Health Information Technology Advisory Committee (HITAC)

Virtual and In-Person

Hubert H. Humphrey Federal Building
200 Independence Avenue SW, Room 505A, Washington, DC 20201

Meeting Notes | November 9, 2023, 9:30 AM – 4 PM ET

Executive Summary

The HITAC Co-Chairs, **Medell Briggs-Malonson** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and presented the minutes from the October 19, 2023, HITAC meeting, which were approved by voice vote. **Micky Tripathi**, National Coordinator for Health Information Technology, welcomed attendees to the meeting, acknowledged departing HITAC members, and provided ONC updates and information on upcoming events. **Shelly Spiro** and **Hans Buitendijk**, Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET) Co-Chairs, reviewed the Task Force's membership, charge, and presented the task force's recommendations. HITAC approved the recommendations. **Avinash Shanbhag**, Executive Director, Office of Technology, ONC, provided a detailed update on the work done by the ONC Office of Technology. **Mike Berry**, Designated Federal Officer, ONC, discussed the HITAC work plan for 2024. **Seth Pazinski**, Director, Strategic Planning and Coordination Division, ONC; **Wesley Barker**, Branch Chief, Data Analysis Branch, ONC; **Chelsea Richwine**, Analyst, Data Analysis Branch, ONC; **JaWanna Henry**, Branch Chief, Interoperability Systems Branch, ONC, provided updates on ONC objectives, benchmarks, and data collection and analysis. **Elise Sweeney Anthony**, Executive Director, Office of Policy, ONC, provided an overview of information blocking regulations. **Jim Hansen**, Senior Counsel, HHS Office of Inspector General, presented on the Office of Inspector General's civil money penalty rule. Alex **Baker**, Branch Chief, Federal Policy Branch, ONC; **Tim Jackson**, Director, Division of Quality and Price Transparency, CMS; **Aryanna Abouzari**, Health Insurance Specialist, Office of Program Operations and Local Engagement, CMS; **Elizabeth Holland**, Senior Technical Advisor, Division of Electronic and Clinician Quality, CMS; **Jessica Warren**, Program Lead, Medicare Promoting Interoperability Program, CMS, provided a detailed update on the establishment of disincentives for health care providers who have committed information blocking.

Agenda

09:30 AM	Call to Order/Roll Call
09:35 AM	Welcome Remarks

09:55 AM	Opening Remarks, Review of the Agenda and October 19, 2023, Meeting Notes – HITAC Vote
10:00 AM	Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Recommendations – HITAC Vote
11:10 AM	Break
11:20 PM	ONC Office of Technology Update
11:50 PM	HITAC 2024 Work Plan
12:15 PM	Lunch Break
01:15 PM	ONC Objectives, Benchmarks, and Data Update
02:10 PM	Break
02:20 PM	HHS Information Blocking Update
03:50 PM	Public Comment
04:00 PM	Final Remarks and Adjourn

Call to Order

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the meeting to order at 9:30 AM and welcomed ONC's Executive Leadership team. The November 9 HITAC meeting was held both in-person at the Hubert Humphrey Federal Building in Washington, DC, and virtually on Zoom.

Roll Call
Members in Attendance
Medell Briggs-Malonson, UCLA Health, Co-Chair
Aaron Miri, Baptist Health, Co-Chair
Shila Blend, North Dakota Health Information Network
Hans Buitendijk, Oracle Health
Sarah DeSilvey, Gravity Project
Steven Eichner, Texas Department of State Health Services
Hannah Galvin, Cambridge Health Alliance
Rajesh Godavarthi, MCG Health, part of the Hearst Health Network
Steven Hester, Norton Healthcare
Kensaku (Ken) Kawamoto, University of Utah Health
Steven Lane, Health Gorilla
Anna McCollister, Individual
Clem McDonald, National Library of Medicine
Deven McGraw, Invitae Corporation
Eliel Oliveira, Harvard Medical School & Harvard Pilgrim Health Care Institute
Kikelomo Oshunkentan, Pegasystems
Naresh Sundar Rajan, CyncHealth
Fillipe (Fil) Southerland, Yardi Systems, Inc.
Bryant Thomas Karras, Washington State Department of Health

