The Office of the National Coordinator for Health Information Technology

Health IT Advisory Committee

Information Blocking Task Force: Recommendations to the HITAC

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The Office of the National Coordinator for Health Information Technology

Agenda

- Task Force Charge
- Recommendations
  - Work Group 1 – Relevant Statutory Terms and Provisions
  - Work Group 2 – Exceptions
  - Work Group 3 – Conditions and Maintenance of Certification
- Questions and Feedback
- Vote on Recommendations

Information Blocking 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 - Recommendations

Health Information Network

Recommendation 1: The TF recommends making the following revisions to the definition of "health information network":

Redlined Version:

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

(1) Determines, oversees, administers, controls, or sets ~~substantially influences~~ policies or makes agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange ~~enabling or facilitating access, exchange, or use of electronic health information~~ between or among two or more ~~unaffiliated~~ individuals or entities.

(2) Provides, manages, or controls, ~~or substantially influences~~ any technology or service that enables or facilitates Health Information Exchange ~~the access, exchange, or use of electronic health information~~ between or among two or more ~~unaffiliated~~ individuals or entities.

Clean Version:

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 individuals or entities, or

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

Health Information Exchange

Recommendation 2: The TF recommends making the following revisions to the definition of "health information exchange":

Redlined Version:

Health Information Exchange or HIE means the act of ~~an individual or entity that enables~~ accessing, transmitting, processing, handling, ~~exchange,~~ or other such use of ~~e~~Electronic ~~h~~Health ~~i~~Information, or the organization ~~primarily between or among a particular class of individuals~~ or entity conducting that act.~~ies or for a limited~~

Clean Version:

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 & Health information Exchange

Potential Alternative Approach for Consideration

A potential alternative approach to the distinction between HIE and HIN could be to eliminate the distinction completely, and simply define HIE and HIN as meaning the same by using the above definition of HIN, and referencing both HIE and HIN as having that meaning.

Electronic Health Information

Recommendation 3: The TF recommends making the following revisions to the definition of "electronic health information":

Electronic Health Information (EHI) means—

(1) Electronic protected health information (as defined in 45 CFR § 160.103); and

(2) Electronic Individual Health Information:

(i) 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.

(ii) On the two-year anniversary of the effective date of the final rule, an individual's consent directives including privacy, medical treatment, research, and advanced care.

(3) Electronic information which can reasonably be used to inform care decisions, including by the patient, that may include pricing information.

Electronic Health Information

Minority Opinion: Concern has been expressed by a minority of the IBTF that the definition of EHI is overly restrictive in that it demands that information should identify an individual. This minority opinion suggests that ONC should adopt a revised definition of EHI in the final rule that would remove the requirement that the information be identifiable. The minority opinion believes this change will ensure that information blocking supports patient access to price information to enable shopping for health care services. ONC should also clarify that "future payment" includes price information.

The minority opinion believes that the proposed ONC definition is inconsistent with congressional intent of the Cures Act and definitions in existing law since 1996 (HIPAA). The Cures Act prohibits information blocking of EHI and this term is not defined in the Cures Act. As such, the minority opinion contends that ONC should look to prior definitions in defining this term to effectuate the intent of Congress.

Recommendation 4: Within the definition of Electronic Health Information, the term "information" shall be read as applying to both "Human Readable" information that can be readily understood by a real person actor without specialized reference (e.g. narrative clinical notes), and also "Machine Readable" information that is interpreted by a computerized actor for use either by computerized processes or a real person actor (e.g., data codified using a terminology or classification).

Price Information

Recommendation 5: The IBTF profoundly agrees that price transparency is a desirable goal that is achievable. We further believe that policy levers are required to move the healthcare ecosystem in that direction given the nature of reimbursement. We believe that tying the information blocking proposals too tightly with potential proposals that would be necessary to promote price transparency may have the unintended consequence of slowing down the finalization of the current ONC rule. The finalization of the current rule could be delayed while language to address price transparency is being considered and drafted.

