The Office of the National Coordinator for
Health Information Technology

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

January 13, 2021, 10:45 a.m. – 2:15 p.m. ET

VIRTUAL

EXECUTIVE SUMMARY

Donald Rucker welcomed members, provided an overview of the meeting agenda and upcoming reappointments and membership changes to the HITAC, and issued his final remarks as National Coordinator for Health IT. The new co-chairs of the HITAC, **Denise Webb** and **Aaron Miri,** reviewed the meeting agenda, and the minutes from the November 10, 2020 HITAC meeting were approved by voice vote. **Carolyn Petersen** and **Aaron Miri,** co-chairs of the Annual Report Workgroup (ARWG), presented an update on the ARWG's recent work on the Annual Report, HITAC members submitted feedback, and a discussion was held. **Al Taylor**, ONC's Medical Informatics Officer, presented an update on the draft USCDI Version 2. **Alex Mugge**, Director and Deputy Chief Health Informatics Officer, CMS, presented the proposed rule for CMS Interoperability and Prior Authorization (PA), and **Steve Posnack**, Deputy National Coordinator, ONC, followed the presentation with remarks. **Bakul Patel,** Director, Digital Health Center of Excellence, FDA, presented an overview of the FDA's Digital Health Center of Excellence. **Lauren Richie** presented the HITAC 2021 draft work plan. No public comments were submitted by phone, but there was a robust discussion and comments in the public meeting chat via Adobe.

AGENDA

10:45 a.m.	Call to Order/Roll Call
10:50 a.m.	Welcome Remarks
10:55 a.m.	Remarks, Review of Agenda, and Approval of November 10, 2020 Meeting Minutes
11:00 a.m.	HITAC Annual Report Workgroup Update
11:45 a.m.	Draft U.S. Core Data for Interoperability Version 2
12:30 p.m.	Break
12:45 p.m.	CMS Interoperability and Prior Authorization Proposed Rule
01:15 p.m.	FDA Digital Health Center Presentation
01:45 p.m.	HITAC 2021 Final Work Plan
02:00 p.m.	Public Comment
02:15 p.m.	Final Remarks and Adjourn

CALL TO ORDER/ ROLL CALL

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the January 13, 2021, meeting to order at 10:45 a.m. and welcomed the new members of the HITAC to their first meeting.

ROLL CALL

Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin, Co-Chair
Denise Webb, Indiana Hemophilia and Thrombosis Center, Co-Chair
Michael Adcock, Magnolia Health
Cynthia A. Fisher, PatientRightsAdvocate.org
Lisa Frey, St. Elizabeth Healthcare
Valerie Grey, New York eHealth Collaborative
Jim Jirjis**,** HCA Healthcare
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
Clem McDonald, National Library of Medicine
Brett Oliver, Baptist Health
Terrence O'Malley, Individual
James Pantelas, Individual
Carolyn Petersen, Individual

Raj Ratwani, MedStar Health
Abby Sears, OCHIN
Alexis Snyder, Individual
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.
Robert Wah, Individual

MEMBERS NOT IN ATTENDANCE

Amy Abernethy, Food and Drug Administration
Steven Hester, Norton Healthcare

FEDERAL REPRESENTATIVES

James Ellzy, Defense Health Agency, Department of Defense
Adi V. Gundlapalli, Centers for Disease Control and Prevention
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Donald Rucker, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Beth Myers, Deputy Director, Office of Policy
Andrew Gettinger, Chief Clinical Officer
Thomas Mason, Chief Medical Officer
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Michelle Murray, Staff Lead

WELCOME REMARKS

Lauren Richie asked members of the HITAC to disclose any outside activity with ONC, and the following information was shared:

- **John Kansky** disclosed that he participates on the board of the Sequoia Project, which ONC awarded a cooperative agreement to serve as the Recognized Coordinating Entity (RCE) to develop, update, implement, and maintain the Common Agreement and the Qualified Health Information Network Technical Framework (QTF). Additionally, he shared that his organization participates in small, occasional contracts with ONC.
- **Raj Ratwani** disclosed that his organization, MedStar Health Research Institute, has a contract with ONC.
- **Ken Kawamoto** disclosed that he has honoraria consulting sponsored research licensing for code development with McKesson, Hitachi, Pfizer, Premier, RTI International, Mayo Clinic, University of Washington, UC-San Francisco, MD Aware, and ONC. Additionally, he was an unpaid board member of HL7.
- **Andy Truscott** disclosed that he is the chair-elect of HL7.
- **Steven Lane** disclosed that he served as the chair of the Sequoia Project and the chair of the Steering Committee for Carequality, both of which are involved in ONC's Trusted Exchange Framework and Common Agreement (TEFCA) RCE work.
- **Carolyn Petersen** disclosed that she is an unpaid board member of HL7.
- **Aaron Miri** disclosed that he is an unpaid board member of the Sequoia Project.

Dr. Donald Rucker welcomed members to the meeting of the HITAC. He thanked the former HITAC co-chairs, **Carolyn Petersen** and **Robert Wah,** for their service and recognized other HITAC members who recently completed their terms of service: **Christina Caraballo, Anil Jain, Steve Ready,** and **Tina Esposito**. He welcomed **Steven Hester** and **Lisa Frey,** who are new members of the HITAC, and the new HITAC co-chairs, **Denise Webb** and **Aaron Miri.** He stated that the co-chairs are both astute leaders and should be ready to meet the challenges and opportunities presented to the HITAC.

Dr. Rucker explained that this meeting would be his final one as the National Coordinator for Health IT, due to the change in the administration, and thanked the HITAC and ONC for the privilege of working on projects like ONC's Cures Act Final Rule, health information technology (IT) standards and policy initiatives, and updates to the U.S. Core Data for Interoperability (USCDI). He discussed input and suggestions ONC received during the initial part of the process to update the USCDI, noting that the selections were bounded by the ecosystem for all electronic health record (EHR) systems in the United States and globally, for the International Patient Summary. He stated that the HITAC will have extraordinary opportunities to influence the further evolution of standards and the integration of clinical and administrative data, and he encouraged the HITAC to focus on the issue of integrating the patient matching, identification, and consent processes.

Dr. Rucker discussed how the COVID-19 pandemic and related relief efforts have highlighted the importance of the exchange of health information, especially at the state and local levels. He emphasized that there are many opportunities to expand health information exchanges (HIEs) to create a competitive atmosphere that fosters robust development of a wide range of services to patients. He explained that the HITAC has an opportunity to rethink the nature of how health data is reported to the government, and he highlighted COVID-19-related issues with out-of-process reporting burdens.

Later in the meeting, **Steve Posnack** thanked Dr. Rucker for his leadership and service to ONC, the HITAC, and the industry and shared that Dr. Rucker was the longest-serving National Coordinator. **Steve** thanked him for his commitment to the HITAC's mission and work.

REVIEW OF AGENDA AND APPROVAL OF MEETING MINUTES

Aaron Miri, HITAC co-chair, welcomed all the participants and thanked the previous co-chairs, **Carolyn Petersen** and **Robert Wah**, for their leadership during their terms as co-chairs and their work on ONC's 21st Century Cures Act. Also, he recognized the leadership shown by HHS and **Dr. Rucker** during the COVID-19 pandemic and, on behalf of the provider community, thanked everyone for helping to "find grace in chaos."

Denise Webb, HITAC co-chair, echoed **Aaron's** comments thanking **Carolyn, Robert**, and **Dr. Rucker** and said that they would be missed. Then, she briefly reviewed the agenda, which included an update from the HITAC Annual Report Workgroup (ARWG), a draft of the USCDI Version 2, a presentation on CMS Interoperability and Prior Authorization (PA) Proposed Rule, a presentation from the FDA Digital Health Center, and a review of the HITAC 2021 Final Work Plan.

Aaron invited members to examine the minutes from the November 10, 2020, meeting of the HITAC. There were no comments or corrections submitted, so he called for a motion. **Sheryl Turney** moved to approve the minutes, and **Steven Lane** seconded the motion. The HITAC approved the November 10, 2020, meeting minutes by voice vote. No members opposed, and no members abstained.

