Meeting Notes

Health Information Technology Advisory Committee
Information Blocking Task Force
March 8, 2019, 11:30 a.m. – 12:30 p.m. ET
Virtual

The March 8, 2019, meeting of the Information Blocking Task Force (IB TF) of the Health IT Advisory Committee (HITAC) was called to order at 11:30 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

Michael Adcock, Co-Chair, Individual
Andrew Truscott, Co-Chair, Accenture
Cynthia Fisher, Member, WaterRev, LL
Valerie Grey, Member, New York eHealth Collaborative
Anil Jain, Member, IBM Watson Health
John Kansky, Member, Indiana Health Information Exchange
Steven Lane, Member, Sutter Health
Arien Malec, Member, Change Healthcare
Denni McColm, Member, Citizens Memorial Healthcare
Aaron Miri, Member, The University of Texas at Austin, Dell Medical School, and UT Health Austin
Sasha TerMaat, Member, Epic
Lauren Thompson, Member, DoD/VA Interagency Program Office
Sheryl Turney, Member, Anthem
Denise Webb, Member, Individual

ONC STAFF

Cassandra Hadley, HITAC Backup/Support
Penelope Hughes, Staff Lead
Mark Knee, Staff Lead
Morris Landau, Staff Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Elise Sweeney Anthony, ONC
Lauren Wu, ONC SME

Call to Order

Michael Adcock, co-chair, welcomed the Task Force and reviewed the agenda. He noted that the workgroups of the IACCTF have met and there will be a review of initial discussion topics from each group. He began the review of the discussion topics from workgroup 1.

Work Group 1: Relevant Statutory Terms and Provisions

- Health information networks/exchanges
  - Scope of definitions
    - Too narrow?
    - Potential for gaming?
- Situations when provider is also a HIN or HIE
  - Penalties
- Intent of definitions to cover external interfaces from a hospital?
- EHI definition
  - Should this definition be augmented to include clarity around actors?
  - Human readable or codified information
  - Exclude aggregated patient information?
- Price information
  - View that we need price transparency and now is the time to address it within the context of information blocking; no other levers to address it available.
  - View that price transparency is important, but out of scope for this rule; unintended consequences need to be considered.
- Practices that may implicate the information blocking provision
  - Discussion regarding scope and implications of examples of potential information blocking
- Parties affected by the information blocking provision and exceptions
  - Definition and scope of "actor"
  - Payers
  - Concern regarding self-insured companies

Andy Truscott reviewed the discussion topics from workgroup 2.

Workgroup 2: Exceptions

- Preventing Harm
  - (a)(1): Concern that this could become a large exception hole (e.g. most people's records have some level of inaccuracy); suggestion to restrict to true data corruption.
  - (a)(2): If there is no obligation upon a provider to correct identification mistakes, why would they?
  - Suggestion to limit to cases where a data holder knows that the data is not applicable to the patient and to create a test.
  - (a)(3): Is this specifically aimed at certain MH conditions?
  - (b) and (c): individualized finding should be recorded somewhere accessible
  - (b)(2): "relevant" vs. "appropriate"
  - Suggestion to define organizational policy
- Promoting the Privacy of EHI
  - Overhead requirements for organizations
  - Suggestion to add language that organizational policies must comply with federal, state, and local laws
  - (b)(2): consent (or dissent) should be documented/recorded
  - (c)(3): meaning of "meaningful"

Workgroup 3: Conditions and Maintenance of Certification – Topics Discussed

Michael Adcock summarized the discussions in this workgroup.