Members Not in Attendance
Cynthia Fisher, Patient Rights Advocate
Lisa Frey, St. Elizabeth Healthcare
Valerie Grey, State University of New York
Hung S. Luu, Children's Health
Arien Malec, Individual
Aaron Neinstein, Notable
Alexis Snyder, Individual

Sheryl Turney, Elevance Health

Federal Representatives
Jim Jirjis, Centers for Disease Control and Prevention
Meg Marshall, Department of Veterans Affairs
Michelle Schreiber, Centers for Medicare & Medicaid Services
Ram Sriram, National Institute of Standards and Technology (*Absent*)

ONC Staff
Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Executive Director, Office of Technology
Seth Pazinski, Director, Strategic Planning and Coordination Division
Mike Berry, Designated Federal Officer
Wesley Barker, Branch Chief, Data Analysis Branch
Chelsea Richwine, Analyst, Data Analysis Branch
JaWanna Henry, Branch Chief, Interoperability Systems Branch, Office of Policy,
Mike Lipinski, Director, Regulatory and Policy Affairs Division
Alex Baker, Branch Chief, Federal Policy Branch
Tricia Lee Rolle, Senior Advisor, ONC

Key Points of Discussion

Welcome Remarks
Micky Tripathi, National Coordinator for Health Information Technology, welcomed in-person and virtual attendees and thanked everyone for joining the meeting. He continued to discuss the new proposed rule to establish disincentives for healthcare providers that have committed information blocking by the Department of Health and Human Services (HHS). He also informed the group of the information session being held on November 15, 2023, which will further discuss the new rule, and directed them to the Information Blocking website for additional resources and to sign up for the information session. **Micky** thanked the HITAC members for their hard work throughout the year and reflected on some of the year's notable achievements. He then reminded the group to register for the upcoming 2023 ONC Annual Meeting set to be held in person in Washington D.C. on December 14 and 15, 2023 and directed everyone to the "Events" page on the HealthIT.gov website and the meeting registration website. He continued to give an update on the Trusted Exchange Framework and Version 1 Common Agreement (TEFCA). He also provided an update on the newly published United Stated Core Data for Interoperability version 4 (USCDI v4) and thanked everyone who participated in the Enabling Patient Access to Health Data for Actionable Results event in October. **Micky** finished by commemorating the hard work and dedication of 11 HITAC committee members whose final terms expire in 2023. Certificates of appreciation were presented to **Cynthia Fisher**, **Lisa Frey**, **Valerie Grey**, **Kensaku Kawamoto**, **Steven Hester**, **Steven Lane**, **Arien Malec**, **Clem McDonald**, **Aaron Miri**, **Alexis Snyder**, and **Sheryl Turney**. He then announced the appointment of **Sarah DeSilvey** as the next HITAC co-chair.

Opening Remarks, Review of the Agenda and October 19, 2023, Meeting Notes – HITAC Vote

Medell Briggs-Malonson and **Aaron Miri**, HITAC Co-Chairs, welcomed attendees, and **Aaron** reviewed the agenda. **Medell** called for a motion to approve the October 19 meeting notes.

Sarah DeSilvey motioned to approve the notes. Aaron Miri seconded the motion. The HITAC approved the October meeting notes by voice vote. No members abstained, and no members opposed.

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Recommendations – HITAC Vote

Medell Briggs-Malonson introduced the Pharmacy Interoperability and Emerging Therapeutics Task Force (PhIET). **Shelly Spiro**, PhIET Co-Chair, began by thanking the task force for their hard work, ONC, the Accel Solutions team, and gave special thanks to **Tricia Lee Rolle**, Senior Advisor, ONC. She continued to give an overview of their work and review the task force charges. **Hans Buitendijk**, PhIET Co-Chair, continued with a brief overview of the task force roster and a review of presentations given to the task force by subject matter experts throughout the year. **Shelly** then reviewed the use cases used as the basis for their recommendations, as well as themes and topics covered. **Hans** proceeded to orient the group to the recommendation report layout and appendix. **Shelly** continued reviewing the general recommendations (R1-18), noting that all recommendations have accompanying rationale detailed in the recommendation report. **Hans** continued to review recommendations of particular interest (R9-19). **Shelly** then reviewed recommendations related to patient matching and record linkage (R20-28), and **Hans** reviewed recommendations related to network participation (R29-33). **Shelly** finished by reviewing the parking lot recommendations (those out of the scope of the charge but worth consideration). **Aaron Miri** then opened the floor for questions and discussion.