HITAC ANNUAL REPORT WORKGROUP UPDATE

Carolyn Petersen and **Aaron Miri**, co-chairs of the Annual Report Workgroup (ARWG), presented an update on the HITAC Annual report for fiscal year 2020 (FY20), which would be followed by a discussion period.

Carolyn gave an overview of the ARWG's scope and explained that in 2020, ONC broadened the scope of the ARWG's charge to accommodate the additional target area of public health, as well as the three priority target areas. She described the ARWG's overarching charge, which was:

- The workgroup will inform, contribute to, and review draft and final versions of the HITAC Annual Report to be submitted to the Secretary of Health and Human Services and to Congress each fiscal year. As part of that report, the workgroup will help track ongoing HITAC progress.

The ARWG's specific charge was:

- To provide specific feedback on the content of the report as required by the 21st Century Cures Act, including:
  - o Analysis of HITAC progress related to the target areas
  - o Assessment of health IT infrastructure and advancements in the target areas
  - o Analysis of existing gaps in policies and resources for the priority areas
  - o Ideas for potential HITAC activities to address the gaps

Carolyn reviewed the ARWG membership, which included herself, **Aaron Miri,** and **Brett Oliver**, and ONC staff, and explained that **Christina Caraballo** served as a member through December 2020, when her term on the HITAC concluded. She briefly reviewed the ARWG's meeting schedules and action items/deliverables for the ARWG and the full HITAC. The next step for the ARWG is to present its draft of the Annual Report to the HITAC. Then, the HITAC will review the report and suggest edits, and, following the addition of any further edits, the HITAC will approve the revised report. Next, the HITAC will transmit the final report to the National Coordinator for Health IT, and the National Coordinator will forward the final report to the Secretary of Health and Human Services and to Congress.

Carolyn explained that, in preparation for drafting the HITAC Annual Report for FY20, the ARWG developed a crosswalk document that considered gaps, challenges, opportunities, and recommended HITAC activities for a set of key topics. Additional topics were added to the ARWG's landscape analysis to raise awareness. The topics were grouped by several target areas, as defined in the Cures Act, which included: interoperability, privacy and security, and patient access to information. She noted that a fourth target area, use of technologies that support public health, was new for FY20.

Carolyn summarized the outline for the Annual Report, which was the same as previous years, and included the following sections:

- Executive Summary
- Foreword and Overview
- HITAC Progress in FY20
- Health IT Infrastructure Landscape Analysis
- Health IT Infrastructure Gap Analysis
- Recommendations for Addressing Health IT Infrastructure Gaps
- Suggestions for Additional HITAC Initiatives
- Conclusion
- Appendices

Carolyn gave an overview of the HITAC's progress in FY20, which included eight HITAC meetings, one HITAC hearing, 45 total meetings of the three HITAC subcommittees, and 52 recommendations to the National Coordinator for Health IT. The activities of the HITAC focused on priority uses of health IT, the intersection of clinical and administrative data, and the USCDI.

Carolyn described the health IT landscape analysis undertaken by the ARWG and explained that the 21st Century Cures Act required an annual assessment of the health IT infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information. This landscape analysis covered key topics in each of the four target areas, as well as federal activities across the target areas. She stated that additional topics were covered in the landscape analysis for awareness. Also, **Carolyn** discussed the health IT gap analysis, clarifying that the 21st Century Cures Act (the Cures Act) required an analysis that identified existing gaps in policies and resources for achieving the ONC FY19-20 objectives and benchmarks and furthering interoperability throughout the health IT infrastructure. The Cures Act also required a process to call out opportunities and recommendations for HITAC activities to address the health IT infrastructure gaps that were previously identified. The ARWG used a tiered approach to these key opportunities, which were:

- Immediate Opportunity: Correlates to planned topics for HITAC consideration within the next one to two years, i.e., calendar years 2021-22, and
- Longer-Term Opportunity: Potential HITAC consideration anticipated to begin in three or more years, i.e., calendar year 2023 or later.

In conclusion, **Carolyn** asked HITAC members for any questions, comments, revisions or parking lot items for the report.

Discussion:

- **Sheryl Turney** suggested that the recommendation regarding vaccine tracking (under "Immediate Opportunities") be strengthened to include more robust recommendations regarding data consumption and interoperability around immunity registries and vaccine monitoring.
  - o **Aaron Miri** voiced his agreement and asked Sheryl to clarify her points around the normalization and standardization of the ingestion of the data while referring to a slide displaying the section in the Annual Report.
  - o **Sheryl** responded that there are third-party apps being developed, including Snowflake, that are trying to address the issue of how to streamline interoperability. She suggested that the structure for the easiest approach, getting the data directly from the provider, is not set up yet. Therefore, an approach that references the data that has been reported to the vaccine registries would be the next best solution, though the registries are not set up to allow easy data consumption, nor are they consistent across the country. She emphasized that the HITAC should reinforce its recommendations around data exchange to allow the country to support the reopening of workplaces.
- **Arien Malec** commented on the vaccine tracking section and suggested that the report should focus on funding mechanisms and associated interoperability requirements to create an ecosystem-based approach with an incentive structure and funding structure that aligns incentives, as opposed to a forced-mandate-based approach. He discussed existing EHR incentive programs and explained that they lack corresponding incentive programs and public health funding models. Another issue was that EHR output did not match the public health input. He suggested that incentive-associated funding should be matched with certification requirements, certification programs, and testing programs to create an end-to-end system.
- **Les Lenert** submitted several comments, which included:

- o He voiced his support for a national patient identifier or other system for national identification based on state/regional identifiers in order to identify patients and track vaccines. He explained that tracking vaccinations and conducting population health programs to target the most vulnerable populations are difficult or impossible across the fractured health systems in the country without a national identified and related systems. Therefore, he emphasized that this is a perfect use case scenario for the implementation of a national identifier or other system of state identifiers.
  - o He discussed issues related to the data flows for public health, all of which were designed to flow upward for policy decision-making purposes. He stated that, though vaccine information systems are among the most standardized public health systems, they are flawed without the existence of a national identifier.
  - o He stated that there is a lack of infrastructure for public health for population reporting and explained that, currently, two-way interoperability is not supported. He emphasized the urgency of this work.
  - o **Aaron Miri** voiced his support for **Les'** comments and added that some states, like California, have empowered dentist offices and others to vaccinate. However, their EHRs do not conform to state reporting mandates.
- **Clem McDonald** voiced his support for **Les'** comments and submitted several comments of his own, which included:
  - o He explained that there have been issues with interactions between public health and clinical data because public health reporting requirements have been divided between diseases and infections. They should aggregate data upwards instead of dumbing it down within the reporting requirement to minimize issues.
  - o He discussed issues related to privacy codes and information around demographic information, like a lack of race codes at some CDC surveillance sites, which has complicated the rollout of vaccination prioritization strategies.
- **John Kansky** thanked the ARWG for the comprehensive report and submitted several comments:
  - o He suggested that the pandemic response has demonstrated the need for the section on the uses of technologies that support public health, like HIEs.
  - o He stated that there is an emerging model that gives HIEs a more official designation at the state level and a responsibility for supporting public health while still entertaining free-market competition. This could be a policy gap or opportunity.
  - o He offered to share a whitepaper on the use of HIEs for public health that he co-authored with David Horrocks from the Chesapeake Regional Information System for Patients (CRISP).
- **Steven Lane** discussed the longer-term opportunity to increase health equity across populations and suggested that this has come up as a high priority in the industry, especially in the context of the COVID-19 pandemic. It might also be an immediate priority for the new administration, so the HITAC should consider moving it up the list.
  - o **Aaron** noted the comment.

In conclusion, **Aaron Miri** explained that a new feature of the FY20 Annual Report was a synthesis of each target area as a real-life scenario or illustrative story. He asked the members of the HITAC to examine these sections, as each one was created from comments from the HITAC, the previous year's reports, and feedback from the industry and the public, and to submit feedback accordingly. **Carolyn Petersen** echoed **Aaron's** suggestions and emphasized that the Annual Report should represent the opinions and thoughts of the full HITAC. Michelle Murray reminded HITAC members that they should review the document and submit comments by Friday, January 22, 2021.

Denise Webb thanked the ARWG co-chairs for their work, and **Aaron Miri** thanked the ONC and Accel teams for their assistance.

