



## Meeting Notes

### Health Information Technology Advisory Committee

#### Information Blocking Task Force

March 22, 2019, 11:30 a.m. – 01:00 p.m. ET

Virtual

The March 22, 2019 meeting of the Information Blocking, Assurances, & Communications Conditions of Certification Task Force (IACCTF) of the Health IT Advisory Committee (HITAC) was called to order at 11:30 a.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

### Roll Call

#### MEMBERS IN ATTENDANCE

**Michael Adcock, Co-Chair**, Individual  
**Andrew Truscott, Co-Chair**, Accenture  
Cynthia Fisher, Member, WaterRev, LL  
Valerie Grey, Member, New York eHealth Collaborative  
Anil Jain, Member, IBM Watson Health  
John Kansky, Member, Indiana Health Information Exchange  
Arien Malec, Member, Change Healthcare  
Aaron Miri, Member, The University of Texas at Austin, Dell Medical School, and UT Health Austin  
Sasha TerMaat, Member, Epic  
Sheryl Turney, Member, Anthem  
Denise Webb, Member, Individual

#### MEMBERS NOT IN ATTENDANCE

Steven Lane, Member, Sutter Health  
Denni McColm, Member, Citizens Memorial Healthcare  
Lauren Thompson, Member, DoD/VA Interagency Program Office

#### ONC STAFF

Elise Anthony, ONC  
Cassandra Hadley, HITAC Backup/Support  
Penelope Hughes, ONC Staff Lead  
Mark Knee, ONC Staff Lead  
Mike Lipinski, ONC Staff Lead  
Lauren Richie, Branch Chief, Coordination, Designated Federal Officer  
Lauren Wu, ONC SME

### Call to Order



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

**Andy Truscott** welcomed the members, reviewed the agenda, and turned the meeting over to Denise Webb.

## Electronic Health Information Export

### Conditions and Maintenance of Certification Requirements Task Force (CMCTF) Discussion

**Denise Webb** shared that the certification and maintenance taskforce was reviewing the electronic health information export and wanted to bring the discussion to this group. The CMCTF felt that the definition of EHI is broad and struggled with the requirements to create an export function.

- **Arien Malec** asked what the legal definition of a medical record is.
- **Sasha TerMaat** shared that the data set that would be received would be the legal medical record. The conversation did not define the legal medical record. There was concern regarding items that might not be considered part of the legal medical record (e.g., unfinished note).
- **Arien Malec** noted that there is a struggle with exceptions within information blocking. Getting the definition of EHI correct is critical. He had concerns about the legal medical record.
- **John Kansky** noted that the designated record set is a convenient definition to use.
- **Denise Webb** noted that the issue around the legal medical record is important, but the other half of the definition related to only data collected, received and retained by certified technology.
- **Michael Lipinski** noted that it has to be a certified developer to hold them accountable.

## Information Blocking Presentation

### MICHAEL LIPINSKI, ONC

**Michael Lipinski** reviewed a prepared presentation to discuss information blocking.

#### Disclaimer

- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the NPRM as it is contained in the NPRM. ONC cannot interpret that information, nor clarify or provide any further guidance.
- ONC cannot address any comment suggestion or statement made by anyone attending the presentation or consider any such comment or suggestion in the rule writing process.
- Please submit comments through the formal process outlined in the Federal Register

#### HHS FY 2015 Appropriations Act

- Congress states “ONC should use its authority to certify only those products that...do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in CEHRT, and make CEHRT less valuable and more burdensome for eligible hospitals and eligible providers to use.”



- Congress requests a detailed report from ONC regarding the extent of the information blocking problem, including an estimate of the number of vendors or eligible hospitals or providers who block information. This detailed report should also include a comprehensive strategy on how to address the information blocking issue.