The TF recommends that ONC instantiates through HITAC a task force specifically charged with producing recommendations for future rulemaking to address improving price transparency across the healthcare ecosystem. This newly instantiated task force should consider:

- That the coding for prices can be published simply by using the rate cards between the providers and the payers.
- Whether to get to price transparency, patients need to know the contract negotiated rates.
- How those involved in the financial transactions to support healthcare delivery should provide the real prices. By CPT code or DRGs, bundled and unbundled?
- Whether prices included in the definition of EHI should reflect all services and payment information by all parties (including, but not limited to, health care providers, health plans, insurers, contractors, administrators, pharmacy benefit managers (PBMs), pharmacies, group purchasing organizations (GPOs), technology companies, health IT developers, laboratories, medical devices, brokers and other similar market players).
- The manner in which contract terms, rebates or other forms of incentive payment or other form of remuneration that is or will be directly attributable to a specific service, patient charge or transaction, to a health care provider, facility, pharmacy, or medical equipment provider for the health care services, drugs, or equipment delivered is logged and communicated.

Health IT Developer of Certified Health IT

Recommendation 6

We recommend clarifying that a developer of health IT is a developer because they create IT designed to perform the access, exchange, or use of EHI whether or not that IT is certified.

The IBTF recognizes that the Cures Act does not provide the necessary statutory powers to promote sanctions against health IT developers who are not producing certified health IT, and that while this may be an enforcement gap, it does not mean that some developers should not be subject to the information blocking provision.

Practices That May Implicate the Information Blocking Provision

Recommendation 7: The definitions of "actors" is a necessary distinction for the purpose of identifying sanctions that can be levied; however, we feel that to implicate the information blocking provision focus should be upon the nature of the information potentially being blocked.

Recommendation 8: *Patient Access* - The Task Force believes that "open" patient access to EHI about them is likely to have relevance to the information blocking provisions. The obligation of actors to provide such access in real-time, and free of charge (beyond approved fee exemptions) is not one that is widely understood or implemented now (even in a "paid" manner). Similarly, providing patients with the tools to appropriately parse EHI to ensure it is understandable to them may potentially have relevance to the information blocking provisions and ONC should investigate whether this is the case.

Parties Affected by the Information Blocking Provision and Exceptions

Recommendation 9: The TF recommends that the parties implicated by the information blocking provisions should be:

- those parties who are using information technology to access, exchange, or use EHI to provide patient care (a "provider");
- those parties who are providing information technology services to access, exchange, or use EHI between parties who provide patient care (a "health information network" or a "health information exchange"); and
- those parties who are producing information technology to access, exchange, or use information about patients (a "health information technology developer").

Parties Affected by the Information Blocking Provision and Exceptions

Recommendation 10: The TF recommends that the preamble be updated to give greater specificity as to the real-world organizational types who could fall into these categories. For example:

- Retail pharmacies who curate patient information concerning prescriptions, medications, clinical histories, payments etc. This information is valuable and should not be blocked.
- Insurance companies who curate patient information concerning medical histories, payments etc. This information is valuable to patients as they seek to obtain insurance coverage for care services.
- Retailers who provide IoT type devices and services to collect patient information from connected consumer devices. This information is valuable to patients as they seek their care to be based upon their entire longitudinal health record.

We recognize that with the healthcare environment being under constant change, parties may act as one or more than one of the "actor" definitions, and the regulations should recognize that.

Parties Affected by the Information Blocking Provision and Exceptions

Recommendation 11: The TF recommends that the preamble should also be updated to give greater specificity as to the real-world organizational types who **would not** fall into these categories and **would not** therefore implicate the information blocking provision. For example:

- Organizations to whom patients have expressed informed **dissent** for information sharing (and this should remain an exception to information blocking under the privacy sub-exception for *respecting an individual's request not to share information*);
- Social media networks who provide access to **non-specific** patient attributable health information; and
- Analytics companies who provide population health insights based upon **non-specific** patient data (although a company who provides insights which may be used specific to an identifiable individual **would** implicate the information blocking provision).

The TF also recognizes that there are other individual entities who a patient may wish to have access to information about that patient, such as care givers, proxies, etc.