DRAFT U.S. CORE DATA FOR INTEROPERABILITY VERSION 2

Al Taylor, ONC's Medical Informatics Officer, presented an update on the draft USCDI Version 2 (v2). He thanked the HITAC for the opportunity to present and provided a brief overview of the USCDI Version update process and timeline, which was depicted on slide number two in the presentation deck. He explained that the preparation process and publication of the draft USCDI v2 have been completed, and Version 2 has been published for public comment and HITAC comment, as well.

Al summarized the submissions to the USCDI ONDEC submission system, and there were over 60 unique submitters. He explained the rubric used to score and evaluate the submissions into the level assignments, which included 109 data elements for Level 2, 55 data elements for Level 1, and 140 data elements at the comment level. Level 2 submissions were the most mature in terms of ready to use or affecting the broadest group. He noted that nearly half of the data elements were duplicate submissions, which indicated the level of involvement by stakeholders.

Al asked the HITAC to examine the overall draft USCDI v2 on slide three in the presentation deck. He explained that the changes made were modest in light of stakeholders being more focused on COVID-19 relief efforts at the time. **Al** highlighted the new data elements and new data classes, adding that several data elements were reorganized into other data classes.

The new data classes and elements in the draft USCDI v2 included:

- Care Team Members
  - Provider Name
  - Provider Identifier
- Diagnostic Imaging
  - Diagnostic Imaging Order
  - Diagnostic Imaging Report
- Encounter Information
  - Encounter Type
  - Encounter Diagnosis
  - Encounter Time
- Problems
  - Date of Diagnosis
  - Date of Resolution

Al explained that a key point of feedback on USCDI v1 was that the issues around clinical notes and how the data elements within clinical notes pose problems, especially the note types. The reclassified clinical notes data elements split diagnostic imaging and laboratory apart from clinical notes, and these data elements included:
- Clinical Notes
  - Consultation Note
  - Discharge Summary Note
  - History & Physical
  - Procedure Note
  - Progress Note
- Diagnostic Imaging
  - Diagnostic Imaging Narrative

- Laboratory
    - Laboratory Report Narrative
    - Pathology Report Narrative

AI explained that updates were made to the existing versions of the terminology code sets that comprised the applicable standards within USCDI Version 1. The USCDI v1 standards included:

- RxNorm - January 6, 2020
- SNOMED CT - September 2019
- LOINC 2.67
- ICD-10-PCS 2020
- CVX - January 31, 2020
- Vaccine NDC Linker – January 31, 2020
- CPT 2020

These were updated in the following manner in the draft USCDI v2:

- RxNorm - January 4, 2021
- SNOMED CT - September 2020
- LOINC 2.69
- ICD-10-PCS 2021
- CVX - November 16, 2020
- Vaccine NDC Linker – November 13, 2020
- CPT 2021

AI described the prioritization criteria for Level 2 data elements during the Version 2 update process and discussed how they applied to several of the updated data elements and data classes while sharing some of his personal insights into the process from the point of view of a physician. These criteria included:

- Significant gaps in USCDI v1 concepts
- Supported by existing ONC Certification
- Modest technical standards development
- Modest aggregate lift for vendor development and implementation, esp. during pandemic

AI explained that, in Version 1, it took over a year and a half to prepare the new data elements to be included, so for Version 2, the USCDI Task Force (USCDI TF) deliberately looked for data elements that already had substantial technical development completed in the standards to ease the process. Part of this work was on the Fast Healthcare Interoperability Resources (FHIR) and the C-CDA implementation guides. He stated that the intent of the USCDI was to reduce the effort needed for implementation across the vendor development and provider communities. Additionally, the USCDI wanted to encourage incremental updates as a way to improve interoperability in health data exchange.

AI described the next steps for USCDI v2:

- HITAC and public review and comment (January – April 15, 2021)
- USCDI V2 (final) standard document published July 1, 2021
- Consider for Standards Version Advancement Process Approved Standard
- Review and refine USCDI version update process

AI presented the 2021 USCDI TF overarching and specific charge:

- Overarching charge:
  - Review and feedback on the Draft USCDI v2 content and process

- Specific charges:
  - Evaluate Draft USCDI v2 and provide HITAC with recommendations for: due April 15, 2021
    - Data classes and elements from USCDI v1 including applicable standards version updates
    - New data classes and elements from Draft USCDI v2 including applicable standards
    - Level 2 data classes and elements not included in Draft USCDI v2
  - Evaluate the USCDI expansion process and provide HITAC with recommendations for: due September 9, 2021
    - ONDEC submission system improvements
    - Evaluation criteria and process used to assign levels to submitted data classes and elements
    - Prioritization process used by ONC to select new data classes and elements for Draft USCDI v2
  - Recommend prioritization areas for USCDI version 3 submission cycle: due September 9, 2021

Al asked the HITAC members to return their attention to the timeline presentation slide and explained the timelines are notional. April 15, 2021, is the deadline for public comment, so he asked that the HITAC try to meet that same deadline to give ONC ample time to process the recommendations for Version 2. Also, he explained that the Version 3 submission process and related tasks should be completed in September 2021.

Aaron Miri thanked **Al Taylor** for the presentation and asked HITAC members to submit questions and comments.

Discussion:

- **Ken Kawamoto** observed that there are many Level 2 submissions, as well as many other already well-established data elements, to consider for inclusion in the USCDI. He voiced his agreement with pushing easier items forward into the USCDI during the COVID era but also asked **Al Taylor** to comment on the availability of resources/bandwidth to identify, process, and complete items that might need more work to prepare.
  - **Al** asked **Ken** to clarify if he meant ONC's or the community's bandwidth.
  - **Ken** responded that he was inquiring about ONC's bandwidth to support the process through work like pilot projects. He stressed the importance of moving items forward that require more significant investments of resources, coordination, and work.
  - **Al** responded that ONC has allowed the community to provide the driving force for the work that needs to be done to mature the terminology and exchange standards. ONC is focusing on submissions that have not been included in the draft of the USCDI and is working to provide a place to organize around data elements that need more work. ONC might work on the development side through its support of the HL7 cooperative agreement.
  - **Ken** responded that this would continue to be a topic of discussion at the USCDI TF meetings, as the issue will likely be recurring.

- **Michelle Schreiber** echoed **Ken's** comments and explained that CMS submitted data elements to USCDI that are used in their quality measures. She emphasized the importance of standardizing those elements as CMS moves toward all-digital measures. She voiced her concern that there are too many proprietary measures that large organizations have paid vendors to develop and discussed an example related to standards for clinical oncology. She asserted that if there is no capacity to easily expand the USCDI, the development of one-off, proprietary elements will create problems. She inquired how the USCDI will work to get greater standardization, and more elements entered into the USCDI to avoid these issues.
  - o **Al Taylor** responded that the issue of consensus standardization of the elements is occurring mainly in two areas, research and cancer because they use many different data elements, data systems, and standards to represent data. He stated that ONC will not be the determining entity; rather, it will allow the community to recognize the limitations of a lack of consensus across standards and to agree on how to best represent its data. Being part of the USCDI means that all EHRs that update to the new version eventually have to agree upon the standards.
- **Clem McDonald** submitted several comments, which included:
  - o He voiced his support of the previous comments and highlighted the issue that the federal government pays for some of this work that later is monetized, so he asserted that having to pay for federally mandated coding systems is a burden and should not be allowed.
  - o He expressed his thanks for **Dr. Rucker's** outstanding work on pushing the standards development process forward.
  - o He would like greater clarity in the wording of the USCDI draft.
- **Arien Malec** echoed **Michelle's** comments on aligning the USCDI to the uses for which interoperable data is required. He suggested that if data cannot be pulled directly out of the EHR systems for adjudication purposes, for example, the role of the USCDI should be questioned. He discussed the possible issue of a disconnect between the information that clinical quality measures or the Social Security Administration are trying to pull and what is routinely collected in EHRs, stating that this creates a larger ecosystem problem. Interoperability requirements and data collection requirements should align with real-world uses and requirements.
- **Steve Posnack** submitted several comments, which included:
  - o He discussed the points **Steven** and **Michelle** made previously, as well as some recorded in the Adobe meeting chat, and recognized that the USCDI must strike a balance with each new version. Policy prioritization will be put in place by the USCDI at some point to promote standardization and assess the community's feedback on certain elements. He discussed the example of how the USCDI put forward a prospective requirement to drive the industry to adopt data elements around device identifiers for implantable devices. During work leading to each version, a balance must be struck, and ONC has tried to create a transparent process (via ONDEC) with a predictable timeline to mitigate these issues.
  - o He announced that three different documents were recently released: the draft USCDI Version 2, the standards advancement process decisions for 2020, and the standards bulletin, which binds together different ONC standards initiatives to provide greater context and more information. He directed HITAC members to these additional documents.
  - o He stated that because the impact of the USCDI happens through the certification criteria for the C-CDA document exchange and secure, standards-based Application Programming Interface (API) for FHIR, ONC will have to use policies to guide the process for certain selections. This will change each year.