Discussion:

- **Medell Briggs-Malonson** thanked the committee for their hard work on these recommendations and commended them for centering patients and caregivers. She added that recommendation 14 was her favorite as it is important for advancing critical care.
- **Ken Kawamoto** noted that the recommendations were many, and prioritization would be key. He said he liked the idea of retail pharmacists interacting with patients like clinical pharmacists and was interested in medical recommendations done in pharmacy. He also asked if there were any existing incentives to encourage retail pharmacists to do what clinical pharmacists do in a clinical setting; if there were none, he asked for thoughts on how to incentivize the retail pharmacists to take on the role of a clinical pharmacist.
  - **Shelly** noted that retail pharmacists are restricted to dispensing because of current insurance payment models, and they are working hard to change that. She added that shifting from dispensing to patient engagement is a top priority to provide comprehensive care. She also noted that they are prepared to develop organizations with ONC and Health Level Seven (HL7) to capture data for the advancement of this area.
  - **Hans** added that there is a lot to be done and setting priorities is a challenge, but if they can identify the order in which to go about the work, it would be helpful.
  - **Aaron Miri** said he echoed his thoughts on technology and provider burdens.
- **Anna McCollister** noted that she was a part of the task force and suggested a review of use cases before developing an implementation guideline, as it gives important context on why the recommendations are important. She said if information is shared within the pharmacy system, it would improve patients' ability to receive their medications. She also encouraged ONC to consider how limited interoperability prevents patients from getting much-needed medication and consider how it can be structured more expansively.

- **Aaron** agreed with Anna and added that patients who are on many medications are often very frustrated with the medication reconciliation process.
- **Filipe Southerland** thanked the co-chairs and ONC for the opportunity to talk about pharmacy as a specialty health IT sector.
- **Hannah Galvin** noted that there are now third-party vendors providing home delivery and blister packaging of medications. She suggested including standards around this vendor space in the interest of patient safety.
- **Steven Hester** reiterated Hannah's comments and noted that oftentimes, patients will ask where medications are coming from. He suggested making that information transparent across the board, considering medications can be found in many different places.
- **Bryant Thomas Karras** reiterated the same comments and that working with public health is challenging. It is important to ensure the implementation of these recommendations is done in a manner that helps, not hurts, the public health infrastructure.
- **Shila Blend** noted that she was part of this task force and asked the group to remember that some pharmacies are independently owned and to take that into consideration when requirements for pharmacies are made.
- **Ken Kawamoto** said there is tremendous potential in this area and noted his excitement to see how it plays out.
- **Steven Lane** motioned to approve the recommendations. **Medell** seconded the vote. **The PhIET recommendations were approved by voice vote. No members abstained, and no members opposed.**

ONC Office of Technology Update

Medell Briggs-Malonson introduced the ONC Office of Technology. **Avinash Shanbhag**, Executive Director, Office of Technology, ONC, began by thanking everyone for their hard work. He continued to review the office divisions and division heads as well as statistics around Electronic Health Record (EHR) certification and adoption rates. He briefly mentioned ONC's work on USCDI. He continued highlighting their work with the Health Resources and Services Administration (HRSA) to reduce the reporting burden and improve data quality and outcomes for health centers. **Avinash** then discussed TEFCA and the importance of a standard mode of communication between networks, and a Qualified Health Information Network (QHIN). He then reviewed Standards Coordination and said their central mission is coordination. He discussed programs like the Health IT Alignment Policy, Cancer Moonshot, Patient-Centered Outcomes Research Trust Fund (PCOR TF), and the Federal Fast Healthcare Interoperability Resources (FHIR) Roadmap, which is not yet published but is in progress. **Avinash** then gave an overview of the Leading Edge Acceleration Project (LEAP), and its activities, exploring the use of advanced FHIR capabilities, and identifying data quality improvements for USCDI elements as two areas of extreme interest. He then ended his presentation by focusing on future work to continue certification, data and network standards, and coordination. **Aaron Miri** then opened the floor for questions and discussion.