## ONC Report to Congress - Defining Information Blocking

- Report Definition and Criteria Information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information. This definition requires three criteria be met:
  1. Interference. Information blocking requires some act or course of conduct that interferes with the ability of authorized persons or entities to access, exchange, or use electronic health information. This interference can take many forms, from express policies that prohibit sharing information to more subtle business, technical, or organizational practices that make doing so more costly or difficult.
  2. Knowledge. The decision to engage in information blocking must be made knowingly. An individual or entity does not engage in information blocking unless it knows (or should know under the circumstances) that its conduct is likely to interfere with the exchange or use of electronic health information.
  3. No Reasonable Justification. Not all conduct that knowingly interferes with electronic health information exchange is information blocking. Accusations of information blocking are serious and should be reserved for conduct that is objectively unreasonable in light of public policy. Conduct that is required to comply with federal or state privacy law would not be “unreasonable” and would not constitute information blocking under these criteria. Public policy must be balanced to advance important interests, including furthering the availability of electronic health information as needed for authorized and important purposes; protecting and promoting patient safety; maintaining the privacy and security of electronic health information; and protecting the legitimate economic interests and incentives of providers, developers, and other market participants to innovate and compete in ways that ultimately enhance technology, health care, and consumer health and welfare

## Information Blocking in the 21st Century Cures Act

21st Century Cures Act, Section 4004:

- Defines “information blocking” (§ 3022(a)(1), PHSA).
- Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking (§ 3022(a)(3), PHSA).
- Empowers the HHS Office of Inspector General (OIG) to investigate claims of information blocking (§ 3022(b)(1), PHSA) and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR) (§ 3022(b)(3)(A), PHSA).
- Prescribes penalties for information blocking (§ 3022(b)(2), PHSA). » Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints (§ 3022(d)(2) and (3), PHSA).

## What Makes You an Information Blocker?

- Information blocking definition



- A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.
- Elements of information blocking
  - Actor regulated by the information blocking provision
  - Involves electronic health information (EHI)
  - Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
  - Requisite knowledge by the actor
  - Not required by law
  - Not covered by an exception

## Consequences of Being an Information Blocker

- Cures Act prescribes penalties for information blocking (§ 3022(b)(2), PHSA)
  - Health IT developers of certified health IT (or other entity offering certified health IT), health information networks, and health information exchanges > Civil monetary penalties up to \$1 million per violation
  - Health care providers > Appropriate disincentives
- ONC proposes a certification ban (§ 170.581) under the ONC Health IT Certification Program for health IT developers
  - “Information Blocking” Condition of Certification (proposed § 170.401)
  - Public listing of certification bans and terminations
- CMS proposes public reporting of clinicians and hospitals who submit a “no” response to attestation statements related to information blocking

## "Actors" Regulated by the Information Blocking Provision

- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Networks (HIN)
- Health Information Exchanges (HIE)

## Health Care Providers

- a hospital
- skilled nursing facility
- nursing facility
- home health entity or other long-term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider



- federally qualified health center
- group practice
- a pharmacist
- a pharmacy
- a laboratory
- a physician
- a practitioner
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- a rural health clinic
- a “covered entity” under certain statutory provisions
- an ambulatory surgical center
- a therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

We are considering adjusting the information blocking definition of “health care provider” to cover all individuals and entities covered by the HIPAA “health care provider” definition.

## Health IT Developer of Certified Health IT

- An individual or entity that develops or offers health information technology and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health IT (one or more) certified under the Program.
- The Cures Act does not prescribe that conduct that may implicate the information blocking provisions be limited to practices related to only certified health IT.
- The Cures Act does not impose a temporal nexus that would require that information blocking be carried out at a time when an individual or entity had health IT certified under the Program.
  - We seek comment on methods to ensure that health IT developers of certified health IT will face consequences under the information blocking provision if they engage in information blocking in connection with EHI that was stored or controlled by the developer or offeror while they were participating in the Program.

## Health Information Networks

- An individual or entity that satisfies one or both of the following
  - Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.
  - Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.
- Two parties are affiliated if one has the power to control the other, or if both parties are under the common control or ownership of a common owner.