- **Ken Kawamoto** shared **Jonathan Nebeker's** question, which was, "How and when can we have access to the rationale for decision-making?"
  - o **Steve Posnack** responded that the priorities used as principles for selecting data elements were shared on a slide in the presentation deck, but the rationale for each data element is not available. He said that they looked at areas with significant gaps and determined what would enrich the USCDI going forward.
- **Les Lenert** submitted several questions, which included:
  - o Is the USCDI adequate for fighting the COVID-19 pandemic in terms of understanding which vaccines and which doses have been administered and related safety issues?
  - o Can the data available in the USCDI be used to assess the quality of vaccination delivery services?
  - o Does the USCDI support computable quality measures on the efficacy of vaccine administration when denominators are constantly changing, and there is a pressing need to target the most at-risk populations?
  - o **Al Taylor** thanked **Les** for the questions and responded that the USCDI is not currently adequate to handle the amount of information that could be captured. However, the USCDI is not intended to solve every problem; rather, it is a core device. Due to the work necessary to update and implement it, the USCDI is not responsive to situations like pandemics, but he stated that there are other, more flexible mechanisms that can better address these issues, both within and outside of ONC. Examples included the Interoperability Standards Advisory (ISA) and other program requirements that can be more quickly implemented through the Centers for Disease Control (CDC), the Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services (CMS).
  - o **Les** asserted that USCDI v2 should move to be more responsive or it risks irrelevance and argued that the issue of a respiratory pandemic was a challenge that the health community has anticipated for decades. They should not work on standards that could be viewed as irrelevant to the present crisis.
- **Jim Jirjis** commented that there is a relaxation of the sharing of the minimum necessary with the proposed Health Insurance Portability and Accountability Act of 1996 (HIPAA) and asked if the expansion of the USCDI through the addition of data elements risks creating situations where patient data is overshared.
  - o **Al Taylor** responded that the USCDI defines the capabilities of collection and exchange, not the actual payload for a particular use for a particular exchange. The content of the exchange falls into the minimum necessary depending on which components are USCDI data elements, which could be a patient's entire record or just their last lab report, depending on what they request.
  - o **Jim** expressed his worry that the entire USCDI could be shared at a payer's request when the information is more than the minimum necessary.
  - o **Al** responded that the USCDI does not define what should be in a response. Rather, it defines what could be in a response, and the request would have to be an appropriate minimum necessary request.
- **Ken Kawamoto** supported **Les'** point that the USCDI should determine how to respond in the case of a pandemic, even if it is not the sole solution. He discussed existing base resources and infrastructure for sharing and emphasized the need for the USDCI TF and the HITAC to be involved in a solution.
  - o **Aaron Miri** expressed his support for Ken's comments and asked about the next steps and action items for the USCDI TF.

- o **Ken** suggested that using immunization resources, sharing immunization data with vaccine passports, and determining which COVID-specific symptoms should be encoded are the next steps. The USCDI process has not addressed the universal mapping and coding of value sets related to vaccines, so this should be done.
- o **Aaron** asked ONC to clarify the next steps for the USCDI TF.
- o **Lauren Richie** reviewed the member list from the prior USCDI TF and asked members to let her know if they are still interested in serving. ONC is determining who will be the co-chairs of the TF, and schedules will be announced shortly. Final recommendations will be completed in time for the April due date.
- o **Aaron** thanked **Lauren** and asked HITAC members to share their thoughts in writing with **AI** and the team at ONC ahead of the first meeting of the USCDI TF.
- **Clem McDonald** suggested that an evaluation/assessment of how the USCDI is doing with its coding and other processes should be launched and any complaints or other issues should be noted and addressed.
  - o **Aaron Miri** thanked Clem for the comment and discussed the example of using SNOMED codes before they were approved. He suggested that increasing clarity in the planning process around standards and adding information around vaccines when they are pending approval would be helpful.
  - o **Clem** asked if the CDC is using a different set of codes for vaccines than the USCDI.
  - o **Aaron** responded that **Clem** was correct and that there are a number of issues that need to be resolved across the landscape. Version 1 began the process, even if it missed some targets, and the work now is to move forward.
- **Jim Jirjis** shared a comment from the Adobe meeting chat that all of the interoperability goals are dependent on the public trusting the system, so the notion of oversharing/going down to the minimum necessary will be important. The public should not feel that "technology is creepy" when it comes to interoperability.
  - o **Aaron Miri** and **Denise Webb** voiced their appreciation for the point.

BREAK

The HITAC took a scheduled break from the meeting that lasted approximately 18 minutes.

CMS INTEROPERABILITY AND PRIOR AUTHORIZATION PROPOSED RULE

Alex Mugge, Director and Deputy Chief Health Informatics Officer, CMS, presented the proposed rule for CMS Interoperability and Prior Authorization (PA). **Steve Posnack**, Deputy National Coordinator, ONC, followed the presentation with remarks. **Alex** reminded HITAC members that the comment period for this proposed rule closed on January 4, 2021.

Alex gave an overview of the Patient Access API and stated that this was a policy that was finalized in the Interoperability and Patient Access final rule (CMS-9115-F), in which CMS finalized the policy to require a select group of CMS-regulated payers to implement a Fast Healthcare Interoperability Resources (FHIR)-based Patient Access API. In this proposed rule, starting January 1, 2023, CMS would require impacted payers to include, as part of the already established Patient Access API, information about the patient's pending and active prior authorization decisions to ensure patients have a better understanding of the prior authorization process and its impact on their care. She listed the following Implementation Guides (IGs) that would be used:

- For claims and encounter information, CMS proposed those be CARIN or Blue Button IGs.
- For the USCDI and clinical information, CMS proposed the DaVinci Payer Data Exchange (PDex) IG.
- For formulary, CMS proposed the payer data exchange (PDex) drug formulary IG.

Alex explained that these IGs would be supportive of the patient access builds and would be repeated throughout the presentation. Also, she explained that the proposed CMS rule would require impacted payers to establish, implement, and maintain an attestation process for third-party application developers to attest to certain privacy policy provisions prior to retrieving data via the payer's Patient Access API, increasing transparency. Additionally, this proposed rule would require impacted payers to report metrics quarterly about patient use of the Patient Access API to CMS to assess the impact the API is having on patients.

Alex described the Provider Access API. She explained that in order to better facilitate coordination of care and in support of a move to value-based care, CMS proposed requiring impacted payers to build and maintain a Provider Access API for payer-to-provider data sharing of claims and encounter data (not including cost data), a sub-set of clinical data as defined in the USCDI Version 1, and pending and active prior authorization decisions for both individual patient requests and groups of patients starting January 1, 2023. Also, CMS proposed the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification to facilitate the exchange of data for more than one patient at a time.