Discussion:
- **Ken Kawamoto** asked if the certification data have been mapped and noted that speed is important as systems can be slow. He also said that public reporting would be useful.
- **Avinash** answered that they are looking at various options for improving speed, including a workshop, to better understand the challenges of working with vendors. He added that this is the first version of data that the industry has reviewed, and it will be used to see what can be improved in the future to improve transparency in data mapping.
- **Aaron** asked anyone with additional questions to send an email or discuss during the break.

HITAC 2024 Work Plan

Aaron Miri introduced **Mike Berry**, Designated Federal Officer, ONC. **Mike** began by [reviewing the work planning development process](#) for the next year and noted there will be 11-13 new HITAC members. He reviewed target areas in the 21st Century Cures Act (Cures Act), HITAC activities completed and in progress, the 2024 calendar, and topics of consideration. He also presented the HTI-2 Proposed Rule Task Force Charge, which will be finalized once the specific rule is released. **Mike** continued to instruct all those interested in participating in the task force to send an email to the DFO. He then reviewed the high-priority topics from the HITAC Annual Reports. He noted that they would receive feedback today and meet in January to finalize plans. **Medell Briggs-Malonson** then opened the floor for questions and discussion

Discussion:

- **Jim Jirjis** asked if the anticipated USCDI task force would be focused on the cancer domain to start with.
    - ○ **Mike** answered yes, that is an initial goal.
- **Ken Kawamoto** suggested large language models be considered. He added that models are sporadic with no standardization, making it unreliable for daily use.
- **Medell** thanked **Ken** for his comments and noted that multiple modes of Artificial Intelligence (AI) are working to make sure it is as safe and equitable as possible.
- **Anna McCollister** addressed live language models in recommendations for HTI-1 and noted the importance of keeping those separate from clinical data sets until they are better understood.
- **Deven McGraw** inquired about the process of establishing a new task force and asked about any expectations for additional task forces to address topics of interest.
    - ○ **Mike** said these topics can be addressed with a task force or a presentation. He noted that there were different modes of format to cover all topics.
- **Deven** said subject matter experts would be needed for some topics that may not fit in a particular group.
- **Medell** agreed.
- **Steven Lane** noted large language models (LLM) as a great opportunity concerning HTI-1 and suggested thinking about it for future iterations of HTI rules. He suggested a task force to further discuss the next steps.
- **Eliel Oliveira** noted the opportunity to have an additional certification tier for the systems and EHRs and expanding certification criteria.
- **Aaron** applauded the work plan and encouraged HITAC to include federal agencies in work on AI. He noted that providers are often approached with AI as a problem solver with no basis. He added that ONC's work was critical to identifying where policy should stand. He also noted the importance of responsible and ethical research.
- **Ken** said this needs to move faster than 12-month cycles of review and noted some areas of concern with AI integration in a clinical setting. He added that this is already being deployed in a clinical setting, and ONC needs to be a part of it.
- **Anna** said patient-generated health data (PGHD) needs to be included to ensure an accurate state of quality measures. She also said "reducing patient burden" needs to be included in the work plan as well.
- **Medell** agreed and noted that the AR WG added that in their work as well. She said it would continue to be at the center of all recommendations from all workgroups.

- **Kikelomo Oshunkentan** echoed **Anna's** comments on PGHD and suggested revisiting attaching personal health records (PHR) to patient charts because having that data incorporated directly into the clinical data gives her great pause.
- **Jim** suggested more formality within each section of individual task force reports centered around patients.
- **Medell** agreed with his comments and reiterated the need to center the patient in all workgroup discussions.

ONC Objectives, Benchmarks, and Data Update

Aaron Miri introduced **Seth Pazinski**, Director, Strategic Planning and Coordination Division, ONC. **Seth** gave an overview of ONC's objectives and benchmarks . He discussed the Cures Act requirements, Federal Health IT Strategic Plan objectives and goals, and health IT coordination activities. He also discussed ONC's Health IT Standards Activities and reviewed the new USDCI v4 data elements. He continued to review the Standards Version Advancement Process (SVAP), Helios Public Health FHIR Accelerator, and the HHS-wide Approach on Health IT Standards Investments. He then discussed the certification program and testing requirements as well as updates on TEFCA and information blocking rules and claims submissions. **Seth** finished by reviewing HITAC target areas in the Cures Act.

