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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# Agenda

- Task Force Charge
- Recommendations (not yet voted on)
  - 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 sets policies or makes 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:

~~a~~Any ~~individual or~~ entity performing the ~~that enables~~ access, exchange, transmittal, processing, handling or other such use of ~~e~~Electronic ~~h~~Health ~~i~~Information ~~primarily between or among a particular class of individuals or entities or for a limited set of purposes.~~ who is not considered a Provider, Health Information Network, or Health IT Developer.

**Clean Version:**

*Health Information Exchange* or *HIE* means:

Any entity performing the access, exchange, transmittal, processing, handling, or other such use of Electronic Health Information who is not considered a Provider, Health Information Network, or Health IT Developer.

# 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, by a provider or patient, including pricing information which can be attributable to an individual patient.

# 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.

The minority opinion believes that the simplest and most logical interpretation of "electronic health information" is to use the definition of "health information" which is not limited to identifiable information. The minority opinion believes that Congress knew there were different terms for "health information", "individually identified health information", and "protected health information" under HIPAA when it drafted the Cures Act and wished to include all of these within the Cures Act. Congress did not use the term Electronic Individually Identifiable Health Information, which would have limited information blocking to identifiable information.

# Electronic Health Information

**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 in the Proposed Rule 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.

We recommend 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:

- How generalized price information can be made readily accessible and available to patients, providers, purchasers, payers and other relevant stakeholders to inform care decisions.
- 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**: [This recommendation has been removed]

**Recommendation 8**: *Patient Access* - The Task Force believes that "open" patient access to EHI about them is likely to have implications that relate to the information blocking provision. 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 implications that relate to the information blocking provision and ONC should investigate whether this is the case.

# Parties Affected by the Information Blocking Provision and Exceptions

**Recommendation 9**: [This recommendation has been removed]

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

Retail pharmacies who curate patient information concerning prescriptions, medications, clinical histories, payments etc. This information is considered EHI and should not be blocked. The IBTF believes that Retail Pharmacy would already be considered a Provider through inclusion as a subpart of all Pharmacies. This is desirable to confirm.

Insurance companies who curate patient information concerning medical histories, payments etc. This information is important to patients as they seek to obtain insurance coverage for care services.

Retailers who provide patient information services through IoT type devices and services from connected consumer devices. This information is considered EHI and must not be blocked.

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 IBTF 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 IBTF 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 access, exchange, or use of 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

# Recovering Costs Reasonably Incurred

**Recommendation 30:** The Task Force **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 Task Force **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.

# Recovering Costs Reasonably Incurred

**Recommendation 32:** Where cost-based pricing mechanism are required, the Task Force **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 Task Force **recommends** that ONC distinguish between **Basic Access** and **Value-Added** Access, Exchange, and Use. Within this recommendation references to Designated Record Set and Covered Entity are interpreted in line with 45 CFR 164.501.

The IBTF suggests that ONC consider the following definitions appropriate:

- **Basic Access** where:
  - If an entity is considered a Covered Entity, information that is included within the Designated Record Set as defined in 45 CFR 164.501; or
  - If an entity is a Provider that is not a Covered Entity, the Designated Record Set as defined in 45 CFR 164.501; or
  - If an entity is considered a HIE, HIN, or developer of health information technology, the information that was collected on behalf of a Covered Entity or non-Covered Entity; and
  - Basic transformation of data required to implement standards (from the core standards list) reasonably required to enable exchange or implement the intended use of a certified technology.
- ***Value-Added Access***, exchange and use not included in Basic Access above.
  - For example, infrastructural systems, capabilities that translate, transform, localize, perform decision support, complex transformations, or use artificial intelligence or machine learning, provide novel renderings of data, etc.

The IBTF notes that the emergent definition of USCDI may provide a useful definitional basis for Basic and Value Added access in the future.

# Recovering Costs Reasonably Incurred

**Recommendation 34:** Notwithstanding the recommended distinction between basic and value-added capabilities, the Task Force **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).

**Recommendation 35:** The Task Force **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.

# Recovering Costs Reasonably Incurred

**Recommendation 36:** The Task Force **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 Task Force **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 Task Force **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 Task Force **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.

# Work Group 2 - Exceptions

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

# Work Group 3 - Recommendations

# Assurances Request for Information

**Recommendation 48:** [This recommendation has been removed]

# 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 is responsible for communicating that each use is to be put to "fair use."

# Work Group 3 – Conditions and Maintenance of Certification

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

# Questions and Feedback