Alex discussed the Payer-to-Payer API, stating that in the Interoperability and Patient Access final rule (CMS-9115-F), CMS finalized a requirement that, at a patient's request, CMS-regulated payers must exchange certain patient health information, and maintain that information, thus creating a longitudinal health record for the patient that is maintained with their current payer. While CMS encouraged the use of a FHIR-based API for this data exchange, they did not require it. Alex summarized CMS's proposals:

- Payer-to-Payer API: CMS proposed enhancing the previously finalized payer-to-payer data exchange requirements for impacted payers by requiring that such exchange be via a FHIR-based Payer-to-Payer API, and that in addition to a sub-set of clinical data as defined in the USCDI version 1, impacted payers would also be required to exchange claims and encounter data (not including cost data), and information about pending and active prior authorization decisions, at a patient's request.
- Payer-to-Payer Data Exchange at Enrollment: CMS proposed requiring impacted payers share claims and encounter data (not including cost data), a sub-set of clinical data as defined in the USCDI version 1, and information about pending and active prior authorization decisions at enrollment, for payers that have a specific annual open enrollment period, or during the first calendar quarter of each year. Payers could efficiently exchange information for one or more patients at one time using the HL7 FHIR Bulk specification, allowing patients to take their health information with them as they move from one payer to another.

Alex explained that, as part of the payer-to-payer API proposal, CMS sought and received comments on this topic and leveraged this information about PA decisions to create the proposal. In it, CMS would encourage patients' newly impacted payers to consider such information from previous payers when making new prior authorization determinations, potentially eliminating the need for patients and providers to repeat the PA process with the new payer. She stated that CMS seeks comment on the extent to which impacted payers should be limited from requiring patients to undergo repeat evaluations for the purposes of reaffirming coverage or PA decisions without first reviewing the medical records and notes of the previous payer to determine if and why a repeat test is needed.

Alex thanked ONC for their assistance during the process and noted that **Steve Posnack** would cover the IGs that ONC would be adopting in his portion of the presentation.

Alex discussed PA APIs proposals, which included:

- Document Requirement Lookup Service (DRLS) API: CMS proposed requiring impacted payers build and maintain a FHIR-enabled DRLS API -- that could be integrated with a provider's electronic health record (EHR) -- to allow providers to electronically locate PA requirements for each specific payer from within the provider's workflow.
- Prior Authorization Support (PAS) API: CMS proposed requiring impacted payers build and maintain a FHIR-enabled electronic Prior Authorization Support API that has the capability to send prior authorization requests and receive responses electronically within their existing workflow (while maintaining the integrity of the HIPAA transaction standards).

Alex directed HITAC members to a graphic in the presentation slides that depicted the PA process as a HIPAA transaction and showed how CMS would maintain the integrity of the standards used in the transaction.

Alex summarized the guardrails around the PA process that CMS proposed, which included:

- Denial Reason: CMS proposed requiring impacted payers include a specific reason for a denial when denying a PA request, regardless of the method used to send the PA decision, to facilitate better communication and understanding between the provider and payer.
- Shorter Prior Authorization Timeframes: CMS proposed requiring impacted payers (not including QHP issuers on the FFEs) to send PA decisions within 72 hours for urgent requests and 7 calendar days for standard requests.
- Prior Authorization Metrics: CMS proposed requiring impacted payers publicly report data about their PA process, such as the percent of PA requests approved, denied, and ultimately approved after appeal, and average time between submission and determination, to improve transparency into the prior authorization process, which will help patients understand.

Alex briefly highlighted several proposed RFIs, which included:

- Methods for Enabling Patients and Providers to Control Sharing of Health Information
- Electronic Exchange of Behavioral Health Information
- Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization
- Reducing the Use of Fax Machines for Health Care Data Exchange
- Accelerating the Adoption of Standards Related to Social Risk Data

Alex thanked all of the stakeholders for their comments and feedback and reiterated that the period for comment on the rule has ended.

Steve explained that, as part of this process, ONC has strengthened its relationship with CMS, which is reflected in the collaborative effort used in this rulemaking process, and the Intersection of Clinical and Administrative Data Task Force (ICAD TF) was created as a result. ONC accompanied CMS's rule with ONC's Proposal for Adoption of FHIR-Based API Implementation Specifics, and **Steve** explained that on behalf of HHS under ONC's authority at PHSA sec 3004(b) that these are proposed for adoption at 170.215(c), "Standards for Health Care Operations." He stated that ONC is not proposing new or revised certification criteria, nor is ONC proposing to require testing and certification to these implementation specifications. The proposal to adopt the DaVinci FHIR IGs for Coverage Requirements Discovery,

Documentation Templates and Rules, and Prior Authorization Support align with the ICAD Task Force report and recommendations approved in November 2020.

Steve provided the list of IGs and specifications proposed for adoption at 170.215(c), which included:

- HL7 FHIR® Da Vinci - Coverage Requirements Discovery (CRD) Implementation Guide
- HL7 FHIR® Da Vinci - Documentation Templates and Rules (DTR) Implementation Guide
- HL7 FHIR® Da Vinci - Prior Authorization Support (PAS) Implementation Guide
- HL7 FHIR® Da Vinci - Payer Coverage Decision Exchange (PCDE) Implementation Guide
- HL7 FHIR® Common Payer Consumer Data Set (CPCDS) Implementation Guide
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide
- HL7 FHIR® Da Vinci - Payer Data Exchange (PDex) US Drug Formulary Implementation Guide
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide

Steve concluded the presentation by thanking everyone for their work and inviting the HITAC to comment.

Discussion:

- **Denise Webb** thanked the presenters and recognized that, because the rule is not final, the presenters might be unable to respond to every question. She stated that, though the rule has good features, she would prefer that it apply to all payers across all benefit plans. She was concerned that it only applies to CMS-regulated payers and not the commercial side of the business and discussed how a patient could move between Medicaid and commercial coverage, where there is no requirement for a payer to send information. This creates a lack of uniformity.
  - o **Alex Mugge** noted Denise's concerns and responded that CMS understands the desire for the rule to apply uniformly across payers but can only control payers within its scope. As a result, the rule does not include Medicare Advantage, but it does apply to Medicaid and CHIP fee-for-service and managed care, as well as the Qualified Health Plans (QHPs). CMS discussed including Medicare Advantage in future rulemaking and explained that payers that will implement the policies have an interest in applying them across all lines of business, which the rule has encouraged.
- **Jim Jirjis** thanked the presenters and **Dr. Rucker** for his influence on the process. He asked if providers would have an opportunity to access the rules for a particular request within the workflow and also if there is a specific reason for a denial. He advocated for making the process easier and specific enough for providers so they could reduce denials and requests.
  - o **Alex Mugge** responded that some conversations have been held regarding denials.
- **Aaron Miri** asked **Alex** to confirm that the intent is that no exorbitant or special fee is necessary for payers or providers to use this interface and that it will be part of the normal transactional costs.
  - o **Alex Mugge** responded that that is the intent and asked for clarification from **Steve** on particular fees. She stated that there should not be a fee for using the API over a fax, for example.

16

- o **Aaron** responded that he applauds the effort and, after discussing the example of running into issues with reimbursement and PA during the administration of COVID-19 vaccines, asked if payers would have to align their PA processes to ensure a faster method.
    - o **Alex** responded that the vaccine effort is a particular case but that the proposal was not for payers to standardize their PA policies across the board. She suggested that some standardization could happen naturally, and CMS will continue this discussion.
- **Arien Malec** voiced his appreciation for the work done by CMS, the ICAD TF, and ONC and shared several concerns, which included:
    - o The comment period and the timeline has been a little accelerated, potentially by the impending administration transition, which he did not think was helpful for what will become a long-running set of policy requirements.
    - o The one piece from ICAD TF's proposals that appeared to be missing is the naming of an attachment standard. He said that looking at what is required to do electronic PA (ePA), a standard for attachments will be necessary to get the clinical documentation over, as well as the ePA guidance.
    - o Transactional fees associated with getting a 278 transaction request from a provider to a payer should be recognized, and he emphasized that there is additional work required to make all those transactions happen.

FDA DIGITAL HEALTH CENTER PRESENTATION

Bakul Patel, Director, Digital Health Center of Excellence, FDA, presented an overview of the FDA's Digital Health Center of Excellence, which was launched on September 22, 2020. Bakul thanked Dr. Rucker**,** along with Steve Posnack, for his leadership as National Coordinator and for securing a strong partnership with the FDA.

