Meeting Notes

Health Information Technology Advisory Committee
Information Blocking Task Force
April 11, 2019, 9:00 a.m. – 11:00 a.m. ET
In Person

The April 11, 2019 meeting of the Information Blocking Task Force (IB) of the Health IT Advisory Committee (HITAC) was called to order at 9:00 a.m. ET by Cassandra Hadley, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Cassandra Hadley conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

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

MEMBERS NOT IN ATTENDANCE

Lauren Thompson, Member, DoD/VA Interagency Program Office

ONC STAFF

Cassandra Hadley, Designated Federal Officer
Mark Knee, ONC Staff Lead
Morris Landau, ONC Staff Lead

Cassandra Hadley turned the meeting over to Andy Truscott, co-chair.

Welcome and Introductions

Andy Truscott shared a brief welcome to the members and reviewed the two areas of focus that would be discussed, the first being the discussion involving the intellectual property, screenshots, and 'fair use' currently referenced in §170.403, and the second being the fees as drafted out of Work Group Two.

Communications: Screen Shots and Fair Use

Discussion

- **Andy Truscott** noted that within the Health Information Technology Advisory Committee (HITAC), the 'fair use' term and definition caused a fair amount of discussion and debate and asked that the members of the Information Blocking Task Force (IBTF) consider to what extent they think the language should be modified.

- **Anil Jain** considered this term from the perspective of an individual doing usability research or assessing the effectiveness of the technology as well as a vendor who seeks to protect their intellectual property. He suggests reviewing a previously established list of reasons outlining why there shouldn't be any blocking of screenshots.

- **Steven Lane** added that a concern of the designation 'fair use' might cause problems with regard to policing of downstream use and shouldn't be the responsibility of the originator.

- **Andy Truscott** considered it generally accepted that the task force didn't want to put the burden on the designator of the original fair use to police all downstream use of the material.

- **Arien Malec** suggested that the law associated with fair use designation is likely well established under fair-use law.

- **Andy Truscott** agreed that a component of established existing intellectual property (IP) law and/or fair use law dictates that those who designate something as fair use are not responsible for policing downstream use.

- **Ken Kawamoto** agreed that even if the term fair use is commonly understood, it should be referenced somewhere within the document, even if it references the official 'fair use' definition with the appropriate text. Further, screenshots, in his experience, seem to be called out as shareable except in limited circumstances and suggests getting further clarity.

- **Andy Truscott** clarified that sharing a patient record amongst clinicians via a screenshot when no other patient record sharing alternative exists should be permitted and went on to describe that what should be prohibited is when a screenshot which is intended for fair use also captured patient health information (PHI).

- **Steven Lane** agreed that it's critical that specific references are made to the definitions of terms such as 'fair use.' He also suggests capitalizing the term.

- **Mark Knee** noted that ONC provides a citation for the definition of 'fair use' from the Copyright Act (17 U.S.C. 107) within the Proposed Rule's preamble, and asked the Task Force if there is agreement that the definition should be listed within the 'Definitions' section.

- **Steven Lane** suggested to narrowly target the information blocking provision to things that people or groups have expressed significant concern about.

- **Andy Truscott** asked the question if a statement should be inserted into the document that clarifies that IP concerns should be treated secondary to patient care.

- **Arien Malec** suggested allowing screenshot sharing for permitted use when patient care is involved. He suggested that short of interoperability, sharing screenshots is a reasonable way to share patient information and those sharing shouldn't live in fear of breaking the rules.

- **Anil Jain** suggested detailing within the document those reasons a screenshot is shared that are appropriate and warranted, reasons it is shared that are likely to occur because there is no alternative and those reasons that it is shared that are completely prohibited.

- **Andrew Truscott** asked if the fair use restrictions are viewed from the standpoint of further restriction starting with a limited set, or is everything allowed except in these limited situations?

    - **Sasha TerMaat** confirmed that the correct answer is the latter - everything allowed except in these limited situations.

