and Security Risks of Apps and 3rd Parties. He noted that they received a lot of comments and feedback on this topic. Actors may provide patients with information that:
  - Focuses on any current privacy and/or security risks posed by the technology or the third-party developer of the technology;
  - Is factually accurate, unbiased, objective, and not unfair or deceptive; and
  - Is provided in a non-discriminatory manner.

He referenced the eight exceptions, which, due to time constraints, he could not go through at great length. He directed them to the public presentation given by ONC on Monday, March 16, which should be available online shortly. He noted that they would able to look at it or listen to it at their leisure and review the slides. These exceptions are divided into two categories: exceptions for not fulfilling requests to access, exchange, or use EHI, and exceptions for procedures for fulfilling requests to access, exchange, or use EHI. He highlighted the privacy exception, which received many comments from the HITAC, and the meaningful opportunity piece, which they believed is addressed.

Then, he addressed content manner and exception, as defined in the presentation. The content conditions include: up to 24 months after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, the EHI identified by the data elements represented in the USCDI standard, and on and after 24 months after the publication date of the final rule, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in § 171.102 of the ONC Final Rule.

As an overview, he noted that it will not constitute information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request, provided certain conditions are met. To satisfy this exception, an actor must meet both of these conditions: content condition and manner condition. The objective is that this exception provides clarity and flexibility to actors concerning the required content of an actor's response to a request to access, exchange, or use EHI and the manner in which the actor may fulfill the request. It supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and use of EHI. He explained how this would work and noted that the EHI content is limited to data that is identified in the USCDI, and that it is not the USCDI itself, with all its associated standards. He stated that this would include notes, if they are in electronic format, and it would also include problems if they were in ICD-10, only, and not SNOMED. He noted that any data requested outside of data identified in USCDI would not need to be provided in those first 18 months.

Then, he described the manner conditions. An actor must fulfill a request in any manner requested unless the actor is:

1) Technically unable to fulfill the request in a manner requested; or
2) Cannot reach agreeable terms with the requestor to fulfill the request.

If an actor fulfills a request in any manner requested, the actor is not required to comply with the Fees or Licensing Exception. However, if an actor responds in an alternative manner, the actor must fulfill the request without unnecessary delay in the following order of priority, only proceeding to the next consecutive paragraph if technically unable to fulfill the request in that manner:

1) Using technology certified to standard(s) adopted in Part 170 that is specified by the requestor.
2) Using content and transport standards specified by the requestor and published by:
    a. Federal Government; or
    b. Standards developing organization accredited by the American National Standards Institute.
3) Using an alternative machine-readable format, including the means to interpret the EHI, agreed upon with the requestor.

He noted that this was an abbreviated presentation for the sake of time, which focused on key pieces and proposals that HITAC and other commenters had highlighted previously.

Carolyn Petersen noted that due to time constraints they would not take questions or comments at this point but possibly revisit the topic in April. She then transitioned to **Beth Myers.**

ONC 21ST CENTURY CURES ACT FINAL RULE HEALTH IT FOR THE CARE CONTINUUM PROVISIONS

Beth Myers thanked everyone on HITAC and on the Health IT for the Care Continuum Task Force that was convened last year to talk through the overarching approach taking place, specifically, for pediatric care for health IT. She noted that it has involved partners from CMS, from AHRQ, from other parts of the department, as well as a wide range of public stakeholders, including standards development organizations, health IT developers, both those who are working on pediatric-specific products and those working on broad universal products that need to be implemented in a wide range of spaces.

She noted that, in the part of the ONC Final Rule that is within the scope of their rulemaking, they adopted an approach that took the directives of the Cures Act for Section 4001 of the Cures Act and, also, looked at what they could do beyond those very specific policies within that law that directed them to adopt recommendations for the voluntary certification to support pediatric care and practice settings. In response to the requirements set forth in section 4001 of the Cures Act, ONC:

1) Developed ten recommendations for the voluntary certification of health IT for pediatric care under the Program, not as a separate certification program. These 10 recommendations were based on clinical priorities that were identified through a collaborative process with the community starting from things like the children's EHR format going all the way back to 2013. She gave more information on the specific criteria they developed to address these recommendations.
2) Identified current and new 2015 Edition certification criteria that support 2 pediatric care and practice settings based on clinical priorities.
3) Focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.

She highlighted some key focal points. She noted that they know that children with complex care needs are seen in multiple settings by multiple different provider types, so, ensuring that that care coordination has complete records is absolutely essential. Also, she emphasized that they wanted to ensure that people who

are performing pediatric care can effectively work with their developers or the developers who are creating a product to support pediatric care settings are able to build the appropriate structure on top of that floor.