Bakul gave an overview of how the Digital Health Center of Excellence (DHCoE) came about and explained that the first guidance document on mobile medical apps, which eventually evolved into multiple policies, gave to the rise of this group. It was installed in the Center for Devices at the FDA. He summarized the topics that would be covered, which included:

- Digital Health Landscape and Areas of Application (Spectrum)
- Goals and Outcomes
- Current Areas of Focus
- Planned Services and Launch Plan

Bakul directed HITAC members to a depiction of the continuum of digital health (DH) at the FDA on slide three in the presentation deck and stated that it shows the convergence of connectivity, data, and computing power for healthcare and related uses across the life of an individual or a patient. He drew parallels to current activities like tracking vaccinations and tracking COVID-19 tests. Some of the key ideas for the platform of care built on the digital economy included:

- Moving healthcare from the clinic to the patient
- Understanding patient behavior and physiology "in the wild"
- Focusing on prevention for early/smaller interventions

Bakul explained that the FDA is focusing on digital health technology at the convergence of computing power, connectivity, sensors, and software used in healthcare. He highlighted some specific, emerging uses the FDA has encountered during the COVID-19 pandemic and covered the general uses, which included:

- As a medical product

- Incorporated into a medical product (including a pharmacological product)
- To develop a medical product
- To study a medical product
- As a companion or adjunct to a medical product, including diagnostics and therapeutics

Bakul discussed the reasons the DHCoE was created, noting that it was part of the planned evolution of the digital health program, and explained that the FDA was asked by Congress to create it as part of the 2017 budget appropriations process. The intent was to drive synergy for digital health efforts, align strategy with implementation, and prepare the FDA for the digital health future. He explained that the DHCoE's goal is to empower stakeholders to advance healthcare by fostering responsible and high-quality digital health innovation and that the DHCoE aims to achieve its goal through the following practices:

- Connect and build partnerships to accelerate digital health advancements.
- Share knowledge to increase awareness and understanding, drive synergy, and advance best practices.
- Innovate regulatory approaches to provide efficient and least burdensome oversight.

Bakul described the DHCoE anticipated outcomes, which included:

- Strategically advance science and evidence for digital health technologies that meets the needs of stakeholders.
- Efficient access to a highly specialized expertise, knowledge, and tools to accelerate access to digital health technology.
- Aligned regulatory approach to harmonize international regulatory expectations and industry standards.
- Increased awareness and understanding of digital health trends.
- Consistent application of digital health technology policy and oversight approaches.
- Reimagined medical device regulatory paradigm tailored for digital health technologies.

Bakul described the DHCoE's functional areas, which were depicted in detail in the presentation slides, and included:

- Dedicated Functions:
  - Regulatory Innovation/Strategic Initiatives
  - DH Technology Support
  - DHCoE Operations and Coordination/Partnerships
  - AI/ML in Medical Products
- Virtual Functions:
  - Advancing Regulatory Science
  - Advanced Manufacturing
  - Regulatory Review Support
  - Advanced Clinical Studies and RWE
  - Medical Device Cybersecurity

Bakul described the DHCoE's plan for internal organization within the FDA in which the FDA DH Advisory Group aligns with the DHCoE Operations and Coordination/Partnerships, which will then align strategies within the CDRF Digital Health Steering Committee. There will be coordinated DH efforts with the dedicated and virtual DHCoE resources. This plan was depicted on slide number nine in the presentation deck.

Bakul listed some of the services the DHCoE will offer, which included:

- CDRH Specific:
  - Set and lead strategic direction in digital health
  - Identify and coordinate regulatory science priorities for CDRH
  - Establish and promote best practices
  - Enable efficient, transparent, and predictable product review with consistent evaluation quality
  - Build new capacity to oversee and leverage DH technologies
  - Create more shared resources
  - Coordinate the development of cross cutting DH policies
- External to the FDA:
  - Provide clarity on regulation
  - Advance international harmonization on device regulatory policy
  - Facilitate and build strategic partnerships
  - Communicate FDA research interests
  - Advance digital health device international standards
- FDA-Wide:
  - Provide DH expertise across the Agency
  - Offer training opportunities for FDA staff
  - Disseminate shared resources
  - Foster collaboration across FDA in common interest areas
  - Facilitate synergies in regulatory science research in digital health
  - Leverage, share, and avoid duplication of work
  - Promote and showcase existing work at the Centers

Bakul gave an overview of the DHCoE's roadmap. He explained that the goal for the roadmap is to bring the benefits of digital health to all Americans, efficiently and collaboratively and included the following phases:

- Raising awareness and engaging stakeholders: Phase 1 – Communication (Fall 2020)
  - Stakeholder Listening Sessions
  - Update and develop resources for FDA staff
  - Begin operationalizing the DHCoE and outcome measurement
  - Amplify current work being done at FDA in digital health
- Building partnerships: Phase 2 – Coordinate (Fall and Winter 2020)
  - Build strategic partnerships for policy, regulatory science, and fellowships
  - Develop resources for external stakeholders
  - Create a digital health community of practice
  - Assemble FDA and CDRH advisory groups
- Building and sustaining capacity: Phase 3 – Amplify (Winter 2021 onwards)
  - Continued strategic partnership building and communication
  - Update and implement regulatory framework for digital health
  - Harmonization with other regulators

In conclusion, **Bakul** thanked the HITAC for the opportunity to present and invited members to submit questions and feedback.

Discussion:

- **Carolyn Petersen** thanked **Bakul** for the presentation and asked how the DHCoE plans to include patient and consumer representatives in its initiatives and how feedback will be used.
    - o **Bakul** responded that they have a Patient Engagement Advisory Committee, which will field these types of questions and feedback, and explained that the first meeting was held several months ago on the topic of Artificial Intelligence (AI) and machine learning (ML) software for patients.
    - o **Carolyn** inquired about the FDA's plans for engaging with the HITAC and leveraging its resources and expertise.
    - o **Bakul** responded that the FDA and the DHCoE look forward to building a regular channel of engagement with the HITAC and recognized **Dr. Rucker, Jim Jirjis**, and others who have helped in the past.
- **Aaron Miri** thanked **Bakul** for the presentation and discussed his experiences as the CIO at UT-Austin with research projects and clinical operations that leverage consumer devices. He asked if the DHCoE would like a sounding board/clearinghouse for studies on the effects of consumer devices and referenced the example of a current study to examine child psychology, sleep time, and links to depression.
    - o **Bakul** explained that the DHCoE will not have the scale for that type of project but could set up a public/private way to work on understanding these issues by giving pre-emptive guidance and providing resources instead of advising on a one-to-one basis. They are still working out these plans.
    - o **Aaron** asked, on behalf of **Clem McDonald**, how engaged the group is with FHIR.
    - o **Bakul** responded that, though he has worked on FHIR, the FDA does not focus on it. Rather, the FDA focuses on implementing interoperability standards but could discuss recognizing FHIR in the future and related implications.
- **Les Lenert** asked about the FDA's plans for developing evaluation paradigms or strategies for e-health and discussed related issues, like problems with telehealth. He would like the FDA to be the leading source to prove that the data are trustworthy, are getting transmitted correctly, and are making a difference in people's lives.
    - o **Bakul** responded that the FDA does not regulate telemedicine but explained that it does regulate lab devices that communicate with other hospital infrastructures and related standards. There is a jurisdiction boundary, but the FDA can recognize standards that would be helpful as a signal for how things should be done.

Aaron Miri thanked **Bakul Patel** for the presentation and shared that he would personally follow up via email.

HITAC 2021 DRAFT WORK PLAN

Lauren Richie presented the final HITAC 2021 Work Plan and announced that some changes have been made since the HITAC examined the plan at the November 2020 meeting.

Lauren gave a brief overview of the Priority Target Areas in the Cures Act for the HITAC, which included:

- Patient Access: The facilitation of secure access by an individual and their caregiver(s) to such individual's protected health information
- Interoperability: Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information

- Privacy and Security: The promotion and protection of privacy and security of health information in health IT
- Use of Technologies that Support Public Health.