Wesley Barker, Branch Chief, Data Analysis Branch, ONC, continued to discuss ONC social needs data updates. He reviewed the agenda and gave a summary of work completed in the last fiscal year. He directed the group to their website where they can find more information and he continued to review upcoming work. He also informed the group that two papers would be published in the next week. **Chelsea Richwine**, Analyst, Data Analysis Branch, ONC, highlighted results from the hospital, physician, and patient surveys. She then discussed the use and collection of social needs data which was collected in all three surveys in detail.

JaWanna Henry, Branch Chief, Interoperability Systems Branch, ONC, discussed Patient and Clinical Perspectives on the Collection, Usage, and Sharing of SDOH Data and gave an overview of the project, its purpose, and its goals. She detailed the focus groups used for the data collection. She noted that these were individual participants, and the data should not be used to generalize the population. **JaWanna** then reviewed the participant's perspectives and concerns, i.e., fear and trust, appropriate questions, information sharing, etc. She also reviewed barriers to providing and sharing SDOH data. Finally, she addressed provider barriers, noting that many providers do not explain to patients why they are asking and documenting certain information.

Discussion:
- **Bryant Thomas Karras** asked if there was a mode of evaluating how many trainees were successfully finding positions in public health and filling the gaps of care. He also asked if there would be an expansion of the Public Health Informatics & Technology (PHIT) Workforce Development Program opportunities.
    - **Elise Sweeney Anthony** said there is data on how the PHIT program is progressing, but no further plans for expansion right now. She added that expansion would be subject to funding.
    - **Bryant** followed up by addressing past efforts for public health training that have disappeared, and he noted a sustainability concern.
    - **Elise** agreed and noted the PHIT program includes aspect to develop a sustainability plan beyond the funded time period.
- **Hannah Galvin** mentioned that there are many resources not used which have the most recent data. She noted the Pew Charitable Trust's patient focus groups that resulted in similar conclusions around social driver's data.

- **Shila Blend** highlighted the importance of privacy. She noted her work in a rural state and the difficulties patients have with wanting to share certain information for fear of bias.
- **Sarah DeSilvey** inquired about the method of integrating providers in the context of the surveys discussed.
  - o **Chelsea** said there are limitations on the survey questions, and they are looking to expand them.
- **Steven Hester** noted the potential to shift how patients are treated. He emphasized the need for emotional intelligence with patient interactions and being prepared for unexpected answers.
  - o **Chelsea** said one thing they are doing is screening hospitals to see if they have programs or strategies in place to address social needs, and the results have been promising. She said they are exploring this the best they can.
  - o **Steven** added that there are secondary products on the market that could be beneficial.
- **Medell** said that many healthcare facilities avoid addressing SDOH because they do not think they have the means to address those needs and added that this information needs to be owned by the patient and community and should be locked and secured. She explained that they are called "drivers" and not "determinants" because they change. She noted that this data is difficult to collect in a simple fill structure.
- **Deven McGraw** referenced her comments in the chat and added that income information does not need to be collected by interview but can be collected by a data broker.
- **Steven Lane** said SDOH are like vital signs, they change every time you measure them. He suggested a matrix of the elements that are easier to collect to begin to build trust. He noted the need to be sensitive to patients' experiences and build trust.
- **Eliel Oliveira** said that some providers are only collecting SDOH data for reimbursement and are not using it to improve healthcare.

HHS Information Blocking Update

Aaron Miri introduced **Elise Sweeney Anthony**, Executive Director, Office of Policy, ONC. She gave an overview of the background information and what ONC has been working on in relation to information blocking, clarifying its definition and addressing the consequences for information blocking actors. **Jim Hansen,** Senior Counsel, HHS Office of Inspector General (OIG), reviewed OIG's CMP final rule details. He gave some background on information blocking enforcement and detailed the general process for admin cases, civil monetary penalties (CMP), complaint sources, and noted agencies for referral, e.g., the HHS Office for Civil Rights, the Federal Trade Commission, etc. He then reviewed enforcement priorities as well as the start date and scope. **Jim** reviewed the scope of entities that can be liable for CMP and reviewed the process of investigation. He continued to review the basis and maximum penalty for information blocking as defined in 45 CFR 171.103(b). He then gave some hypothetical examples of violation(s) for clarity. **Jim** continued to discuss the process for determining the CMP amount and the process of resolution, as well as, the consequences of not reaching a resolution. He noted that any violations allow 60 days for those charged to pay or appeal. He ended by addressing the information blocking self-disclosure protocol, noting that there were no updates; he just wanted to inform the group of its existence. **Elise** referred the group to the chat, where she posted relevant links and added that there was more information on www.federalregister.gov for those who did not have access to the chat comments.