Parties Affected by the Information Blocking Provision and Exceptions

Recommendation 12: The TF recommends adopting a position of inclusion for implication based upon an actor's involvement with EHI as well as their role in the healthcare ecosystem. We recommend specifically identifying that an entity should not share EHI where a patient has expressly stated their information should not be shared (and this should remain an exception to information blocking under the privacy sub-exception for *respecting an individual's request not to share information*).

Recommendation 13: The TF recommends adding the following text to the preamble and ensuring alignment of existing text to it:

> *The healthcare environment is under constant change. A tight definition of the term "Actor" may only be valid on the day it is authored and for a short time afterwards. By focusing the definition of a relevant "Actor" upon the function they undertake and including covered actors through their actions as opposed to their inclusion within a group we seek to afford evolutionary coverage through this regulation.*

Work Group 1 – Relevant Statutory Terms and Provisions

- ***Questions and feedback***
- ***Vote on recommendations***

Work Group 2 - Recommendations

Preventing Harm

Recommendation 14: Modify the regulatory text in (a) to read "…arising from any of the following -- " prior to sub-items (1) – (3).

Recommendation 15: Modify the regulatory text in (a) (1) to read "Technically corrupt (defined as data that has lost its base integrity and is no longer understandable by the information technology system that created it) or inaccurate data accessed in a patient's electronic health record for intent of access, exchange or use".

Recommendation 16: Add to the regulatory text a sub-item (d) that the practice should be documented in the electronic health record or system recording the EHI by the appropriate user when the exception arising from using conditions (a) - (c) and must contain the reasoning and criteria used in the judgement of the user who is engaging in the practice under this exception.

Recommendation 17: The regulatory text in (b) is confusing; the word "practice" refers to the information blocking potentially occurring under an exception. Perhaps rephrasing "If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—".

Preventing Harm

Recommendation 18: The regulatory text in (b) is confusing; the word "practice" refers to the information blocking potentially occurring under an exception. Perhaps rephrasing "If the practice (referring to the permissible information blocking activity) relies on an organizational policy, the policy must be—".

Recommendation 19: Recommend adding clear guidance (in preamble) of when this exception should be used versus the exceptions for infeasibility and maintenance.

Recommendation 20: Consider adding examples of where exceptions related to preventing harm from corrupt or inaccurate data or incorrect patient identification may interact with the exception for infeasibility.

Promoting the Privacy of EHI

Recommendation 21: The TF recommends adding language indicating that organizational policies must comply with federal, state, and local laws.

Recommendation 22: The TF recommends that in section (b)(2) express consent (or dissent) should be documented and recorded.

Recommendation 23: The TF recommends that in section (c)(3) the reference to "meaningful" is replaced with "clear and prior notice."

Recommendation 24: The TF recommends that organizational practices that are extra to HIPAA or other relevant legislation should clearly be forbidden. For example, policies that restrict transmission to individuals via email where such is the requested form and format of access. In many cases documented organizational policies are used to deny access where access is required.

Promoting the Privacy of EHI

Recommendation 25: The Task Force **recommends** that the final rule should specify that organizations should implement policies which ensure compliance with patient consent to information sharing (or lack of information sharing).

Recommendation 26: The TF recommends that if an actor functions in multiple states, some of which have more restrictive laws, the actor should implement policies and procedures that accommodate those more restrictive laws only in circumstances where they are required and not extend those greater restrictions to situations where they are not required by law.

Promoting the Security of EHI

Recommendation 27: The TF recommends that if the entity requesting patient information can be reasonably considered "legitimate" in that they have passed relevant authentication mechanisms and can reasonably be considered to have appropriate organizational policies in place to protect patient information, then ignorance of that requestor's specific controls is no reason to claim this exception.

Recommendation 28: The TF recommends modifying the regulatory text to reflect that if the requestor is the patient (data subject) themselves, and the patient is fully informed to the risks of their information not being appropriately secured, this exception cannot be claimed.

Recommendation 29: The TF recommends that actors should not have flexibility to adopt security practices, even when grounded in some standard, that are commercially unreasonable relative to leading practices for sensitive data, in ways that limit and restrict access to data for permissible purposes, unless there is some overriding legal obligation. As an example, although FedRAMP High or SRG High are defined standards, requiring FedRAMP High ATO as a standard for any data requester would serve to limit interoperability, unless there were some overriding security concern (e.g., MHS or VHA records that contain data relevant to national security).