- Information blocking
  - No issues
- Assurances
- Ambiguity in "full compliance and unrestricted implementation" language in preamble
- Intent of (a)(3)
- (b)(1) Scope of retention
- (b)(1): Comparison of time periods for record retention and records access
- b) (1): Proposal of 3-year retention period for voluntary withdrawals; proposal for infinite retention period
- Self-developers
- Assurances - Request for information on participation in the TEFCA
  - Cannot comment without seeing TEFCA
- Communications
  - IP issues
  - How to protect developer community from nefarious purposes
  - Intent/definition of "fair use"
  - Whistleblower protection
  - Notification to vendor
  - Scope of "non-user facing"
    - Proposed amendment: Adjust definitions to clarify that administrative functions of HIT would be "non-user facing aspects" based on the assessment that those communications are not matching the purpose described in 21st Century Cures (Cures) and also a limited set of users.
  - Screenshots
    - Whether layouts are/should be considered IP
    - Purpose of prioritizing communication between health care entities; comparing configuration between healthcare entities should pose minimal risk to IP rights.
    - Possible proposal: Draw a distinction around purpose of use. (Think also in relation to "fair use" definition. Fair use might be applicable or insufficient.)
  - Discussion of (D)(2)(iii) and (iv):
    - Possible proposal: Should be amended to a list of which third party content might appear in a screen. Enumerating elements per screen is not feasible.
    - Extensive conversation of (D)(2)(iii) and (iv) and the complexity/impossibility of doing this.
  - Discussion of (E):
    - Possible proposal: Effort for notice and contracting is only 40 hours for clerk, massively underestimated. Recommend that ONC should revise estimate. More roles involved than clerk, work involved on the part of the recipients.
    - Possible proposal: Eliminate 2-year timeframe and propose update at next renewal.
- Discussion of (b)(2)
  - Possible proposals:
    - (b)(2)(i) - Can we add contract "renewal" in here?

        - (b)(2)(ii) - State a roadmap within two years, with compliance not to be unreasonable
- Enforcement
    - Ban is serious, but fair given the process proposed by ONC.
    - Possible proposal: Use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination.

Andy Truscott asked the members if there were any concerns regarding the summaries shared.

Discussion

- **Arien Malec** shared that the definition of electronic health information (EHI) and health information network (HIN) places a large number of entities into the scope of information blocking rules, particularly information blocking exception and pricing rules. He questioned if anyone has looked at the unintended consequences, as well as Congress' intent relative to information blocking. His read places a whole set of activities (e.g., clearinghouse, record retention) under information blocking and pricing restrictions and it is not clear to him that this was the intent.
    - **Andy Truscott** confirmed that this has been discussed, as well as health information exchange (HIE). There has been a lot of feedback across all workgroups.
    - **Arien Malec** suggested walking through a few examples, such as the ones he mentioned to help clarify the concern. He does not believe that the breadth of organizations that could be included aligns with the original intent of Congress, as the intent was not to make this apply to market-based services that were already working well.
- **John Kansky** commented that good policy is as good and precise as it can be. Policy needs to be made as clear as possible to achieve the desired end, minimize the cost to comply with the regulation, and be able to withstand push-back from the industry if it is too broad. He noted that precision is best.
- **Arien Malec** noted that the requirements to comply with the pricing provision impact services already working well for providers and payer services. For example, this could result in raising the price of commodity services that already work well (e.g., claims). With an additional compliance burden, the price will go up. This is not addressing market failure, but putting a burden on practices that are currently working in practice.
    - **Arien Malec** shared that in general, it is the provider organization. Pricing comes from the payer through a remit. It is the provider that is the ultimate source for payer information. Putting those services under information blocking could lead to increased costs.
- **Steven Lane** noted that provider, in this case, was used broadly (e.g., laboratory, imagining, pharmacy, clinicians).
- **Arien Malec** shared that he has an interest in increasing price transparency and other tools that allow for flexible decision making. Had Congress intended for these issues to be addressed, Congress would have written that into the legislative text.
- **Arien Malec** noted the need to more finely tune the policy interest to the consequences of information blocking information. He did not feel that the NPRM strikes the right balance.
- **Cynthia Fisher** noted that it is important to look at the definition and note the importance of having access to healthcare information. There needs to be a functional fair and competitive market place. The function of Cures is having a free market place.
- **Arien Malec** noted that his basic concern is based on the broad definition, as he fears that it will stifle innovation.