Elise then introduced **Alex Baker**, Branch Chief, Federal Policy Branch, ONC; **Tim Jackson**, Director, Division of Quality and Price Transparency, CMS; **Aryanna Abouzari**, Health Insurance Specialist, Office of Program Operations and Local Engagement, CMS; **Elizabeth Holland**, Senior Technical Advisor, Division of Electronic and Clinician Quality, CMS, and **Jessica Warren**, Program Lead, Medicare Promoting Interoperability Program, CMS. **Alex** began with disclaimers, public comment guidance, and background information. He reviewed "provider" as defined for the purposes of information blocking and relevant statutory

terms and provisions, i.e., "appropriate agency" and "disincentive." He continued to further detail the process of investigation and referral as well as the OIG's anticipated approach to information blocking investigations. He then reviewed the general provisions for the application of disincentives, transparency for information blocking determination, disincentives, and penalties. **Elizabeth** then detailed the proposed disincentive programs: Medicare Promoting Interoperability Program, and the Quality Payment Program. **Tim** continued to review the Medicare Shared Savings Program (SSP) and discussed the impact of the disincentives imposed. He also gave two estimates for clarity on the scope of impact. Finally, he acknowledged that the disincentives covered would only cover a small subset of providers and requested input on suggestions of disincentives to be considered in future rulemaking, as well as suggestions on providers that should be prioritized in the future. He directed the group to some additional resources available. **Medell Briggs-Malonson** reminded the group to submit comments to Regulations.gov by 11:59 pm Eastern Time on January 2, 2024.

Discussion:

- **Steven Lane** voiced concerns over the limited number of providers for which these disincentives would apply and noted them as insufficient to dissuade information blocking. He suggested focusing on opportunities to expand the scope of the rule and returning to the impact of providers in a year or two. He also suggested disallowing a claim of hardship exemption and implementing a mode of prioritization with labs at the top as they typically do not share information. He continued to suggest adding behavioral health providers, non-physician providers, registered dieticians, and physical occupational therapists as they would all be exempt as it currently stands.
- **Jim Jirjis** asked for confirmation that if a provider has already suffered a penalty for information blocking, no additional penalties would be imposed.
  - **Elizabeth** confirmed and addressed previous comments stating that all clinicians would be subject.
- **Bryant Thomas Karras** said he is curious to see what will happen with this. He noted that the penalties are not sufficient.
- **Alex** reminded folks that the calculation takes every MIPS-eligible clinician, all their earnings and takes a median.
- **Aaron Miri** echoed **Steven's** thoughts and noted that this should help alleviate the problem of information blocking. He inquired on what the process would be if an individual brought claims of information blocking where information was being withheld from the patient themselves. He asked if the Office for Civil Rights (OCR) would be involved at that point.
  - **Tim** said there is a provision about duplicate penalties, and that needs to be kept in mind. He added that there would be coordination between agencies to evaluate any such claims.
  - **Mike Lipinski** added that the situation would be handled differently if handled through the regulations of information blocking or HIPAA right of access.
- **Eliel Oliveira** echoed the comments made and added that the large HIEs would not be affected by penalties while the small ones would likely shut down and affect the communities trying to collaborate with SDOH.
  - **Jim said** the OIG cannot comment on specific factual scenarios as they would all be case-specific. He did note that it would depend on the definitions and scenarios involving HIE definitions relevant to information blocking.

- **Deven McGraw** asked Jim what constitutes "knowledge that you are information blocking" and if they need to be aware of the conduct that constitutes a violation.
  - ○ **Jim** reiterated that he could not comment on specific scenarios like that.
- **Shila Blend** suggested more guidance on what constitutes an "excessive fee."
- **Mike** said they have established criteria used to determine a reasonable fee based on the specifics of the claim as well as fees that could not be charged.

QUESTIONS AND COMMENTS RECEIVED DURING PUBLIC COMMENT
None received.