Recovering Costs Reasonably Incurred

Recommendation 30: The TF recommends that ONC combine the regulatory text currently supplied for 171.204 and 206 into a single allowed fee exception that clearly defines allowed and disallowed fee categories.

Recommendation 31: The TF recommends ONC use terminology that distinguishes between pure cost or expense recovery with no provision for margin or profit where this is intended and use terms such as "cost-based pricing" where margin or profit is allowed and "market-based pricing" where no restrictions on pricing are needed.

Recommendation 32: Where cost-based pricing mechanism are required, the TF recommends that the method for assessing the cost basis be reasonably associated with the complexity or cost of providing capabilities. Such methods could include reasonable heuristics, estimates or other commonly used methods. For example, size of organization, as measured in revenue or operating expense, is a commonly used heuristic to define pricing for exchange services, because revenue/expense is commonly available and directly correlated with patient flow, which is directly correlated with data volumes. Requiring activity-based accounting mechanism sufficient to account for the direct cost of providing, e.g., access services, is burdensome and is not a common or usual accounting practice. The Task Force believes that reasonable heuristics or estimates are sufficient to avoid arbitrary fees that could constitute information blocking without placing undue burden on actors.

Recovering Costs Reasonably Incurred

Recommendation 33: The TF recommends that ONC distinguish between ***basic access*** (to the data or facts about the patient or patients, to the legal medical record or Designated Record Set, etc., including prospective patient specific pricing for procedures, etc.) through standards (from the core standards list) reasonably required to enable exchange or implement the intended use of a certified technology (e.g., HL7 LRI/LRO lab interfaces for a results and orders capability, or NCPDP SCRIPT standards for a prescribing capability); and other forms of value-added access, exchange and use (e.g., infrastructural systems, capabilities that translate, perform decision support, use artificial intelligence or machine learning, provide novel or clinically validated renderings of data, etc.).

Recommendation 34: Notwithstanding the recommended distinction between basic and value-added capabilities, the TF recommends that when the output of value-added services are incorporated into, or form, an essential part of the legal medical record, or are routinely used for decision making, they constitute part of the set to which basic access is required (e.g., if a vendor supplies clinical risk scoring services based on the basic record, those services may be offered at market rates; if the risk score is incorporated into or used by clinical staff to make clinical decisions, the individual risk score accordingly becomes part of the record and forms part of basic access to which basic access fee regulation is applied).

Recovering Costs Reasonably Incurred

Recommendation 35: The TF recommends that ONC distinguish between IPR that are ***essential*** to access and IPR that allow for value-added services. The former would include standards-essential IPR or any IPR licensing associated with terminology either defined in certified standards or reasonably required based on regulatory requirements or customary use.

Recommendation 36: The TF recommends that allowed fees for basic access be on a pure direct cost recovery basis only. In many cases, where basic access is provided via widely deployed consensus-based certified standards built into health IT, such direct costs would be minimal. The Task Force does **not** recommend that the cost to develop standards be part of the cost basis for fees for basic access; rather any such costs should be a part of the fees for the health IT. The Task Force believes this approach provides a significant incentive to adopt standards; actors who do not provide access through widely deployed consensus-based standards would have an incentive to do so to reduce the total cost structure of access. The Task Force recommends that the cost basis for fees basic access **not** include reasonable mapping to standards (that is, such one-time costs would be a cost of producing Health IT, not a cost of access); such mapping would include mapping of proprietary terminologies used internally to the standard terminologies used externally (e.g., internal problem list terminologies to SNOMED CT, or proprietary medication databases to RxNorm). Exceptions would include cases where data or terminology sets exist that are not reasonable to include in mapping to standards AND where sufficient mechanisms of basic access exposing the non-standard data exist. In these cases, there are market-based mechanism (e.g., systems integrators) sufficient to set prices for non-standard data mapping.

