Meeting Notes
Health Information Technology Advisory Committee
Information Blocking Task Force
April 04, 2019, 9:00 a.m. – 11:00 a.m. ET
Virtual

The April 04, 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 Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

MEMBERS IN ATTENDANCE

Michael Adcock, Co-Chair, Individual
Andrew Truscott, Co-Chair, Accenture
Cynthia Fisher, Member, WaterRev, LL
Valerie Grey, Member, New York eHealth Collaborative
Steven Lane, Member, Sutter Health
Anil Jain, Member, IBM Watson Health
Aaron Miri, Member, The University of Texas at Austin, Dell Medical School, and UT Health Austin
Lauren Thompson, Member, DoD/VA Interagency Program Office
Sheryl Turney, Member, Anthem
Denise Webb, Member, Individual

MEMBERS NOT IN ATTENDANCE

John Kansky, Member, Indiana Health Information Exchange
Arien Malec, Member, Change Healthcare
Denni McColm, Member, Citizens Memorial Healthcare
Sasha TerMaat, Member, Epic

ONC STAFF

Mark Knee, ONC Staff Lead
Morris Landau, ONC Staff Lead
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer
Lauren Wu, ONC SME

Call to Order

Lauren Richie turned the meeting over to Andy Truscott, co-chair.

Andy Truscott worked to create a consolidated document that has the original text, the recommendations, and then a comparison of the original and recommendations. This document will eventually be shared with the HITAC for approval and then to the National Coordinator.

Andy Truscott reviewed the recommendations from workgroup 3.

Workgroup 3 Output Review

§ 170.402 Assurances

Denise Webb walked through the suggested changes in this section. The items in red identify the changes. Only the items with changes are represented below.

- (3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the scope of the technology's certification, and the health IT developer shall provide honest communication and expert advice as required by a user.
- (iii) If for a shorter period of time, a period of 3 years from the date of withdrawal by the health IT developer of a certified health IT product from certification.
- (i) 24 months of this final rule's effective date, or
- (ii) 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition
- (3) ONC will preserve on the CHPL (or in another format) a list of the start and end dates of each previously certified health IT product.
  - **Lauren Wu** commented that she believes the CHPL already does this, but will verify.
  - **Denise Webb** suggested not being so prescriptive in referring to CHPL, as this could potentially change. The intent is to be transparent.

§ 170.403 Communications

- Any person who makes a communication covered by (2)(i) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity.
- (2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to "fair use".
- (iii) The developer has put all potential communicators on sufficient written notice of a list of third-party content included in the health IT that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and
- (3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that they are either:
  - o (i) protected by other legislation or regulation; or
  - o (ii) false or unlawful.
- (2) Contracts and agreements.
  - o (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.

- (ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.

- (iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.

§ 170.580 ONC review of certified health IT or a health IT developer's actions

- (c) Notices initiating direct review, of potential non-conformity, of non-conformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued simultaneously via certified mail and email.
    - o There was some discussion around this, but the group decided to keep this as is.

Proposal and request for comment on public listing of certification bans and terminations

Andy Truscott reviewed the recommendations.
- **Proposed Recommendation:** Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.
- **Proposed Recommendation:** We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender.
- **Commentary**
    - o Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate. The sense of the Task Force was that knowledge of past bans was important for stakeholders.
    - o We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender. The sense of the Task Force was that a minimum ban time period could have unintended consequences.

The task force agreed with the recommendations and commentary.

Request for comment on application of Conditions and Maintenance of Certification to self-developers

Denise Webb reviewed the recommendations.
- **Proposed Recommendation:** Call out an exception to (a)(2)(ii)(A) for self-developed systems, so that communications by health IT users aren't restricted by being employees of the same company doing the development.
- **Commentary**
    - o The provisions of information blocking and assurances would apply to self-developers also. Most of the provisions of Communications would also apply to self-developers. The Task Force identified one area that would require modification for self-developers, which was in (a)(2)(ii)(A) where the Task Force noticed that employees of a developer can have their communications restricted, but that this could have the consequence of limiting communications of users of the self-developed health IT for the reasons identified under Cures.
- **Regulatory Text Recommendation**

    o *Developer employees and contractors*. A health IT developer may prohibit or restrict the communications of the developer's employees or contractors. Healthcare organizations self-developing certified systems are not permitted to restrict the communications of their user employees with respect to these provisions.