Lauren summarized the agenda for discussion, which included:
- Review revised list of topics and timeline for HITAC activities in 2021
- Review current commitments
- Discuss opportunities for other HITAC work in 2021 and beyond

Lauren provided a recap of the 2021 HITAC planning process, during which the following steps were undertaken:
- Reviewed transcripts and meeting notes from prior HITAC discussions
- Reviewed HITAC recommendations, including the HITAC Annual Report for FY19
- Considered legislative requirements, existing work plans, and emerging issues
- Obtained input from the HITAC co-chairs

Lauren explained that the snapshot of current HITAC activities was updated since it was previously present, and these activities included:
- Completed in Calendar Year 2020 (CY20):
  o COVID-19 Panel Hearing
  o EHR Reporting Program (User Criteria)
  o FY19 HITAC Annual Report
  o Overview of ONC Cures Act Final Rule
  o 2020-2025 Federal Health IT Strategic Plan
  o Intersection of Clinical and Administrative Data Task Force Report
- In Progress:
  o COVID-19 Follow-Up (As Needed)
  o HITAC Annual Report for FY20
  o USCDI v2
- Not Started:
  o Interoperability Standards Priorities Task Force – Annual Review and Publication
  o Trusted Exchange Framework and Common Agreement
  o EHR Reporting Program (Developer Criteria)
  o Intersection of Clinical and Administrative Data Task Force (part 2)

Lauren presented the final HITAC 2021 Work Plan for calendar year 2021, which was depicted on slide number six in the presentation materials. She described the HITAC's confirmed activities for 2021, which will include:
- An administrative meeting
- Several HITAC Annual Report Workgroup (ARWG) meetings
- A public health and HIE hearing
- Several scheduled task forces:
  o USCDI TF
  o EHR Reporting Program TF
  o ICAD TF
- Several other task forces, whose timing is yet to be determined:
  o TEFCA TF

21

       o   ISP TF

       o   EHR Contract Guide

Lauren discussed additional potential HITAC activity by Target Area for 2021, which included the following topics:

- Use of Technologies that Support Public Health
  - o Telehealth Delivery
- Interoperability
  - o Improving Interoperability of Lab Data
  - o Integrating and Using Imaging Data
  - o Payer-to-Provider Health Information Exchange
- Privacy and Security
  - o Data Privacy/Secondary Uses of Data
  - o Data Segmentation for Privacy
- Patient Access to Information
  - o Patient-Generated and Patient Reported Data

Lauren encouraged HITAC members to submit any further feedback.

Denise Webb thanked everyone for contributing to the discussion and encouraged HITAC members to submit questions in writing, either in the Adobe meeting chat or via email, as several of the ONC team members had to leave the meeting. She assured them that all comments would be addressed.

Aaron Miri invited HITAC members to submit comments on any of the presentations that were given at the current meeting.

CMS Presentation Discussion Continued:

- **Les Lenert** asked how CMS was testing their proposed standards in real-world environments and at scale to ensure that they have the intended impact on healthcare. He thanked the presenters for the proposals but suggested that the standards would be revolutionary for healthcare. He asked if there were funding and impact evaluations on healthcare business processes and on the efficiency of healthcare and if there are plans for large-scale pilots that would be sponsored by the Innovation Center.
- **Clem McDonald** discussed how the FDA and the Innovation Center could sponsor the pilots but stated that big IT companies, Medicare, insurance companies, and the healthcare industry would also be involved. He suggested that there is a disconnect between the standards in the industry and the FDA, which should be addressed.
  - o **Aaron Miri** voiced his agreement that the Innovation Center's work could reduce the number of vendors that claim FDA certification without adopting modern standards on the provider side.

PUBLIC COMMENT

Lauren Richie opened the meeting for public comment. There were no public comments submitted by phone.

Questions and Comments Received via Adobe Connect

Lauren Richie: Hello, we will get started shortly

Abby Sears: Abby is here

Abby Sears: I am trying to be

Steven Lane: Adobe is no longer offering me video capabilities

Carolyn Petersen: Looks like you are back now.

Steven Lane: Yes. Thanks to Katie.

Holly Miller, MD: Thank you Dr. Rucker!

Al Taylor, ONC: Do you want me on camera during my presentation?

Adi Gundlapalli (CDC): Thank you Dr. Rucker for your leadership and collegiality during these past years!

Arien: Thank you Dr. Rucker

Jim Jirjis: Dr. Rucker. I have appreciated your vision, thoughtfulness and approach. You have moved the puck an amazing distance to the benefits of our communities and patients

Ellen Milhiser: Is anyone else having connectivity problems, with the meeting dropping off, or is it just me?

Alix Goss: Yes, I'm experiencing connectivity problems.

Leslie Lenert MD: Don, thank you again for your explary *[sic]* leadership as a government official. Thank you for staying through all four years, for all your sacrifices to do so, and for your constant efforts on behalf of our country

Steven Lane: Care teams often involve individuals who are not Providers. Will the new Name and Identifier elements apply only to Providers or to all Care Team Members (when they are available)?

Holly Miller, MD: Will Community Based Organizations (CBOs), when involved in meeting SDOH needs be included in care teams?

Alexis Snyder: Agree with Steve, was thinking the exact same thing about care team members

Sheryl Turney: DOn, *[sic]* thank you so much for your leadership and vision. It has been an honor to serve with you! Best wishes in your future endeavors!

Steven Lane: Updated version standards will each presumably need to be included in the SVAP if the USCDI version that includes them is to be similarly included.

Clem McDonald: THe *[sic]* NPI can accomodate *[sic]* most all kindds *[sic]* of care providers. those who bill medicare must have an NPI. But pretty sure the ohers *[sic]* can obtain an NPI

Carolyn Petersen: Re: care team members, it would be valuable to have some options for what and how info is in the record. For instance, I am happy to provide transportation to medical appointments to elderly neighbors, but would not be a contact for questions re: meds, day-to-day health status, etc.

Jim Jirjis: For problems/diagnoses how we will handle the uncertaanty *[sic]* and lack of precision for date of diagnosis and date of resolution When it is pneumonia that may be easier (day, month, year) but for diabetes the patiet *[sic]* may be the source and may say something like "i dont *[sic]* know sometime between 2000 and 2002"

Ken Kawamoto: @Jim: USCore Condition profile (http://build.fhir.org/ig/HL7/US-Core/StructureDefinition-us-core-condition.html) allows specification of this type of uncertainty. Whether it is supported by EHR systems is I think vendor-dependent.

Jim Jirjis: dead link

Jim Jirjis: getting 404 not found

Carolyn Petersen: Try the link without the end parenthesis

Jim Jirjis: brilliant!

Clem McDonald: where are the level 2 items listed. I haven't found them yet

Steven Lane: As the submitter of both Date of Diagnosis and Date of Resolution, I specified that these data fields would need to support Fuzzy Dates for just the reasons Jim mentions.

Avinash Shanbhag: Heres's *[sic]* the link https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#blocktabs-uscdi_data_class_element_list-3

Steven Lane: My understanding is that most EHR vendors support Fuzzy Dates, though their methodology may vary. This will need to be addressed.

Jim Jirjis: Also, what is the difference between an *[sic]* narrative versus report?

Jim Jirjis: for imaging

Jonathan Nebeker: I have a question: When will the report be released and will it include detailed rationale to support decisions. If not, how do we get more insight to the rationale? This goes to Ken's question. Maybe someone else can read my question, if you call on my raised hand.

Ken Kawamoto: Sorry, my earlier link had an extra character at the end. This should work: http://build.fhir.org/ig/HL7/US-Core/StructureDefinition-us-core-condition.html

Ken Kawamoto: I can read Jonathan's question if his hand-raise is called (coordinated via text)

Jim Jirjis: So Ken, I see that strings are allowed for "super-fuzzy" dates

Ken Kawamoto: Yes. E.g., in Epic, there are several areas where strings are allowed. E.g., "sometime in my early 20s"

Clem McDonald: Love Michelle's comments - we should just say no to pay for coding system that are arerqued *[sic]* by the feds

Ken Kawamoto: These types of dates are fine for human consumption, that machine-consumption/interpretation can be problematic without sophisticated natural language processing

Avinash Shanbhag: The Standards bulletin (https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin) provides ONC's rationale. There is a public feedback process before finalizing the V2..

Jim Jirjis: the evil close parenthesis problem strikes again with this link

Matthew Rahn: Hopefully this link works better for the Standards Bulletin
https://www.healthit.gov/topic/standards-technology/onc-standards-bulletin

Matthew Rahn: Per Steve's Comment, here is a link to the Standards Version Advancement Process
https://www.healthit.gov/topic/standards-version-advancement-process-svap

Jonathan Nebeker: OK. I don't see any rationale in the doc on ONC's site. I modify my question. How and when can we have access to the rationale for decision making?