Recovering Costs Reasonably Incurred

Recommendation 37: The TF recommends that allowed fees for access, exchange and use essential IPR be set on a RAND-basis. Such fees would not be "reasonable" if they materially discourage access, exchange or use, or impede the development of competitive markets for value-added exchange and use services. The TF recommends that access, exchange and use-essential IPR license grants be sufficient for actors to provide access and/or deliver exchange and use services; for example, IPR grants for terminology sets that are access, exchange and use essential should be sufficient to allow access, exchange and use for permissible purposes. To put this another way, actors would not be able to accept IPR licenses that restrict access only those who also have IPR rights.

Recommendation 38: The TF recommends no further restrictions on permitted fees; the Task Force believes that the above restrictions on permitted fees are sufficient to address monopoly rents or gatekeepers and enable market-based pricing for additional services.

Responding to Requests that are Infeasible

Recommendation 39: The TF recommends the following revisions to the regulatory text:

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Request is infeasible*.

(1) The actor must demonstrate, in accordance with paragraph (a)(2) of this section, that complying with the request in the manner requested would impose a substantial burden on the actor that is unreasonable under the circumstances, taking into consideration—

….

(vii) whether similarly situated actors provide similar access, exchange or use;

….

(b) *Responding to requests*. The actor must ~~timely~~ respond to all requests relating to access, exchange, or use of electronic health information, including but not limited to requests to establish connections and to provide interoperability elements in a timely manner under the circumstances which shall not exceed 10 business days. Such response shall include ~~(c) *Written explanation*. The actor must provide the requestor with~~ a detailed written explanation of the reasons why the actor cannot accommodate the request.

(~~d~~c) *Provision of a reasonable alternative*. The actor must work with the requestor in a timely manner to identify and provide a reasonable alternative means of accessing, exchanging, or using the electronic health information as applicable.

Licensing of Interoperability Elements on RAND Terms

Recommendation 40: The TF recommends the following revisions to the regulatory text:

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Responding to requests*. Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within 10 business days from receipt of the request by:

(1) Negotiating with the requestor in a reasonable and non-discriminatory fashion to identify the interoperability elements that are needed;

(2) Offering an appropriate license with reasonable and non-discriminatory terms; and

(3) Beginning negotiations with the intent to furnish a quotation for a license

(b) *Reasonable and non-discriminatory terms*. The actor must license the interoperability elements described in paragraph (a) of this section on terms that are reasonable and non-discriminatory.

(1) *Scope of rights*. The license must provide all rights necessary to access and use the interoperability elements for the following purposes, as applicable.

(i) Developing products or services that are interoperable ~~with the actor's health IT, health IT under the actor's control, or any third party who currently~~ us~~es~~ing the licensed ~~actor's~~ interoperability elements ~~to interoperate with the actor's health IT or health IT under the actor's control.~~

(ii) Marketing, offering, and distributing the interoperable products and/or services to potential customers and users.

(iii) Enabling the use of the interoperable products or services in production environments, including accessing and enabling the exchange and use of electronic health information.

Maintaining and Improving Health IT Performance

Recommendation 41: The TF recommends that ONC generalize the maintenance exception to cover the following:

- Rate limiting or disabling use of the health IT by user or actors whose use is unusual or would cause degradation of overall performance
- Reasonable and usual practices where SLA or maintenance windows are not named in contract
- Out of SLA performance with reasonable good-faith activity to restore service in a timely matter
- Force majeure or other highly unusual events out of the control of the actor.
- Failure to consider these exceptions raises the risk that ordinary failures to achieve good faith service restoration would be adjudicated as information blocking, rather than through normal contractual resolution processes, and would create a paradoxical incentive for actors to insist on negotiating lower SLA achievement targets.
- While we understand that some actors have caused information blocking by abandoning technology, we believe such instances are rare and would not trigger the exceptions noted above.

Maintaining and Improving Health IT Performance

Recommendation 42: The TF recommends making the following revisions to the regulatory text:

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) *Maintenance and improvements to health IT*. An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT, provided that the actor's practice is—

(1) a reasonable, good-faith activity lasting ~~For~~ a period of time no longer than necessary to achieve the maintenance or improvements for which the health IT was made unavailable; and

(2) Implemented in a consistent and non-discriminatory manner.~~; and~~

~~(3) If the unavailability is initiated by a health IT developer of certified health IT, HIE, or HIN, agreed to by the individual or entity to whom the health IT developer of certified health IT, HIE, or HIN supplied the health IT.~~

(b) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

(c) *Security-related practices*. If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.