The task force agreed with these recommendations.

Workgroup 1 Output Review

Andy Truscott reviewed the changes from workgroup 1.

§ 171.102 Definition of Electronic Health Information

Andy Truscott noted that while the changes seem minimal, the workgroup had extensive discussions around these definitions.

Electronic Health Information (EHI) means—
(1) Electronic protected health information (as defined in HIPAA); 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(s) for the provision of health care to an individual.

- **Sheryl Turney** commented that the group worked hard to come strike the appropriate balance in this definition and affirmed that there was a lot of discussions to get here.
- **Steven Lane** confirmed his agreement with this definition.
- **Denise Webb** expressed concerns about the breadth of the definition. She noted that the Conditions and Maintenance of Certification Task Force (CMCTF) is recommending a narrower scope.

Discussion regarding the definition of "health IT developer of certified health IT"

- **Steven Lane** shared that there could be a disadvantage created by this based on certification status. He thought there should be an even playing field for all, regardless of whether they seek certification.
- **Cynthia Fisher** asked the group to think about how we got here. We are where we are because patients don't have access to their data and get the best quality of care. We are here to deliver patients their data comprehensively.
- **Steven Lane** commented that the whole industry has been bolstered by the incentive program. Whether a developer chooses to be certified, it doesn't change the fact that there was a lot of money provided to build the current health IT infrastructure (the current market for products).
- **Anil Jain** noted his appreciation for having a level playing field. There is a need to be sensitive to a large organization that has other parts of the portfolio that were never intended to engage in certification. Don't want to create a cottage industry of subsidiaries that are avoiding certification; this would be an unintended consequence.
- **Andy Truscott** clarified for the group that if any organization has one product that is certified, the organization is considered in scope for all conduct.
- **Andy Truscott** noted that there are four actors referred to in 21st Century Cures Act (Cures Act):

- o Providers
- o Health information exchanges
- o Health IT developers
- o Health Information networks

§ 171.102 Definitions of Health Information Exchange and Network

Andy Truscott noted that there are different uses of health information exchange in the regulation. Seeking to bring clarity. The different actors have different sanctions against them. When reviewing the definitions, the group was trying to look at the actor's function. Some organizations will be both a provider and a health information network. The goal was to clarify without changing the scope.

Below are changes the work group is considering to the definitions proposed by ONC. The changes below are not fully redlined to show how the changes being considered compare to ONC's proposed definitions.

Health Information Exchange or HIE means the act of accessing, transmitting, processing, handling, or other such use of Electronic Health Information, or the organization or entity conducting that act.

Health Information Network or HIN means an individual or entity that satisfies one or several of the following—

(1) Determines, oversees, administers, controls, or defines policies or agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more ~~unaffiliated~~ individuals or entities.

(2) Provides, manages, or controls, any technology or service that enables or facilitates Health Information Exchange between or among two or more ~~unaffiliated~~ individuals or entities.

Discussion

- **Denise Webb** felt it was tightened and nothing was lost. ONC's definition has room for interpretation and is vague. The definition clarifies a word that is used in various ways.
- **Michael Adcock** agreed with Denise Webb.
- **Andy Truscott** commented that the group thought this definition was much clearer. In the Cures Act, there are different uses of the terms.
- **Mark Knee** noted that ONC proposed a functional definition for HIN. Congress made these four buckets of actors and ONC was careful to avoid a definition of one actor that would swallow the other actors.
- **Andy Truscott** noted that the ecosystem is fast moving and changing. This group is supposed to bring those changes to Congress's attention to act accordingly.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The next meeting of the IB TF is on Friday, April 5 at 11:30 a.m. ET.

Lauren Richie adjourned the meeting at 11:00 a.m. ET.