QUESTIONS AND COMMENTS RECEIVED VIA ZOOM WEBINAR CHAT
Accel Solutions: Good morning, the HITAC meeting will begin shortly.

Steven (Ike) Eichner: Steve Eichner

Steven (Ike) Eichner: For what standard was errata published?

Susan Clark: It will feel so weird not to have Dr. Lane on HITAC!!

Medell K. Briggs-Malonson: Thank you to each HITAC member for your service to this committee and our country!

Susan Clark: Yay Sarah!! I am a big fan. She will be great as co-chair.

Medell K. Briggs-Malonson: Congratulations Sarah!

Pooja Babbrah: Congratulations Sarah!!!

Clem McDonald: Am finally connected.

Pooja Babbrah: We can hear her online

Brittney Seiler: We can hear Shelly on virutal

Brittney Seiler: *virtual

Steven Waldren: Online can hear her

Steven (Ike) Eichner: I can hear (virtual)

Aaron Miri: Shelly we can hear you in the room

Steven Lane: Clem - You missed your public acknowledgement by Micky. THANK YOU for your service and the opportunity to work with you.

Medell K. Briggs-Malonson: We are actively working on optimizing the audio. Thank you again.

Mike Berry (ONC): Thank you for joining the November 2023 HITAC meeting. Meeting materials can be found at https://www.healthit.gov/hitac/events/health-it-advisory-committee-62

Mike Berry (ONC): Please feel free to share your comments in Zoom chat throughout the meeting. Chats to "Everyone" will be included in the meeting minutes. Thank you!

Steven Lane: @Clem - We discussed privacy issues at length in the task force. The goal is to leverage pharmacists and their staff as an extension of the multidisciplinary care team. Many acknowledged that the public perception is that community pharmacies may not have the same privacy practices as other providers and facilities. This clearly needs to change, both the perception and the reality, if pharmacies are to fulfill their promise as providers.

Richard Sage: @steven +1

Susan Clark: +1 Steven

Aaron Miri: +1 on common definitions / consistency between definitions, surveys etc.

Susan Clark: This is an incredible set of recommendations. Thanks to all who contributed.

Eliel Oliveira: +1 @Medell

Richard Sage: We need to work hard to evolve pharmacists from incentives to dispense to incentives for clinical services, and encourage technology to move from dispensing to clinical services.

Katie Russell: I think the understanding on seeing information related to medication stocks and patient navigation services is great but its also important to understand that the task force focused on recommendations that ONC could act on

Medell K. Briggs-Malonson: There is a live closed captioner present. Please activate the closed captions to view the transcript.

Hans Buitendijk: Which Health IT Modules are considered "eligible"? Those already certified to the original API criterion and could/should be updated? or any HIT module that is a source of EHI/PHI could (should) adopt and be certified to the API criterion?

Kim Lundberg: https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/uscdi-in-action-onc-and-hrsa-launch-uscdi-initiative-to-support-uds-modernization

Kim Lundberg: Clem - See above

Sarah DeSilvey: Just to note, as a rural FNP working in a FQHC UDS is my quality world, very aware of opportunities for standards to assist with outcomes and reporting, so very grateful for the aims of HRSA/ONC collaboration and UDS+

Shelly Spiro: Sounds better

Adele Stewart: 👍

Kim Lundberg: https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers

Kim Lundberg: Here is an overview of IB quick stats, but the ONC data team can respond in more detail

Kim Lundberg: https://www.healthit.gov/data

Kikelomo Oshunkentan: @Michelle, I believe that it is not "mandatory" until 2024.

Deven McGraw: In case we run out of time, SDOH data doesn't always come in by asking the patient. It was revealing to me that income data is one of the most sensitive categories - and yet health systems can easily

gather income data from data broker sources. It may not current be used for treatment purposes, but as an SDOH element, it could be used in treatment. We need to be mindful of this sensitivity. Few patients realize this data may already be collected by their physician offices or health care systems.

Sarah DeSilvey: A nod to Medell's comment, Gravity Project does assist with the delineation and definition of subtypes of broad domains. Such as housing insecurity into its subtypes/dimensions of inadequate housing, housing instability, and homelessness (each with their own questions from a standards perspective). And also recommending and building in best practice and evidenced based process including prefacing with "the why" of screening and safety statements for different types of concerns.