- **Denise Webb** read the current language on fair use within the document preamble, which the task force members considered and it was noted that below this fair use language is a reference of 17 U.S.C 107, the official fair use language from the Copyright Act.

- **Mark Knee** noted that the definition from the Copyright Act could be inserted into the document.

- **Andrew Truscott** suggested that discussion of 'fair use' should be paused so they can collectively move on to the next item on the agenda. He then took the action item to consider the text as it's currently written, if it has sufficient teeth, or if more is needed within the regulatory text

- **Ken Kawamoto** suggested adding language allowing redacting / blurring to remove sensitive content. This regulation shouldn't preclude blurring content, especially at the request of the vendor.

    - **Anil Jain** followed on saying that adding such language would introduce another level of complexity

    - **Andrew Truscott** agreed to make a note to consider the implications of blurring / redacting.

    - **Sasha TerMaat** suggested redactions are actually covered in D1. Explaining that the text reads, 'you cannot require alterations except to redact PHI.'

Exceptions: Cost Reasonably Incurred and Licensing

- **Arien Malec** setup the discussion by providing a brief history of the deliberations of Work Group 2. Their sense was that the way § 171.204 and § 171.206 were divided up made it difficult to understand which fees were and were not permitted. They concluded that it would be better to have a single section covering permitted fees. Thus, any fee is a restriction on interoperability unless it is permitted. A second thread of discussion centered on the recognition of the distinction between activities for exchange or use that are value-added and that establish fair pricing and other activities that are impeded by rent-seeking behavior, where market forces aren't a good mechanism for pricing. The distinction they sought was to differentiate appropriate pricing mechanics that address rent-seeking behavior to ensure the data flows and distinguish that from other services where the market forces are appropriate. The approach they took was to make a distinction between access to legal medical records, and forms of IPR that stand in the way of access exchange and use. Given this, the fees exception should be focused on basic access and intellectual property rights (IPR) that impedes access or use. He closed by asking the task force if the approach taken by Work Group 2 was understood so they can reach consensus.

    - **Sasha TerMaat** confirmed the policy framework Arien is proposing is that the two sections are combined and within the new combined section is to distinguish between what basic access and other types of activities that are market-based.
        - **Arien Malec** confirmed.
- **Arien Malec** walked through the recommendations enumerated within the document.

    - **Andrew Truscott** suggested the electronic health information (EHI) definition is moving in the right direction and will support future transparency efforts. He followed up with a question regarding the use of the various classification type sets and whether or not they are standards essential.
        - **Arien Malec** confirmed that they were.

    - **Andrew Truscott** asked, related to the recommendation "The TF recommends that ONC distinguish between basic access…" what the term 'basic access' means in terms of fees. **Arien Malec** answered that they're contemplating pure cost recovery for basic access. **Andrew Truscott** went on to clarify that additional interfaces which conform to certify standards would be considered basic access, therefore pure cost recovery.
        - **Arien Malec** confirmed this.

    - **Andrew Truscott** asked if there is an exhaustive list of certified standards, and if so, no examples need to be included in the document. He went on to suggest if anything was missing from this list, that it be corrected rather than add the caveats into this document.
        - **Arien Malec** confirmed this.

    - **Cynthia Fisher** mentioned that a component of the EHI is price transparency (i.e. to enable a patient to have access to payment information (past, present, and future)). The issue she sees is that patients often receive unmatched fragmented bills months aftercare is provided. As this is part of the medical records, she asked, should they consider having

Health Level Seven (HL7) include payment along with clinical information as an HL7 Fast Healthcare Interoperable Resource (FHIR) standard? She went on to explain that payers provide cost estimators, but that doesn't reflect reality and patients do not understand real costs.

- Much debate followed with the resulting conclusion focused on **Arien's** existing effort to capture within the current draft to 'lay the tracks' to allow cost information to flow. The task force will also commit to examining the EHI definition to determine if it was in the spirit of what the 21st Century Cures Act was meant to cover. **Andrew Truscott** went on to boil down much of the discussion by clarifying that transparent pricing information is not being fully shared due to procedural and policy limitations rather than limitations of capabilities to share that information. Further, it is not the charge of the IBTF to discuss the policy and procedural issues related to transparent pricing.

