



Meeting Notes

Health Information Technology Advisory Committee

Information Blocking Task Force

Workgroup 3: Conditions and Maintenance of Certification

March 21, 2019, 4:00 p.m. – 6:00 p.m. ET

Virtual

The March 21, 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 Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted Roll Call.

Roll Call

MEMBERS IN ATTENDANCE

Andrew Truscott, Co-Chair, Accenture

Sasha TerMaat, Member, Epic

Denise Webb, Member, Individual

MEMBERS NOT IN ATTENDANCE

Michael Adcock, Co-Chair, Individual

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

ONC STAFF

Penelope Hughes, ONC Staff Lead

Mark Knee, ONC Staff Lead

Morris Landau, ONC SME

Lauren Richie, Branch Chief, Coordination, Designated Federal Officer

Lauren Wu, ONC SME

Lauren Richie called the meeting to order and turned it over to **Andy Truscott, co-chair**.

Revisit outstanding issues

REAL-TIME EDITS



§ 170.402 Assurances

Andy Truscott and Sasha TerMaat made real-time edits to provide details based on the proposals that were previously discussed with the workgroup. The additions are noted with red text below.

(b) *Maintenance of Certification.*

(1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for:

(i) A period of 10 years beginning from the date each of a developer's health IT is first certified under the Program; or

(ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations.

(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.

(2) A health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10) within:

(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.

§ 170.402 Assurances - Request for information on participation in the Trusted Exchange Framework and the Common Agreement

Andy Truscott and Sasha TerMaat made the following addition: The Task Force believes it would not be responsible to make recommendations within this RFI until the next draft of TEF is available.

§ 170.403 Communications

Andy Truscott and Sasha TerMaat worked together to make real-time edits. The following addition was made:

There was a discussion of administrative functions of HIT could unintentionally reveal significant intellectual property of health IT developers. For example, the security configuration of health IT are less important in meeting the needs of communications protected under 21st Century Cures.

There was a discussion of concerns of sharing screenshots, the value that health IT developers put on time spent designing and improving screens and user interfaces, and that there are valid reasons why screenshots are both required to be shared and could also be considered "fair use." The goal was that the communications protected under 21st Century Cures should not permit unintended use, such as using screenshots to attempt to copy screen designs from a competitor. Some members of the Task Force felt that the "fair use" provisions of the preamble already prohibited copying for competitive reasons. However, the restriction that screenshots be permitted to be communicated under fair use principles is not in the regulatory text, and the group felt that it deserved further consideration. The intent of the Task Force was that the actor disclosing a screenshot is responsible for determining that the disclosure's



purpose does meet the “fair use” expectations and that further redisclosures would have to similarly meet the fair use expectations, and in doing so appropriately protect from potential intellectual property infringements.

Andy Truscott questioned 170.403 (a)(1)(v): The business practices of developers of health IT related to exchanging electronic health information.

- He felt that this was unclear, but it came directly from 21st Century Cures (Cures).
- Mark Knee noted that the group could make a recommendation.

Andy Truscott and Sasha TerMaat worked together to add the following regulatory and preamble text recommendations.

a) Conditions of certification

(3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that that are either:

- (i) protected by other legislation or regulation; or
- (ii) false or unlawful

Sasha TerMaat shared alternative language that could potentially be included in the preamble. The workgroup didn’t finish the discussion on this topic and will follow-up with this during the next call.

Alternative framing:

(3) A health IT developer may prohibit or restrict any communication to the extent:

- (i) the communication is unlawful (such as violations of securities law or court orders);
- (ii) the content is false, deceptive, or likely to cause confusion (such as trade libel or trademark infringement);
- (iii) the content is protected by law from disclosure (such as attorney-client privileged communications);
- (iv) the content is subject to a lawful obligation on the health IT developer to prohibit or restrict such communication (such as third-party intellectual property);
- (v) the content was obtained without authorization (such as by a hacker);
- (vi) the communication is to or for the benefit of a competitor or extends beyond the information reasonably required for a specific issue regarding the subject matters enumerated in paragraph (a)(1) (such as the disclosure of a significant number of screen shots revealing broad functionality of an individual developer’s certified health IT rather than a limited number of screen shots for an academic study of a specific usability issue across multiple developers’ certified health IT)

PREAMBLE TEXT RECOMMENDATION

The goal of the unprotected communications provision is to not extend protections of necessitate permitted restrictions for this category of communications. Unprotected communications includes communications such as false communications, communications protected by attorney-client privilege, communications sent by persons who improperly obtained the information (such as a hacker), etc.

Sasha TerMaat had concerns about the definition of health IT developer, understanding that this falls under the purview of the other workgroup.



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

Sasha TerMaat and Andy Truscott worked on editing this section made the changes noted in red text to the regulatory text.

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.

(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.

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

Sasha TerMaat worked to revise the thoughts from the workgroup into the language below.

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.

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.

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

Sasha TerMaat worked to update the language below:

(A) *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.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment.

Next Steps and Adjourn

The next meeting will be held on Thursday, March 28 at 12:00 p.m. ET.

Health Information Technology Advisory Committee

Office of the National Coordinator for Health Information Technology



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