- **Cynthia Fisher** noted that they need to agree to disagree. She felt that the status quo is not working and there needs to be a change.
- **John Kansky** shared that this is about balancing the responsibility to have a regulation that moves to data and pricing transparency and balancing with a regulation that is implementable, enforceable, and doing so at a reasonable cost.
- **Aaron Miri** shared examples of how things are not working. He noted the need to better incentive to ensure pricing information is available.
- **Denni McColm** shared that she made it clear in her workgroup that pricing is outside the scope. She suggested that ONC provide details of what is happening with price transparency. Hospitals had to publicize pricing as of January 1, 2019.
    - **Mark Knee** agreed to share anything in Cures that relates to price transparency.
- **Cynthia Fisher** reminded the group to look at this from the perspective of the patient.
- **Mark Knee** noted that there is only a request for information on pricing within the NPRM.
- **Steven Lane** shared that he felt that keeping "price" in the definition is in the best interest of patients and providers. He believes this is the intent of Congress.
- **John Kansky** shared that regarding the point that payment is in the definition, his understanding is that the definition was borrowed from the Health Information Portability and Accountability Act (HIPAA). ONC is asking whether pricing should be included or not. He noted that HIPAA was designed for information that should be protected, and this is how defining information that should be shared.
- **Arien Malec** noted that he is pro-transparency. The issue is the unintended consequences of the application. He felt there is a disincentive for innovation which impacts price information from flowing. He wants to be sure that information that is open from one hand is not closed with another.
- **Denise Webb** questioned that there could be a conflict with USCDI and EHI.
    - **Mark Knee** shared that he will follow-up with the folks who wrote the USCDI section, but he does not believe there is a conflict.
- **John Kansky** when thinking about the ability for a provider to comply with a regulation, the implementation of that seems to have gotten more difficult and costlier.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Comments in the public chat

Sheryl Turney: I will be joining shortly sorry closing a call

Lauren Richie: ok

Sheryl Turney: I am on

John Kansky: I just joined

Andy Truscott: Welcome :)

Lauren Richie: noted

John Kansky: I share the questions and concerns Arien is expressing in terms of broad definitions and unintended consequences

Andy Truscott: yep

Andy Truscott: I know :)

Denni McColm: Are we confusing pricing of revenue cycle services with price transparency of health care services?

Andy Truscott: I think so

Andy Truscott: Denni: did that help?

Steven Lane: I second Aaron's comments.

Arien Malec: Information blocking applies to the definition of Electronic Health Information in Sec 171, which is "(1) Electronic protected health information; and(2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual."

Valerie Grey: this is proposed definition not a definition contained in Cures correct?

Andy Truscott: Correct. From the proposed rules.

Denise Webb: are payment and price one in the same from a definition perspective? I don't think they are the same

Steven Lane: Good point. We need to be specific and answer this question.

Andy Truscott: It's one of the points that are going to be discussed in the workgroup. Along with other semantics.

Steven Lane: We would need to consider adding Price to USCDI.

Steven Lane: USCDI appears to have been designed primarily to support exchange between clinical stakeholders.

Steven Lane: *stakeholders

Arien Malec: This issue is inherent to Cures - which requires "all" data.

Arien Malec: not just that which is available via standards.

Andy Truscott: Arien: That is also a good point and a discussion within the EHI definition.

Valerie Grey: It seems important to define what is meant by price. Chargemaster pricing is different than negotiated price and different from price a consumer with insurance would pay versus the amount someone without insurance would pay ... hard to talk about exchanging information without resolution on what price is ....

Andy Truscott: Arien: There's the concept of "reasonable".

Steven Lane: All data in the medical record, but price information comes into play before a service is provided. It is only after the service is bought and paid for that the cost would become part of the record.

Steven Lane: We should pick back up here at our next meeting

Arien Malec: Yes, the Unreasonable exception in 171.205 could apply, but if the data are electronic, unreasonable can't be used to block the information.

Arien Malec: Actors have to provide reasonable alternatives.

Mark: agreed

Andy Truscott: Arien: Yes. Something that came up in the Screenshot discussion.

Next Steps and Adjourn

The next IB TF will be on Friday, March 15 at 11:30 a.m.

Lauren Richie adjourned the meeting at 12:30 p.m. ET.