- **Sasha TerMaat** asked if the recommendations section refers to certification standards or any standards. **Andrew Truscott** and **Arien Malec** agreed that it should refer only to certification standards.

- **Andrew Truscott** noted that different standards have different remuneration models and asks if essential IPR pushes some people toward a certain license such as Systematized Nomenclature of Medicine (SNOMED).
  - **Arien Malec** answered that yes, essential IPR would have the intended effect of making sure the American Medical Association (AMA) license Current Procedural Terminology (CPT) in terms that met the reasonable and non-discriminatory (RAND) pricing terms.

- **Andrew Truscott** noted that the term 'pure direct cost' can have several different meanings and could include, for example, labor. **Arien Malec** answers that they've excluded the development cost to develop the certified standards that are needed to get the application certified as well as reasonable mapping to standards, which are considered part of basic access. He goes on to note that the intent of this section is to include as customary the one-time mapping cost for a given set of custom code.
  - After much discussion, **Arien Malec** agreed to clarify the nuance of which mapping is and isn't included, and reiterated that the intent is for the recommendation to be clear that it is more expensive for an EHR vendor to provide ad hoc access than to ensure one-time basic access through a certified standard.

- **Andrew Truscott** asked if a mapping can enter public domain usage? For example, in the case of a mapping which has been created by Vendor A between a standard and something local. Should the provider have to pay again when Vendor B needs to do the exact same mapping?
  - **Arien Malec** will take this concern into consideration.

- **Sasha TerMaat** asked if basic access and essential access considered to be the same? **Arien Malec** answers that basic access is access to legal medical records and prospective

pricing. Essential IPR is IPR that are reasonably required to expose the data and have it be interpreted and used.

- **Denise Webb** asked if these recommendations are going into the preamble.
  - **Andrew Truscott** answered that the recommendations are only recommendations for consideration.

- **Andrew Truscott** asked again about why a vendor mapping, once complete, wouldn't be freely available. **Arien Malec** answered that a vendor has an obligation under basic access provisions to make the data usable, usually by mapping to a standard. He goes on to suggest an open application programming interface (API) rather than a 'brittle' mapping.
  - **Steven Lane** suggested mapping vendors custom codes to standard data set should be subsumed in the cost in the cost of the product rather than be a separate cost, and there is agreement that this represents the proposal.
  - **Arien Malec** summed up in the following way: there are appropriate ways of enabling access, exchange and use and not impeding the development of value-added services and the pricing mechanisms are sufficient to ensure that information flows. Needed are additional examples. Finally, there is an opportunity relating to mappings of proprietary terminology where more discussion is needed.

- **Andrew Truscott** suggested that, with regard to the recommendations, the task force define the outcome they are seeking to achieve in order to help give ONC a clear policy direction.

Cassandra Hadley opened the lines for public comment.

Public Comment

There was no public comment.

Comments in the Public Chat

John Kansky: John Kansky joined

John Kansky: I am stepping away for about 10 minutes... I'll be back

Cassandra Hadley: ok, thank you

Steven Lane: Hand up

Cassandra Hadley: got you

John Kansky: I'm back

John Kansky: Thanks to the workgroup for calling out the issue with common HIE pricing models. I believe the prohibition on this common pricing approach was unintended, but addressing that prohibition is

important to avoid disrupting HIE pricing models that are essential to their sustainable business models. Thanks!

John Kansky: FYI -- In many/most cases where payors share information with HIEs, financial data (i.e. pricing and payment) is not included

Cassandra Hadley: John, you can just jump into the conversation

John Kansky: hand is up

Cassandra Hadley: I told Andrew

Cassandra Hadley: Please jump in though

John Kansky: will do

Mark Knee: Steven cut you!

Next Steps and Adjourn

Cassandra Hadley adjourned the meeting at 11:00 a.m. ET.