(d) *Responding to requests that are infeasible.* If the unavailability of health IT is due to highly unusual events out of the control of the actor such as a natural disaster, the actor does not need to satisfy the requirements of this section, if the practice complies with all requirements of §171.205.

Additional Exceptions (Request for Information)

Recommendation 43: The TF recommends that the status of contractual obligations that may be in conflict with information blocking obligations be explicitly clarified by ONC as being void. The simplest solution would be to interpret the intent of Congress to preempt specific contractual terms that are in conflict with the 21st Century Cures Act.

Recommendation 44

Trusted Exchange Framework and Common Agreement

In ONC's Proposed Rule, ONC noted that they are considering whether they should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement (CA). The release of the second draft of the Trusted Exchange Framework (TEF) late in the public consultation period for the Proposed Rule has given the IBTF the opportunity to comment upon the TEF and the CA.

Considerable discourse has taken place, with two distinct views being articulated:

- That compliance with the TEF should provide a "safe lane" which demonstrates to ONC/HHS Office of Inspector General (OIG) that information blocking is not taking place; and
- That providing a "safe lane" is a protectionist approach which should not be adopted and the TEF should be a series of good practice guidelines.

We urge ONC during the rulemaking process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision, potentially through adoption of the TEF, and the need to investigate information blocking activities where warranted – and not inadvertently provide bad actors with an opportunity to circumvent regulation compliance.

Complaint Process

The IBTF supports ONC's proposal on the information blocking complaint process as it is written in the Proposed Rule with no further edits or comments.

Disincentives for Health Care Providers (Request for Information)

Recommendation 45: The TF recommends that ONC work with CMS to build information blocking disincentives into a broad range of CMS programs, and that ONC work with other Federal departments and agencies that contract with providers (e.g., VHA, DoD MHS, IHS, CDC, etc.) to similarly build information blocking disincentives into contracting and other programs.

Recommendation 46: The TF recommends that providers attest to comply with information blocking requirements as a part of Conditions of Participation, Conditions for Coverage, contracts, and other similar relationships, covering both FFS, value-based care, and direct payment relationships, and that findings of information blocking by OIG, findings violations relating to information blocking attestations of the False Claims Act by FTC, or other similar enforcement actions trigger disincentives up to and including removing organizations from participation or coverage.

Work Group 2 - Exceptions

- ***Questions and feedback***
- ***Vote on recommendations***

Work Group 3 - Recommendations

Information Blocking Condition of Certification

The IBTF supports ONC's proposal on the Information Blocking Condition of Certification as it is written in the Proposed Rule with no further edits or comments.

Assurances – Condition of Certification

Recommendation 47: The TF recommends the following revisions to the regulatory text:

(a) *Condition of Certification.*

…(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.

…(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) ~~within~~ 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition.~~, whichever is longer.~~

(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.

Assurances Request for Information

Recommendation 48: The release of the second draft of the TEF late in the public consultation period for the Proposed Rule has given the IBTF the opportunity to comment upon the TEF and the CA.

Considerable discourse has taken place, with two distinct views being articulated:

That compliance with the TEF should provide a "safe lane" which demonstrates to ONC/OIG that Information Blocking is not taking place; and

That providing a "safe lane" is a protectionist approach which should not be adopted and the TEF should be a series of good practice guidelines.

We urge ONC during the rulemaking process to consider carefully the enduring demand of the Cures Act to promote information sharing and prohibit information blocking amongst all actors involved in the provision and administration of care. We believe that a careful balance needs to be struck to encourage compliance to the information blocking provision, potentially through adoption of the TEF, and the need to investigate information blocking activities where warranted – and not inadvertently provide bad actors with an opportunity circumvent regulation compliance.

