

Meeting Notes

Health Information Technology Advisory Committee Information Blocking Task Force Workgroup 3: Conditions and Maintenance of Certification March 12, 2019, 12:00 p.m. – 2:00 p.m. ET Virtual

The March 12, 2019, meeting of the Information Blocking Task Force Workgroup 3: Conditions and Maintenance of Certification of the Health IT Advisory Committee (HITAC) was called to order at 12:00 p.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 Sasha TerMaat, Member, Epic Lauren Thompson, Member, DoD/VA Interagency Program Office Denise Webb, Member, Individual

MEMBERS NOT IN ATTENDANCE

Aaron Miri, Member, The University of Texas at Austin, Dell Medical School, and UT Health Austin Sheryl Turney, Member, Anthem

ONC STAFF

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

Call to Order

Lauren Richie called the meeting to order, conducted roll call, and turned the meeting over to the cochairs.

Mark Knee kicked off the meeting to go back to open questions from previous meetings.

Outstanding Discussion Items

ADMINISTRATIVE FUNCTIONS

Penelope Hughes provided insight into the administrative functions to help the workgroup with their discussion.

- Sasha TerMaat and Denise Webb felt that there should be some clarity around the administrative functions.
- Sasha TerMaat shared that one of ONC's arguments for using screenshots is that there is a large user base, but this is not true of administrative functions which have a much smaller set of users. It is not clear that the intent of 21st Century Cures (Cures) was to show all of the options that are available in an administrative screen. She recommended to exclude administrative activities would be based on the intellectual property, it is not supported well by ONC's argument, the linkage to Cures is weak, and it is more vulnerable from an intellectual property and security perspective.
- Denise Webb thought it was important to provide examples to ONC.
- The workgroup agreed to come back to this so that they can think through appropriate examples.

FAIR USE

Penelope Hughes provided additional information in regard to fair use.

- Andy Truscott expressed concern with the "logic test."
- The workgroup made a recommendation to note the unintended consequences of "fair use" and that other usages should be further explored by ONC. The group was concerned about risks to vendor intellectual property; they do not want to infringe on innovation.

SCREENSHOTS

Penelope Hughes provided additional information regarding screenshots. She noted that screenshots in communication on protected areas ordinarily is fair use.

- Andy Truscott noted a challenge when a screenshot is used for communication of EHI.
- The workgroup suggests distinguishing the purpose of use. This also may be related to the definition of fair use.

TIMELINE

• The workgroup concurred with their previous recommendation to lay out a roadmap for compliance within two years, with compliance not to be unreasonable.

COMMUNICATIONS FRAMEWORK

Sasha TerMaat suggested the following addition that the workgroup agreed to add. She proposed adding an additional bucket of unprotected communication to ONC's framework that could include:

- False communications
- Communications protected by attorney-client privilege

CERTIFICATION BAN

- The workgroup noted this is related to the discussion they had around implications of certification.
- Ban is very dramatic as far as consequences it is of any product. Discussion of how a health IT product might have several hundred products and one product's non-conformance might not affect other products. The impact of the ban could significantly affect health system.
- The workgroup discussed proposing the use of both email and certified mail for all notices concerning violations of the Conditions of Certification.

PUBLIC LISTING OF CERTIFICATION BANS AND TERMINATIONS

- **Denise Webb** commented that if a developer has sought reinstatement and is no longer under the ban, it seems that continued punishment to still list doesn't seem appropriate. She also noted that as a customer, you would not to know that the developer had previously been banned.
- Andy Truscott felt that it was entirely appropriate.
- Sasha TerMaat could see both sides, similar to Denise.
- Lauren Wu clarified that there currently is one developer that is banned and this is separate from an ONC direct review.
- The workgroup proposed that communication of past records (ban with start and end date, if lifted) seems appropriate.

SELF-DEVELOPER

- The workgroup thought through the following items in regards to self-development.
- Information Blocking
 - Irrelevant whether self-development here.
- Assurances
 - Self-developed products could/should make the same assurances.
- Communications
 - Unqualified protections the same for self-developed.
 - Permitted prohibitions and restrictions would be the same.
 - Recommend that there is differentiation that the self-developer may be a health system and should be an exception (a)(2)(ii)(a).
 - Health IT developers can restrict the communications of their employees or contractors. But if the developer is a health system, there probably needs to be some qualification. Don't want them to prohibit/restrict.
 - Users aren't restricted by virtue of being employees of the same company doing the development.

ASSURANCES

- The Workgroup recommended that, for products that are withdrawn by the developer, a retention period (for full records) of three years after the withdrawal is sufficient.
- ONC should retain records on the Certified Health IT Product List (CHPL) indefinitely for ongoing reference.

ASSURANCES

Request for information on participation in the Trusted Exchange Framework and the Common Agreement (TEFCA)

• The workgroup recommends that once TEFCA is available recommendations should be made.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The workgroup will review their recommendations during the next call on March 14, 2019 at 4:00 p.m. ET.

Lauren Richie adjourned the meeting at 2:00 p.m. ET.