She noted that they are looking at the certification criteria and how they address the clinical priorities, but she noted that they recognized that, in order to be most appropriate for pediatric care, needs between types of providers might vary. She highlighted work they have done with some partners, which will be added to their website under the health IT for pediatric care and practice settings page. There will be information for health IT vendors and developers to see some of these resources and tools that have been developed through pilots, through other federal partners, and through standards developing organizations that cover the next phase or the next technical specification needed to address pediatric care needs in a variety of settings. Also, she stated that they have worked with ONC's technology team to update their interoperability standards advisory to identify, with a form of tagging, standards that are under review within the interoperability standards advisory for pediatric care.

Discussion:

- **Steven Lane** noted that he shared some comments and questions in the Adobe chat notes, and he asked for additional clarification related on information blocking. In his reading of the rules, he noted, providers are required to provide electronic access to the data elements in USCDI beginning six months after the final publication of the rule in a manner that is technically feasible, acceptable, etc. He asked if this means that clinician notes, which are not included in USCDI Version 1 must be provided electronically upon request to patients in a manner that they request, including access via the patient portal where that access exists and technical capability exists, which is what some people have referred to as open notes.
    - **Michael Lipinski** responded that, before addressing this specific question, he wanted to offer a piece of clarification that he forgot during his presentation.
        - He noted that when he talked about how they refocused on the HIN definition, he wanted to be clear to everyone that it is still a functional definition. There are no particular entities precluded from being able to meet the HIN definition. So, a plan or a provider, if it does everything that they have listed there in the HIN definition, they would be a HIN. He noted that this might differ from some HIPAA statutes and regulations on what are covered entities.
        - Second, he addressed Steven's question. He stated that clinician notes are identified in the USCDI, and, if an actor, which would be a healthcare provider in this case, if they had them electronically available in the EHI format and they can be provided through the patient portal or even through an API, then it is considered EHI. He noted that there might be exceptions.
    - **Elise Anthony** highlighted that it is six months from the publication date, not effective date, when the information that Mike just described would be required to be made available.
    - **Michael Lipinski** added that, if you received the request, you could reach an agreement on costs and if there is a need for a license to get access to that EHI, including the notes. Or, he noted, if you are the requester, you are not going to agree to the terms yourself. You don't want to pay anything for it. So, if they're technically able to, you would drop down to alternative manner, which is certified health IT. So, he noted, many providers have certified view download transmit (VDT) functionality. If they have VDT functionality and the notes in electronic format and the requester is fine with getting them then, that should happen.
- **Arien Malec** stated that he had a hard time parsing the "between and among standard," which is the definition of exchange and the "enable to exchange with each other standard" for HIE/HIN. He noted

that his guess is the differences are the operative words. In figuring out the dividing line between an entity that is primarily engaged in doing work on behalf of one party to get information to another party, he stated that his understanding is that it would not be an HIE/HIN. He wondered if they can help sort out where the operative dividing line would be between an entity of one type that would not be considered HIE/HIN, and an entity of the other type that would be considered an HIE/HIN.

- **Michael Lipinski** responded that they were clear in the rule that they were not going to carve out certain entities. He noted that they did give a couple of examples of entities they thought would no longer meet the definition, such as social networking or internet service providers.
- **Arien Malec** responded that he is having a hard time distinguishing the operative definition.
- **Michael Lipinski** described a pictorial representation in his response.
  - He explained that, for them, it was as if there was a straight line and he was passing the data through, which is "the entity that may or may not be the HIN". And then, they are doing something with data or maybe just providing infrastructure to get data to the other entity, whether it is a reporting agency or the government of some sort. He noted that, even if there were six nodes or even hundreds on the one end, that wouldn't matter.
  - For clarity, he explained that it would not matter how many nodes are on either end of this. Obviously, he noted that three are needed as a basis for the HIN definition. However, what is important is entities on either side are able to exchange with each other. So, he stated, if you had all of those providers on one end and all they are doing is funneling their information through to one other entity, that would not be a HIN, but if they were able to exchange with each other through the services or the agreement of that entity in the middle, then, that would be a HIN, as long as there were three of them, it was for payment treatment and operations, and meets all of the other parts of the definition.
  - Then, on the other end, they should be able to also exchange with the parties on the other end indiscriminately, if they so choose. He stated that it is about providing the ability for everybody either through the agreement or the technological services to be able to exchange information with each other.
- **Arien Malec** thanked him for his clarification and noted that might be useful to have a set of for instances or some FAQs in this area.
- **Donald Rucker** noted that part of what they wanted to do here is not to have folks who are doing clearinghouse functions and who are not distributing it in a classic network sense. He explained that, for them to not be covered under this concept is hard to define, and this was an effort to define it.