An entity is established within a state for the purpose of improving the movement of EHI between the health care providers operating in that state.



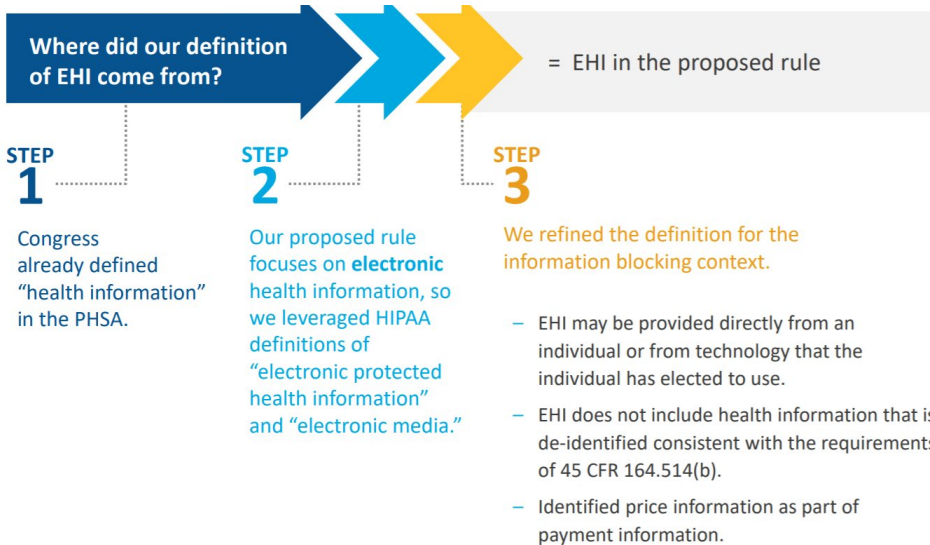
A large health care provider (or other entity) functioning as a HIN.

## Health Information Exchanges

- An individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes.
- HIEs include but are not limited to regional health information organizations (RHIOs), state health information exchanges (state HIEs), and other types of organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties or for particular purposes
- An HIE might facilitate or enable the access, exchange, or use of EHI for a limited scope of participants and purposes (such as a clinical data registry).
- If an HIE facilitates the access, exchange, or use of EHI for more than a narrowly defined set of purposes, then it may be both an HIE and a HIN.

## Electronic Health Information

- We propose to define electronic health information (EHI) to mean electronic protected health information (as defined in HIPAA), and any other information that:
  - is transmitted by or maintained in electronic media (as defined in 45 CFR 160.103)
  - 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
  - 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 for the provision of health care to an individual.





## Observational Health Information

- “Observational health information” includes:
  - Health information about a patient that could be captured in a patient record within an EHR and other clinical information management systems;
  - Information maintained in administrative and other IT systems when the information is clinically relevant, directly supports patient care, or facilitates the delivery of health care services to consumers.
- Information blocking concerns are especially pronounced when conduct concerns EHI that is created or maintained during the practice of medicine or the delivery of health care services.

## Additional information that could be considered EHI

- EHI that is created through aggregation, algorithms, and other techniques that transform observational health information into fundamentally new data or insights that are not obvious from the observational information alone. This could include, for example, population-level trends, predictive analytics, risk scores, and EHI used for comparisons and benchmarking activities.
- An individual’s health insurance eligibility and benefits.
- Billing for health care services.
- Payment information for services to be provided or already provided, which may include price information.

## Price Information – Request for Comments and Information

- The fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, health systems, plans, plan sponsors and other key health care stakeholders.
- ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information.
  - We seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking.
- Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers.
  - The overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.