Kikelomo Oshunkentan: +1 Sarah

Mike Lipinski: https://www.federalregister.gov/documents/2023/07/03/2023-13851/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector

https://www.federalregister.gov/documents/2023/11/01/2023-24068/21st-century-cures-act-establishment-of-disincentives-for-health-care-providers-that-have-committed

https://www.healthit.gov/topic/information-blocking

Han Tran: Does this mean that a physician who works for an eligible hospital/CAH participating in Promoting Interoperability might face penalties even if the physician themselves did not engage in information blocking?

Han Tran: (if the eligible hospital/CAH engaged in information blocking and was subject to the penalty)

Jessica Warren: For IPPS, it's a hospital-wide penalty (regardless of where the info was blocked).

Jessica Warren: If one Physician blocked the transfer of info, the hospital itself could be penalized...not the specific individual.

Jessica Warren: For MIPS, this is on the provider level (provider, individual practice).

Jessica Warren: Also for MIPS, if they report as a 'group,' if one individual in the group blocks the transfer of information, this could lead to penalty for the entire group, not only the individual.

Aaron Miri: Thank you @Jessica and @Elizabeth - this is VERY important to make sure the entire market understands.

Steven Waldren: @Jessica, I wonder if it depends which "health care provider" performs the act? The physician or the practice, since both are "health care providers" under the definition. Either way seems like ACO providers are getting disproportionately penalized.

Felix Umetiti: is there an established information blocking determination appeal process for providers?

Elizabeth Holland: no appeal process

Elizabeth Holland: from the CMS side

Jessica Warren: @steven, it would depend on whether they fall under MIPS or IPPS...for us (PI MIPS, PI Hospital), the potential penalty remains the same (program failure). This is also the same penalty structure for not meeting program/performance category requirements.

Elizabeth Holland: also please know that this is a proposed rule so we are limited in what we can say....definitely submit comments

Felix Umetiti: thank you! @elizabeth - I'm wondering if maybe there's some sort of appeal recourse through OIG when they submit that notice of referral

Jessica Warren: Thank you for the reminder Elizabeth. We read every single comment, so submit away :)

Deven McGraw: Although the penalties (disincentives) will be assessed against providers, so providers have a vested interest, patients who continue to face obstacles in getting their health information, also have a strong vested interest in assuring that these penalties result in behavior change.

Susan Clark: Excellent comments, Steven! I agree with all you have said.

Deven McGraw: Interesting interplay between the hardship exception on the payment side and the infeasibility exception on the Info blocking side

Shelly Spiro: @Steven thank you for mentioning pharmacy and pharmacist. The FDA does not license pharmacies and pharmacists. The State Boards of Pharmacy provides the license.

Michelle Schreiber: appreciate all the feedback on types of providers. I would clarify that many types of providers participate in MIPS - not just physicians.

Sarah DeSilvey: Thank you, Dr Schreiber.

Aaron Miri: I can't give enough Kudos to ONC / OIG / CMS.   Way to go team. This is a massive achievement in the industry and ushers in an entirely new world.   Bravo.

Medell K. Briggs-Malonson: +1 Aaron

Eliel Oliveira: Jim, what I meant is that HIEs/HINs not required to use certified systems and what is their risks of CMPs. Examples revolved around Certified HIT users and developers and examples on HIEs/HINs would be helpful too.

Alesia Hovatter: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule: Public Comment Period is Open until 11:59 p.m. ET on January 2, 2024. You may submit public comments at the following link: https://www.regulations.gov/document/CMS_FRDOC_0001-3695

Thompson Boyd: Thank you for your service.

QUESTIONS AND COMMENTS RECEIVED VIA EMAIL
No comments were received via email.

FINAL REMARKS
- **Mike Berry** reminded the HITAC members of the next meeting in January.
- **Aaron Miri** thanked everyone for all their years of support as this was his last meeting with HITAC.
- **Medell Briggs-Malonson** thanked **Aaron** for his leadership on behalf of ONC and HITAC.

ADJOURN
The meeting was adjourned at 3:51 p.m.

The November 9, 2023, meeting notes were approved by Wendy Noboa, Acting Designated Federal Officer, Medell Briggs-Malonson, HITAC Co-Chair, and Aaron Miri, HITAC Co-Chair, on December 11, 2023.