COVID-19 ACTIONS TAKEN BY HITAC

Carolyn Petersen gave a brief overview of actions taken by the HITAC with regards to the COVID-19 pandemic and noted that discussion has taken place behind the scenes. She asked HITAC members to send comments, questions, or topics of interest to her or **Robert Wah** by the end of Friday, March 27. She will collate all feedback and will forward it on to the full HITAC membership. As with the Annual Report, the entire process will be completely transparent. The goal is to get a call or task force set up for the next week. She asked members to include their preference for either a one-time call or something that continues for longer, like a task force of workgroup. She noted that they will follow federal guidelines, with regards to the advance notice given, but they will move forward with the process expeditiously.

PUBLIC COMMENT

Michael Peter from the American College of Radiology (ACR): Hi. This is Mike Peters from ACR. This is a question that, hopefully, you can respond to with clarification. The enforcement discretion for info blocking will be exercised until OIG promulgates the enforcement rule. But where this is talked about in the rule is where it applies to CMPs for developers. What isn't clear is if this enforcement discretion also applies to investigation and implementation of provider disincentives. Could someone please clarify?

In response, **Michael Lipinski** clarified that there are no provider disincentives at this time. So, to be compliant with the statute, the secretary must identify those disincentives through a notice in comment rulemaking and that has not occurred.

Cait DesRoches from Open Notes: My first question I think was already answered, which is what disincentives are in place ensure that healthcare providers are providing access to patients, specifically, to their notes given that we think that among all of the new data elements that are required, notes are the thing that is going to be a stumbling block for a lot of providers. So, I'm wondering what the plan is for clarifying what those disincentives are. That is my first comment.

Second, I was wondering if there are any plans to move beyond something like a simple attestation to ensure that notes are being rolled out within organizations in a way that is robust and, actually, leads to patients using the notes. We've learned over the years that simply flipping the switch within Epic or Cerner is not enough to ensure that patients know that the information is there and know it is valuable for them to use it. I'd urge you to think hard about developing measures that ensure that patients are actually able to use those notes in a way that is simple and easy for them.

The third is I have looked through the rule, and I am still a little confused about what will ONC's response be to complaints against providers that are submitted by individuals that are saying my provider is not making my clinical notes available to me. I'm wondering what the response from ONC will be. I know that, for vendors and tech developers, there is a financial disincentive, but I didn't see that there was anything in there for providers. So, I'm wondering what ONC is thinking about that. Thank you.

Robert Wah thanked the public for their comments and lamented that, due to the interest of time, the HITAC was unable to have time to take another comment at this point. He apologized for the fact that the schedule was too packed for adequate time for discussion and questions, but he noted that they always try to accommodate as many possible. In this particular case, they were not as successful as they have been.

Questions and Comments Received via Adobe Connect

Joanna: good morning!

Michelle Barry: Good Morning!

Gabriel Perez: Good Morning everyone.

Jim Jirjis: Good morning

Alexis Snyder: Good Morning

Michael Adcock: Good morning, I am on the call waiting for the next available operator

Carolyn Petersen: Good morning!

Leslie Lenert MD: Good morning...still waiting for an operator

Anil Jain: Morning -- same, waiting for operator - then line hung up...

John Kansky: Me too. I got dropped but dialed back in

Michael Adcock: Me too

Jim Pantelas: Hah, the operators are slow this morning!

Brett Oliver, MD: Waiting on operator as well

Carolyn Petersen: We'll wait for HITA members to get in

Mark Segal: FYI, when I called public audio phone number, operator said I needed a password or to be on roster

Michael Adcock: I'm on the call, but have been put on mute

Michael Adcock: Apparently there is a connection issue on my line

Laura Conn (for Adi Gundlapilli): Laura Conn is on for CDC (Adi Gundlapili

Jonathan Nebeker: Those of us with operational duties mah be in and out. Earthquates in Utah aren't helping.

Lauren Richie: understood Jonathan

Lauren Richie: thank you Laura

Valerie Grey: This is Val Grey, I'm on, sorry I'm late ....

Lauren Richie: hi Val, no worries

Arien Malec: I'm on.

Lauren Richie: Hello Arien

Lauren Richie: Hello Arien

Jim Pantelas: Can we build in provisions and rules for release of privacy requirements that can allow for expedited release in instances of emergencies? It's nopt that we change things on what we do today - just that we understand the need in future?

Laura Conn (for Adi Gundlapilli): I would suggest a special HITAC call on COVID-19 response so we could have additional CDC folks on the line.

Christina Caraballo: I agree with Laura.

