



Meeting Notes

Health Information Technology Advisory Committee

Information Blocking Task Force

Workgroup 3: Conditions and Maintenance of Certification

March 7, 2019, 4:00 p.m. – 6:00 p.m. ET

Virtual

The March 7, 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 4:00 p.m. ET by Seth Pazinski, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Roll Call

Andrew Truscott, Co-Chair, Accenture

Michael Adcock, Co-Chair, Individual

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

WORKGROUP 3 MEMBERS NOT IN ATTENDANCE

ONC STAFF

Cassandra Hadley, HITAC Backup/Support

Penelope Hughes, Staff Lead

Mark Knee, ONC Staff Lead

Morris Landau, ONC Back Up/ Support

Seth Pazinski, HITAC Backup/Support

Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

Lauren Wu, ONC SME

Call to Order

Seth Pazinski called the meeting to order, conducted roll call, and turned the meeting over to the co-chairs.

Andy Truscott kicked off the meeting quickly getting into the discussion of communications within the conditions of maintenance and certification.



§ 170.403 Communications

Non-user-facing aspects of health IT

- Administrative functions such as configuring user access classes -- is that non-user facing?
- **Sasha TerMaat** noted that there is ambiguity in the preamble, need to address to show that Configuration of the User Facing Aspects counts as a user-facing aspect?
- The workgroup agreed to recommend to propose an amendment to adjust definitions to clarify that administrative functions would be non-user facing aspects based on the assessment that those communications are not matching the purpose described in 21st Century Cures and also a limited set of users.

Intellectual property

- **Sasha TerMaat** questioned how to balance public good purposes with the nefarious actors who may want to replicate intellectual properties.
- **Aaron Miri** suggested that the discloser of information takes responsibility for intellectual property misappropriation.
- The workgroup asked ONC to provide legal expertise on the definition of fair use that includes examples.
- **Sasha TerMaat** shared that the purpose is important for initial disclosure, as well as for redisclosure.

Screenshots

- **Sasha TerMaat** shared that from her perspective, screenshots are considered intellectual property. She felt that ONC is underestimating the value.
- **Andy Truscott** also noted that many developers consider investments in screen design significant.
- The workgroup asked ONC to provide additional information on the layouts. The workgroup interpreted that layouts are not intellectual property, but asked for confirmation.
- **Sasha TerMaat** shared that health systems do not like to share information via a screenshot because they would have to log the disclosure which could be inadvertently forgotten manually.
- The workgroup discussed that communication between healthcare entities should be prioritized. The purpose of the use is important. This is also related to fair use and may be applicable or insufficient.
- Discussion of purpose again, prioritizing communication between healthcare entities. Comparing configuration between healthcare entities should pose minimal risk to intellectual property rights.
- In regards to (D)(2)(iii), the workgroup questioned what this provision means.
 - **Denise Webb** questioned whether this is to share what may appear in the screenshot. Putting out a written notice on every screen is far too onerous, there could be thousands of screens with thousands of aspects.
 - The workgroup proposed to amend to a list of third-party content that might appear in a screen. Enumerating elements per screen is not feasible.

Premarket Testing and Development

- **Denise Webb** commented that the beta-time periods is too prescriptive; it doesn't seem necessary to set a period.



Contracts and agreements

- **Sasha TerMaat** shared that the effort seems to be dramatically underestimated by ONC.
- The workgroup suggested that the estimates need to be revised.
- There were also concerns about the timeframes; two years is not a long time for this work.
- The workgroup suggests eliminating the two-year timeframe and proposes an update at the next renewal.
 - **Lauren Wu, ONC**, shared that two years was proposed for alignment with other certification proposals of 24 months.
 - The workgroup felt this was different though and there should be some flexibility.
- **Aaron Miri** suggested for (b)(2)(i) to add renew, showing evidence that it is being worked toward.
 - **Andy Truscott** suggested that a roadmap within two years, with compliance not to be unreasonable

§ 170.580 ONC Review of Certified Health IT or a Health IT Developer's Actions

- **Lauren Wu** shared that there isn't a regulation text because proposing a section of the regulation text that already exists today.
- **Denise Webb** noted that the ban seems dramatic, in regards to consequence. Health IT product might have several hundred products, and one product's non-conformance might not affect other products. The impact of a ban could significantly impact a health system.
- **Lauren Wu** noted that there is a specific process that will be followed; this isn't something that would happen overnight. She noted that this is in the preamble. There would be a corrective action plan posted on the Certified Health IT Product List (CHPL).
- **Aaron Miri** noted that ONC and FTC could investigate at the same time; it isn't mutually exclusive.
- **Lauren Wu** noted the Office of the Inspector General (OIG) is also involved in information blocking, ONC's role is in regards to ONC health IT developers, this is an example of where there could be an overlapping authority by an agency.

Nature and Types of Non-Conformities Request for Comment

- **Sasha TerMaat** noted that this should be delivered by certified mail and email.
 - **Mark Knee** noted that email is the default method of communication, but a comment is sought on this.
- The workgroup recommended that both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination.
 - **Denise Webb** noted that if it starts the clock, perhaps mail will be the best route of notifying.

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 Workgroup 3 will be on Tuesday, March 12 at 12:00 p.m. ET.

Lauren Richie adjourned the meeting at 6:00 p.m. ET.