Jonathan Nebeker: Thanks

Arien: Amen -- pandemic preparendness *[sic]* has been on since the anthrax scare in <checks notes> 2001

Arien: public health use cases for interoperability have been a national piority *[sic]* since the beginning of ONC.

Arien: Let's not pretend that interoperabilty *[sic]* for pandemic preparedness is a novel and unforeseen use case.

Ken Kawamoto: There is some work ongoing in restricting unnecessary data, e.g., by the Argonaut project. However, I completely agree Jim's point should be a priority.

Clem McDonald: Steve's comments about the tension and balance betteen *[sic]* alternative forces are right on.   An importan *[sic]* tension is between the desire of external parites *[sic]* (researchers, imagined benefits of more detailed coded clinical data) and the clinician time cost for collecting the data. One can impaging *[sic]* clinician spending *[sic]* full time on documentation and no time on care. This is espescially *[sic]* important issue for some aspiration what may not really have the benefit expected

Ken Kawamoto: Once people realize what is being shared, they could become very concerned.

Ken Kawamoto: E.g., when wanting to share your COVID test result, you end up providing access to your HIV test result

Ken Kawamoto: Or to share you age and gender, you end up sharing the login to your personal health record and last 4 digits of your SSN + your cell phone #

Steven Lane: FHIR should allow more targeted requests and responses. CDA has greater challenges re the sharing of data above and beyond minimum *[sic]* necessary. Can't define and support use case-specific documents for everything.

Jim Jirjis: Easy to say that minimal necessary is the approriate *[sic]* ask, but not sure the technologies will support that complexity and oversharing may occur

Matt Reid: The AMA agrees with Jim and Ken's concerns regarding the oversharing of data and potential unintended consequences.

Leslie Lenert MD: Steve, FHIR resources are still relatively complex data objects and many are heirarchical *[sic]* objects (objects built of other objects). We might need more work to define what minimum necessary is by user type and setting

Jim Jirjis: Thanks Steven, that was the basis for my comment about will FHIR 4 restful API empower such precision exchange of content. I worry that the new HIPAA rule that relaxes the minimially *[sic]* necessary requirement whith *[sic]* care coordination will lead to misuse and erosion of privacy

25

Jim Jirjis: Agree, Leslie

Steven Lane: For Public Health data exchange, an assertion by the PH agency is sufficient to address the HIPAA requirements re Minimum Necessary, but there may still be unnecessary data moving around with associated privacy risks, even if it is legal.

Brett Oliver: Clem you are spot on. If the data needed is gathered independent of the patient care clinician, that is one thing. Ask our end users to gather more data without that consideration is problematic (both for burnout and the gathering of accurate data).

Jim Jirjis: Yes public health is the least of my concerns

Andy Truscott: I'm in. I think this should be considered and then advised to HITAC.

Steven Lane: ONC staff supporting the USCDI TF should collect and summarize all of the great comments from this discussion and bring them to the first meeting of the TF.

Jim Jirjis: patiente *[sic]* and society will conly *[sic]* continue to support interpoperability *[sic]* if we do not cross the "creepy" boundary" and oversharing may create some risk there

Steven Lane: +1 to Jim's comment re "creepy" :-)

Carolyn Petersen: +1 to Jim Jirjis's points re: patients' comfort level.

Ken Kawamoto: With 3rd party vendors accessing our EHR systems, we are tending to see vendors who ask things like Observation.search?category=laboratory to get all labs, vs. looking for specific labs. WIth one reason for this being the lack of universal encoding with LOINC codes. I.e., this is one way that 3rd party vendors are finding relevant data that are NOT standardized, like a COVID test result that was not properly encoded in LOINC. End result -- the HIV test result goes to the 3rd party vendor.

Jim Jirjis: Just for the record--not claiming special expertise in creepiness!" :)

Matt Reid: Agree, information only flows at the speed of trust. Lose that trust and information exchange will lag.

Steven Lane: Insofar as InfoBlocking is built on USCDI V1, it will be helpful to analyze the success of that effort as we endeavor to move forward to future versions.

Carolyn Petersen: We have to find the balance between various ecosystem subcommunities and what patients/consumers will tolerate. If people opt out of care because they don't trust the system, we have not achieved a Win.

Carolyn Petersen: But we do know it when we see it, Jim. (-:

Jim Pantelas: Thanks.

Steven Lane: InfoBlocking implementation has led to increased engagement of Patient Family Advisors in HIT configuration efforts, at least at my organization. This has led to a more refined appreciation of the broad range of what patients want. We need to look for solutions that give individuals more personal control over what gets shared with whom in what context.

Andy Truscott: Oversharing vs Information Blocking needs to be considered too. Would be useful to added Security / Privacy aspects to USCDI as well.

Sandra Mitchell: The VHIE Clinical Data Quality Team, under Dr Nebeker/ Dr Anderson/Todd Turner, continuously monitors the received and disclosed payloads and provides the analysis and review tools to the commercial vendors and the individual VHIE partners. So we provide real world production feedback - check with Dr Steven Lane o

Steven Lane: The analytical work of Sandy Mitchell's team has been exemplary and should be a model for expansion to other data sharing networks/frameworks.

Don Rucker: Thanks Steve!

Jorge Ferrer: Congratulations Don!

Jim Jirjis: why not Medicare advantage?

Alexis Snyder: Very good point Jim!!

Sheryl Turney: I will hold my question which is related to slide 5 bullet 2. Thank you for all of the work that all put into this rule which addresses many of the recommendations that ICAD brought forward. Related to the attestation process, perhaps some clarification is needed to determine if this can be addressed at the time the app is registered for the patient vs. each time the API puts in a request. The current wording of the rule does not appear to clarify this point.

Don Rucker: Bakul, Thanks!

Alexis Snyder: "In the Wild" -perhaps not the best term

Jim Jirjis: Maybe for some of us patients!

Aaron Miri: This is a great proposal. Perhaps this will help companies choose more formal routes for FDA certification instead of labeling their products for " general wellness" and thus lessening the ability for providers to trust the data from these systems?

Jim Jirjis: We would love to continute *[sic]* the discussion

Clem McDonald: I lost my connection. Just wanted to know how engages in FHIR were they

Arien: YES

Arien: incorporate FHIR into lab, diagnostics, etc.

Lauren Richie: Members of the public: To make a comment please call:1-877-407-7192(once connected, press "*1" to speak)

Sheryl Turney: I already typed my question in the chate

Leslie Lenert MD: I was talking about funding from the CMS Innovation Center

Catherine Hoang: Thank you all!

Carolyn Petersen: Thanks, Aaron and Denise, for a greaet *[sic]* and well-run meeting!

Lisa Frey: Thank you for including me.

Donna Doneski: We at NASL (the National Association for the Support of Long Term Care) extend our since appreciation to Dr. Rucker for your leadership and the extraordinary work that you and your entire ONC team have done over the past few years. We especailly *[sic]* wish to acknowledge your guidance and engagement with all of us in the post-acute care sector. Best wishes for all future endeavors.

Jim Pantelas: Good job Denise & Aaron!

Alix Goss: Infomrative *[sic]* meeting and looking forward to 2021 workplans advancing. Thank you!

Michelle Barry: Great Meeting!

Questions and Comments Received via E-Mail

Rosemary Kennedy, CEO, eCare Informatics: I would encourage the FDA to engage with FHIR to increase adoption and use of standards prior to FDA submission. This streamlines integration with EHRS.

FINAL REMARKS

Aaron Miri thanked everyone for listening and attending and remarked that there were over 100 attendees. He stated that he looks forward to a productive upcoming year and thanked Dr. Rucker and the entire team at ONC for their efforts. **Denise Webb** thanked all attendees for the great dialogue and input, and recognized ONC and Accel Solutions LLC for their support. The co-chairs asked everyone to be safe.

ADJOURN

Lauren Richie reminded members that anyone who is interested in remaining on or joining the USCDI Task Force should contact her immediately.

The next meeting of the HITAC will take place on February 10, 2021.

The meeting was adjourned at 2:00 p.m. ET.