## Interoperability Element

- We use the concept to analyze the likelihood of interference under the information blocking provision, and to structure some of the proposed exceptions.
- “Interoperability element” refers to any means by which EHI can be accessed, exchanged, or used.
  - Includes functional elements, technical information, technologies, services, licenses, rights, privileges, and other conditions necessary to support the many potential uses of EHI.
- An actor who controls an interoperability element of health IT that could be used to access, exchange, or use EHI is at risk of violating the information blocking provision if the actor refuses to allow others to license or use that interoperability element on reasonable terms.



- This applies regardless of whether the person who requires use of the interoperability element might complement or compete with the actor's own technology or services.

## Interfere with Access, Exchange, or Use

- “Interfere with, prevent, or materially discourage ”
  - The terms “interfere with” and “interference” are used inclusive of prevention, material discouragement, and other forms of interference that implicate the information blocking provision.
  - We interpret “interference” broadly and to take many forms.
- “Access, exchange, or use”
  - These concepts are closely related
    - EHI cannot be used unless it can be accessed, and this often requires that the EHI be exchanged among different individuals or entities and through various technological means.
  - We propose to adopt interrelated definitions:
    - “Access” means the ability or means necessary to make electronic health information available for use, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained. » “Exchange” means the ability for EHI to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used.
    - “Use” means the ability of health IT or a user of health IT to access relevant EHI; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose.

## Practices That Implicate the Information Blocking Provision

### OVERARCHING PRINCIPLE

- To implicate the provision is not necessarily to violate it.
- Practices that implicate the information blocking provision:
  - Imposing formal restrictions on access, exchange, or use of EHI
  - Imposing informal restrictions on access, exchange, or use of EHI » Disabling or restricting the use of a capability that enables users to share EHI with users of other systems
  - Implementing capabilities in ways that limit the timeliness of access, exchange, or use of EHI
  - Imposing terms or conditions on the use of interoperability elements that discourage their use
  - Discouraging efforts to develop or use interoperable technologies or services by exercising influence over customers, users, or other persons
  - Discriminatory practices that frustrate or discourage efforts to enable interoperability
  - Rent-seeking and opportunistic pricing practices
  - Implementing health IT in non-standard ways that substantially increase the complexity or burden of accessing, exchanging, or using EHI (for instance, not complying with section 3004 of the PHSA or consensus standards)

## Knowledge Standard





- Health Care Providers
  - “...knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information...” emphasis added.
- Health IT Developers of Certified Health IT, HINs, and HIEs
  - “...knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information...” emphasis added.

## Required by Law

- It refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.
  - We have distinguished between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law.”
- Example – Privacy Practices Required by Law
  - The HIPAA Privacy Rule requires that a covered entity must agree to the request of an individual to restrict disclosure of protected health information (PHI) about the individual to a health plan if the disclosure is for the purpose of carrying out payment or health care operations and not otherwise required by law and the PHI pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full. 45 CFR 164.522(a)(1)(vi).

## Overview of Exceptions

- The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.
- If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.
- Proposed exceptions to the information blocking definition
  - 171.201 — Preventing harm
  - 171.202 — Promoting the privacy of EHI
  - 171.203 — Promoting the security of EHI
  - 171.204 — Recovering costs reasonably incurred
  - 171.205 — Responding to requests that are infeasible
  - 171.206 — Licensing of interoperability elements on reasonable and non-discriminatory terms
  - 171.207 — Maintaining and improving health IT performance

**Michael Lipinski** thought this was a good stopping point and agreed to help share additional information along with Mark Knee at a future workgroup meeting.

**Lauren Richie** opened the lines for public comment.

## Public Comment

There was no public comment.



## Comments in the Public Chat

**Sheryl Turney:** Sheryl Turney is on

**Aaron Miri:** Aaron Miri is on

**Carolyn Peterson:** Carolyn Peterson is on

**Lauren Richie:** thank you all. Confirmed

## Next Steps and Adjourn

The next meeting of the IACCTF is on Friday, March 29 at 11:30 a.m. ET

**Lauren Richie** adjourned the meeting at 1:00 p.m. ET.