The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Information Blocking Task Force: Draft Recommendations to the HITAC

Andrew Truscott, co-chair
Michael Adcock, co-chair

March 19, 2019

Task Force Draft Presentation: Outline

- Task Force Members
- Task Force Charge
- Progress and Draft Recommendations
  - » Work Group 1 – Relevant Statutory Terms and Provisions
  - » Work Group 2 – Exceptions
  - » Work Group 3 – Information Blocking, Assurances, and Communications Conditions and Maintenance of Certification and Enforcement
- Questions and Feedback

Task Force Members

Name	Organization	Role
Andrew Truscott	**Accenture**	**Co-Chair**
Michael Adcock	**Individual**	**Co-Chair**
Steven Lane	Sutter Health	Member
Sheryl Turney	Anthem Blue Cross Blue Shield	Member
Denise Webb	Individual	Member
Sasha TerMaat	Epic	Member
Aaron Miri	The University of Texas at Austin	Member
Arien Malec	Change Healthcare	Member
Valerie Grey	New York eHealth Collaborative	Member
Anil Jain	IBM Watson Health	Member
Cynthia Fisher	WaterRev	Member
John Kansky	Indiana Health Information Exchange	Member
Lauren Thompson	DoD/VA Interagency Program Office	Member (Federal Rep)
Denni McColm	Citizens Memorial Healthcare	Member

Task Force Charge

- **Overarching Charge**: Provide recommendations on policies related to information blocking; the "information blocking," "assurances," and "communications" conditions and maintenance of certification requirements; and the enforcement of all the conditions and maintenance of certification requirements.
- **Specific Charges:** Provide recommendations on the following topics:
  - Information Blocking:
    - ONC definitions/interpretations of certain statutory terms and provisions, including the price information request for information
    - Seven exceptions to the information blocking definition, and any additional exceptions (request for information)
    - Complaint process
    - Disincentives for health care providers (request for information)
  - "Information blocking," "assurances," and "communications" conditions and maintenance of certification requirements
  - Enforcement of all the conditions and maintenance of certification requirements

Work Group 1 – Structure

Group 1 - Relevant Statutory Terms and Provisions

Topics

- Health information networks/exchanges
- EHI, including the price information request for information
- Practices that may implicate the information blocking provision
- Parties affected by the information blocking provision and exceptions

Members

- Sheryl Turney
- John Kansky
- Denni McColm
- Cynthia Fisher

Work Group 1 – Progress and Recommendations

- **Health information networks/exchanges (HIE/HIN)**
  - The definitions for and distinction between HIE and HIN should be clearer
    - ➢ Discussed whether the scope of proposed definitions align with the intent of the Cures Act
    - ➢ Working on recommendations for revisions to regulation text and preamble
- **EHI definition**
  - **Proposed recommendation**: Add language in preamble that clarifies that "information" is inclusive of human or machine readable form

Work Group 1 – Progress and Recommendations

- **Price information**
  - Multiple views on addressing price transparency in this rule
    - View that price transparency is important, but out of scope for this rule; must consider unintended consequences
    - View that patients need price transparency now and this rule is the appropriate lever for addressing the issue
  - Reviewing ONC's Request For Information (RFI) regarding price information and will provide more detail about the scope and parameters of price information that would be included
  - Considering the implications of including such information in the definition

Work Group 1 – Progress and Recommendations

- **Practices that may implicate the information blocking provision**
  - Discussed scope and implications of examples of potential information blocking
  - Considering updates to examples
- **Parties that may implicate the information blocking provision**
  - Discussed ONC's use of the term "actors" for regulated entities under the information blocking provision
  - Discussed examples of entities that would/would not be considered an "actor" under the proposed definitions of health care provider, health IT developer of certified health IT, health information network, and health information exchange
  - Considering clarifying language and examples in preamble

Work Group 1 – Progress and Recommendations

Questions/Discussion

Work Group 2 - Structure

Group 2 – Exceptions

Topics

- Preventing Harm
- Promoting the Privacy of EHI
- Promoting the Security of EHI
- Recovering Costs Reasonable Incurred
- Responding to Requests that are Infeasible
- Licensing of Interoperability Elements on RAND Terms
- Maintaining and Improving Health IT Performance
- Additional exceptions (request for information)
- Complaint process
- Disincentives for health care providers (request for information)

Members

- Valerie Grey
- Anil Jain
- Arien Malec
- Steven Lane

Work Group 2 – Progress and Recommendations

- **Preventing Harm**
  - Corrupt or inaccurate data, (a)(1): Concern that this could become a large exception loophole (e.g., most people's records have some level of inaccuracy)
    - ➢ Considering proposal to restrict requirement to true data corruption
  - Misidentification of patient's EHI, (a)(2): Suggestion to limit to cases where a data holder *knows* that the data is not applicable to the patient and to create a test
  - Proposal to define "organizational policy"
  - Proposal to clarify the documentation requirement for when there is an individualized finding

Work Group 2 – Progress and Recommendations

- **Promoting the Privacy of EHI**
  - Concern regarding potential overhead requirements for organizations; proposal to address in preamble
  - Proposal to add language that organizational policies must comply with federal, state, and local laws
  - Sub-exception for precondition not satisfied: Proposal that consent (or dissent) should be documented/recorded
  - Sub-exception for health IT developer of certified health IT not covered by HIPAA: Proposal to define/explain meaning of "meaningfully disclosed"
- **Promoting the Security of EHI**
  - Proposal to clarify the documentation requirement for when there is an individualized finding
  - Consensus that when the requestor is the data subject (patient), then security is no reason to prevent sharing, unless there is legitimate doubt of the identity of the patient
    - ➢ Determining whether to make a recommendation