Communications

Recommendation 49: There was concern in the TF that ONC's timeline for updates to contracts was insufficient and that the work was significantly underestimated by ONC's regulatory impact analysis. There was an example raised from a member of the group of needing to hire four additional lawyers to complete the work in that timeframe. The intent was to instead have health IT developers propose a plan for contract updates in 2 years, and update contracts at next renewal or within 5 years.

The Task Force recommends the following revisions to the regulatory text:

(2) Contracts and agreements.

(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, ~~amend the contract or~~ 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.

Communications

Recommendation 50: It was discussed that attempting to enumerate on a screen what might be third-party content that was the intellectual property of a third party was infeasible. Instead, health IT developers could provide a list of third-party content that might be present.

The Task Force recommends the following revisions to the regulatory text:

> (iii) The developer has put all potential communicators on sufficient written notice of a list of third-party content included in the health IT ~~each aspect of its screen display that contains third-party content~~ that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights;

Recommendation 51: There was discussion of whether administrative functions of health IT could unintentionally reveal significant intellectual property of health IT developers. For example, the security configuration of health IT is less important in meeting the needs of communications protected under the Cures Act.

The Task Force recommends clarifying in the preamble that appropriate administrative functions of health IT could be included as "non-user facing aspects" based on the assessment that those communications are not matching the purpose required by the Cures Act and that also affect a limited set of users.

Communications

Recommendation 52: There was 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 the Cures Act 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.

The Task Force recommends the following revisions to the regulatory text:

(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".

Communications

Recommendation 53: In (2)(i)(A), the group felt that it was reasonable for health IT developers to request that they be notified when a disclosure required by law takes place, and that this was accommodated in the current regulatory text.

Recommendation 54: In (2)(i)(C), the group felt that notification to health IT developers prior to (or simultaneous with, if prior was not possible) public reporting would be beneficial for resolving security vulnerabilities prior to the knowledge being widespread.

Recommendation 55: In (2)(i) the group felt that a specific protection might be called for those individuals who highlight information blocking practices and identify them to the appropriate authorities so that the individual is not subject to retaliatory action by the actor identified by the whistleblower. Obviously ONC would need to phrase it so that a whistleblower would not be able to leverage this as mechanism to avoid sanctions for other activities (e.g. performance etc.).

The Task Force recommends the following addition to regulatory text:

> (E) Communicating information about a health IT developer's failure to comply with a Condition of Certification, or with any other requirement of this part, to ONC or an ONC-ACB. 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.

Communications

Recommendation 56: The Task Force recommends an additional category of communications that would not be protected (neither receiving unqualified protection nor their restriction necessitating a permitted restriction). The intent was that this category would include communications such as false communications, things protected by attorney-client privilege, and so forth. The Task Force did not intend for false communications such as libel to be protected as an unintended consequence. Other examples of unprotected communications might include communications sent by a person who improperly obtained the information or received it from somebody who did not have the right to provide the information, such as a hacker.

The Task Force recommends clarifying in preamble that the goal of the unprotected communications provision is to not extend protections of necessitate permitted restrictions for this category of communications. Specifically, where a communication is unlawful (such as violations of securities law or court orders); the content is false, deceptive, or likely to cause confusion (such as trade libel or trademark infringement); the content is protected by law from disclosure (such as attorney-client privileged communications); 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); or the content was obtained without authorization (such as by a hacker).

The Task Force recommends the following addition to regulatory text:

> (a)(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:
>
> (i) protected by other legislation or regulation; or
>
> (ii) false or unlawful.

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

Recommendation 57: The TF recommends the following addition to the regulatory text:

§ 170.505 Correspondence.

(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.

The TF recommends that ONC also clarify in preamble that ONC should use both email and certified mail for notices of initiating direct review, potential non-conformity, non-conformity, suspension, proposed termination, termination and ban. Notices regarding appeals would be the same.

Certification Ban

Recommendation 58: Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.

Recommendation 59: 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

Recommendation 60: The Task Force recommends that ONC 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.

The corresponding addition to the regulatory text is as follows:

> § 170.403 Communications.
>
> (a)(2)(ii)(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.

Work Group 3 – Conditions and Maintenance of Certification

- ***Questions and feedback***
- ***Vote on recommendations***

Questions and Feedback

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