Steven Lane: Agree that we should have a special HITAC meeting and effort re COVID-19

Alexis Snyder: I konw that we are behind on time, but could we ask folks presetning to slow down as bit- it is hard to keep up

Lauren Richie: noted alexis, we'll try to adjust accordingly

Alexis Snyder: thank youy Lauren, this speakers rate of speech is much better

Jim Pantelas: In. This real world testing, Arte developers allowed to use actual patient files? If not, are we anticipating providing a sand box of real world pseudo data so that all are working with the same datasets?

Alexis Snyder: good question

Laura Conn (for Adi Gundlapilli): I have to drop at noon but Adi and I will be watching for how we can support discussions of COVID-19 HIT activities and needs.

Carolyn Petersen 2: Thanks, Laura. We will announce something about that within this meeting and we will circle back with you and Adi.

Laura Conn (for Adi Gundlapilli): Thanks Carolyn

Ahier, Brian (MITRE): How will the meeting resume at 11:50 AM?

Lauren Richie: Since we are behind schedule, we did not take a break. Robert just gave an update on plans for the remainder of the agenda.

Liz Salmi: We can hear you!

Mark Segal: Please clarify if a standards organization or industry group that establishes policies that may be voluntarily adopted or referenced in regulation is an HIE/HIN. What about a company that develops interfaces or connectivity solutions for other actors or administers exchange on their behalf.

Amanda Woodhead: The recording of the in depth ONC webinar on Information Blocking is now available at www.healthit.gov/curesrule under the resources section.

Meryl Bloomrosen: Amanda- are the webinar slides available?

Amanda Woodhead: Hi Meryl! They will be posted shortly once the 508 compliance is complete.

Amanda Woodhead: The slides and recording of the Overview webinar (held on 3/11) is available in the resources section as well.

Meryl Bloomrosen: Amanda- THANK YOU!

Denise Webb: On page 1240 in 171.302(b)(2) of the regulatory text of the final rule states an excluded fee condition such that the fee exception does not apply to "A fee based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual." What is the impact of the Wash DC District Court opinion issued on the CIOX v. Azar case where the court opinion is that the fee limitation set forth in HIPAA applies only to an individual 's request for access to their own records and does not apply to individual's request to transmit to a thrid-party (i.e., fees can be charged when the eHI is going to a third party). The information blocking regulation seems to conflict with this. Can someone in ONC, such as Mike Lipinski, speak to this?

Steven Lane: As HITAC members do not seem to have time to voice questions today I will document here two questions I had hoped to raise regarding the final Information Blocking rules: (1) Do the rules prohibit providers from requiring a patient to sign an authorization to electronically exchange their EHI (i.e., “opt in”) where this is not required by law? (2) • Do the rules limit providers’ ability to delay the online release of test results, e.g., for all results, abnormal vs. normal results, “sensitive” vs. other results, or for specific providers or patients?

Carolyn Petersen 2: Thanks, Steven. We are looking at doing more on the Rule provisions in future meetings, so appreciate the questions.

Alexis Snyder: Steve jsut aksed my question too. Currently folks can agree or not agree to be part highway access between facilities but I wonder if this is going to disspear?

Alexis Snyder: Will providers be able to share between systems without obtaining sign off of patient?

Cait DesRoches: Can you clarfiy the following: 1) What disincentives

Cait DesRoches: Can you clarify the following: 1) what disincentives are in place to ensure that healthcare providers are providing patients with access to all of the data required in the USCDI, including notes. 2) are there any plans to move beyond simple attestation to ensure that access to clinical notes is rolled out within organizations in a way that benefits patients (e.g. simple, easy access with education for patients and providers)? 3) what will be the response to information blocking complaints against providers submitted to ONC by patients regarding not having access to their clinical notes?

Cait DesRoches: FYI - the operator is telling me that there is no public comment

Katherine Campanale: Please press *1 and you will be placed in the queue

CLOSING REMARKS AND ADJOURN

Donald Rucker and the HITAC co-chairs, **Carolyn Petersen** and **Robert Wah**, thanked members for their thoughtful participation and feedback. Donald Rucker noted that the comments made in the Adobe chat will be examined and incorporated. Also, he noted that he looks forward to getting everyone’s thoughts on the HIT elements of the COVID-19 strategy.

Lauren Richie reminded members that the next HITAC meeting is scheduled for April 15, 2020. Also, there is a Condition of Certification and Certification of Maintenance public webinar on March 19, 2020. The next ICAD task force meeting is March 24, 2020. She reminded everyone to go to healthIT.gov for more information on upcoming meetings for HITAC.

Carolyn Petersen asked members to send Robert and her their comments regarding the health IT aspect of COVID-19 response by end of the day Friday, March 28. They will collate those comments and will get those out to members, as well as an update about the next meeting, task force, or steps.

The meeting was adjourned at 1:00 p.m. ET.