Work Group 2 – Progress and Recommendations

- **Recovering Costs Reasonably Incurred**
  - Proposal to clarify “objective and verifiable”
  - Proposal to be clearer in regulation text that reasonable profits are allowed
  - Concerns about the application of this exception in real life
    - Operational burden for finance/accounting, technical accounting, pricing, legal, etc.
  - Proposal to clarify meaning of “non-standard” implementation
  - Proposal to clarify “intangible asset”
  - Discussed distinction between exceptions for costs reasonably incurred and RAND licensing

Work Group 2 – Progress and Recommendations

- **Responding to Requests that are Infeasible**
  - Concern that “start-ups” with “limited” resources (talent and capital) could use this exception to not participate in the information sharing
    - ➢ Determining whether to make a recommendation
  - Discussion of meaning and application of providing a “reasonable alternative.”
    - ➢ Determining whether to make a recommendation
  - Requirement that the actor “timely respond” is unclear
    - ➢ Determining whether to propose a revision/clarification

Work Group 2 – Progress and Recommendations

- **Licensing of Interoperability Elements on RAND Terms**
  - Proposal to add requirement that licensors must publicly post contact info for requestors to contact them and that requestors must use that publicly posted list to contact licensors
  - Proposal that 10-day response period in (a) is unreasonable for initial offer
    - Considering proposing alternate time frame
  - Proposal to build in timeframe for licensor to acknowledge receipt of request into the overall response timeline
    - Suggestion of 72 hours to acknowledge receipt
  - Discussion about meaning of “royalty” and whether it is the right term
    - Considering proposing alternative language
  - Discussion about use “standards-essential technologies.”
    - Considering proposing alternative language

Work Group 2 – Progress and Recommendations

- **Maintaining and Improving Health IT Performance**
  - Must consider this exception in the context of vendor planned and unplanned downtime and impact of vendor SLAs that may shift responsibility from healthcare entities to vendors that are congruent with this exception
    - ➢ Considering proposing additions to exception
  - Proposal to address situation where one customer does not agree to the proposed period of unavailability which is required to maintain or improve the system, but others do
- **Additional exceptions (request for information)**
  - Need to see final TEFCA before reaching conclusions about TEFCA exception
  - Discussed Business Associate Agreements (BAA) and how they interact with the Cures Act
    - ➢ Considering recommendation to clarify whether the Cures Act preempts BAAs, or alternatively to propose a BAA exception
- **Complaint process** – Not yet discussed
- **Disincentives for health care providers (RFI)** – Not yet discussed

Work Group 2 – Progress and Recommendations

Questions/Discussion

Work Group 3 - Structure

Group 3 - Conditions and Maintenance of Certification

Topics

- Information blocking
- Assurances
- Communications
- Enforcement of all the conditions and maintenance of certification requirements

Members

- Denise Webb
- Sasha TerMaat
- Lauren Thompson
- Aaron Miri

Work Group 3 – Progress and Recommendations

- **Assurances**
  - **Proposed recommendation**: For products that are withdrawn by the developer, a retention period of 3 years after the withdrawal is sufficient.
  - **Proposed recommendation**: ONC should retain records on the Certified Health IT Product List (CHPL) indefinitely for ongoing reference of which products were certified over which time period (as it does today).
  - **Proposed recommendation:** Revisit TEFCA RFI to make recommendations when revised draft of TEFCA is published (or have the TEFCA Task Force address it).

Work Group 3 – Progress and Recommendations

- **Communications**
  - **Proposed recommendation**: Adjust definitions to clarify that administrative functions of HIT could be “non-user facing aspects” based on the assessment that those communications are not matching the purpose described in 21st Century Cures and also affect a limited set of users.
  - **Proposed recommendation**: (D)(2)(iii) should be amended to a list of which third party content might appear in a screen. Enumerating elements per screen is not feasible.
  - **Proposed recommendation**: Unintended consequences of “fair use” and other usages should be further explored by ONC. There are concerns about risks to vendor intellectual property that the task force wishes to be sensitive to; do not wish to impinge upon innovation. Also, ONC should draw a distinction around purpose of use in relation to “fair use” of screenshots, with the intention that the discloser is responsible for ensuring the appropriateness of the purpose.
  - **Proposed recommendation**: ONC should revise estimate in Regulatory Impact Analysis. Effort for notice and contracting is underestimated at 40 hours for clerk. More roles are involved than clerks, including work involved on the part of the recipients.

Work Group 3 – Progress and Recommendations

- **Communications**
  - **Proposed recommendation**: Amend (b)(2)(i) and (b)(2)(ii) as proposed in underlines:
    - (b)(2)(i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.
    - (b)(2)(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.
    - (b)(2)(iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.
  - **Proposed recommendation**: ONC should add a category of communications titled "Unprotected Communications" to their framework. Communications in this category would not be extended these protections, including communications such as false communications, communications protected by attorney-client privilege, etc. "Unprotected Communications" should not receive unqualified protection or necessitate permitted restrictions.

Work Group 3 – Progress and Recommendations

- **Enforcement**
  - **Proposed recommendation**: ONC should use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, and termination.
- **Ban**
  - **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.
- **Self-developers**
  - **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 virtue of being employees of the same company doing the development.

Work Group 3 – Progress and Recommendations

Questions/Discussion

Public Comment

To make a comment please call:

Dial: 1-877-407-7192

*(once connected, press "*1" to speak)*

All public comments will be limited to three minutes.

You may enter a comment in the
"Public Comment" field below this presentation.

Or, email your public comment to onc-hitac@accelsolutionsllc.com.

Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.