Health Data, Technology, and Interoperability (HTI-2) Proposed Rule: Information Blocking Information Session

Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule

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AGENDA

→ Brief Review: purpose of HTI-2 Proposed Rule, What "Information Blocking" Is (and Isn't)

→ Information blocking proposals – Definitions

→ Information blocking proposals – Existing Exception Updates

→ Information blocking proposals – Proposed New Exceptions

→ Where to learn more and how to submit comments

Purpose of HTI-2 Proposed Rule

Implementing the 21st Century Cures Act

- APIs that allow EHI to be accessed, exchanged, and used without special effort

- Reasonable and necessary activities that do not constitute information blocking

- Establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA

Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 "Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats"

- E.O. 13985 "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" and E.O 14091 "Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government"

- E.O. 14036 "Promoting Competition in the American Economy"

- E.O. 14058 "Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government"

Leveraging Health IT and Advancing Interoperability

- HITECH Act

- Interoperability Advancement

- ONC Health IT Certification Program

What Are We Proposing to Do?

- Advance health IT infrastructure nationwide

- Minimize data silos so health IT users can access information from various settings

- Emphasize technology solutions that are easier to adopt, particularly in settings with limited resources

- Enhance interoperability across health care and public health

- Advance equity

- Support patients' access to lawful reproductive health care, and

- Strengthen support for actors honoring patients' individual privacy preferences

Information Blocking Definition & Its Existing Exceptions

Quick Review: Elements of the Information Blocking Definition
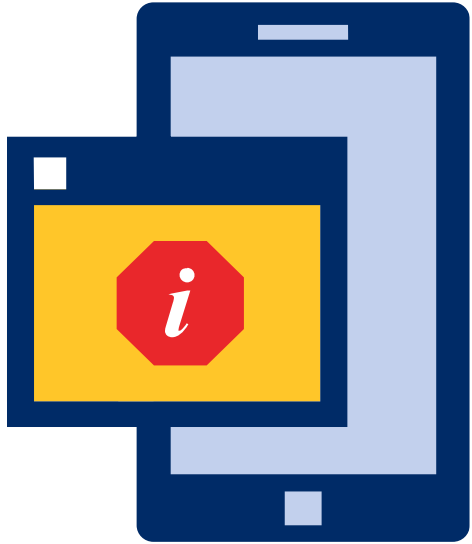
To be "Information Blocking," a practice (act or omission) must:

- ❑ Be done by actor regulated under the information blocking statute;

- ❑ Involve electronic health information (EHI);

- ❑ Be likely to interfere with access, exchange, or use of EHI;

- ❑ Be done with requisite knowledge by the actor;

- ❑ Not be required by law; and

- ❑ Not be covered by an exception.

Information Blocking Exceptions in Effect Today

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm Exception

2. Privacy Exception

3. Security Exception

4. Infeasibility Exception

5. Health IT Performance Exception

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI

6. Manner Exception

7. Fees Exception

8. Licensing Exception

Exceptions that involve practices related to actors' participation in TEFCA

9. TEFCA Manner Exception

Information Blocking Proposals in HTI-2

Overview of Information Blocking Proposals

Defined Terms Enhancements

- Health Care Provider, Health IT, Business Day

- Certain practices meeting "interference" definition

Existing Exceptions Updates

- Infeasibility – revise 2 conditions

- Privacy – expand 2 sub-exceptions

- TEFCA Manner – Request for Comment

Proposed New Exceptions

- Protecting Care Access

- Requestor Preferences

Information Blocking — Defined Terms Enhancements

"Interfere With" or "Interference"

PROPOSAL

Add a new section (§ 171.104) to the information blocking regulations that would codify that certain practices (acts and omissions) constitute "interference" for purposes of the information blocking definition.

BENEFITS

- The proposal would give actors (and those who seek to interact with them to access, exchange, or use EHI) confidence that certain practices of the following general kinds will be "interference" for purposes of the information blocking definition:

  - Actions taken by an actor to impose delays on other persons' access, exchange, or use of EHI;

  - Non-standard implementation of health IT and other acts to limit interoperability of EHI or the manner in which EHI is accessed, exchanged, or used by other persons;

  - Improper inducements or discriminatory contract provisions; and

  - Omissions (failures to act) when action is necessary to enable or facilitate appropriate information sharing, such as where access, exchange, or use of an individual's EHI is required by law or where it is permitted by law and not subject to restrictions requested by the individual (to which an actor has agreed).

- Proposal would not set a fixed universe of practices that could constitute "interference," leaving important room for case-by-case assessment across current variations in health IT and future innovations.

Information Blocking — Existing Exceptions Updates

Privacy Exception Updates

Privacy Exception – Sub-Exception for Denying Individuals Access on "Unreviewable Grounds"

PROPOSAL

- Broaden the applicability of existing sub-exception (§ 171.202(d)) so that it would be available to any actor responding to a request for EHI under the same circumstances and subject to the same requirements an actor that is also a HIPAA covered entity or business associate could deny an individual access on "unreviewable grounds" without the denial constituting information blocking.

- Update name of sub-exception to be shorter and to align with proposed broader availability

BENEFITS

- Improved consistency for individuals, who may seek access to EHI from both actors who are required to comply with the HIPAA Privacy Rule and actors who are not required to comply with the HIPAA Privacy Rule.

- For actors not required to comply with the HIPAA Privacy Rule, assurance that they could choose to deny individual access on "unreviewable grounds" without committing information blocking (under the same circumstances and subject to the same requirements as an actor that is also a HIPAA covered entity or business associate could under the sub-exception as it stands today).

- Simpler exception for all actors.

Privacy Exception – Sub-Exception for Respecting Individual's Request Not to Share EHI with Others

PROPOSAL

- Broaden the sub-exception's availability by removing its existing limitation to individual-requested restrictions on EHI sharing that are permitted by other applicable law.

- Shorten the title of the sub-exception for ease of reference.

BENEFITS

- Improved assurance for any actor who elects to honor an individual's request for restrictions on sharing of the individual's EHI that applying those restrictions will not be considered information blocking if the requirements of this sub-exception are satisfied.

- Simpler exception that is easier for actors to avail themselves of, if they want to grant an individual's request for restrictions.

- Enhanced assurance for individuals that information blocking regulations support actors' choices to honor the individual's request and not share EHI when the individual asks it not be shared.

Infeasibility Exception Updates

Infeasibility Exception — Overview

(a)(1) *Uncontrollable events*… (no change proposed)

(a)(2) *Segmentation* (update proposed)

(a)(3) *Third party seeking modification use* (update proposed)

(a)(4) *Manner exception exhausted* (no change proposed)

(a)(5) *Infeasible under the circumstances* (no change proposed)

(b) *Responding to requests* (must be met in complement to at least 1 condition from paragraph (a)) (update proposed)

Infeasibility Exception — *Segmentation* Condition Update

PROPOSAL

Expand application of the condition to circumstances where an actor cannot segment from other EHI the EHI that they cannot share or have chosen to withhold. Specifically, the *expansion* would make the condition applicable where the actor has chosen to withhold EHI consistent with:

- Privacy sub-exceptions applicable to denials of individual access on unreviewable grounds (§ 171.202(d)) or health IT developer of certified health IT not covered by HIPAA (§ 171.202(c))
- Proposed new Protecting Care Access Exception (§ 171.206)

BENEFITS

- Would accommodate more circumstances where another exception would apply to an actor choosing to withhold some EHI under an applicable exception but the actor cannot unambiguously segment that EHI from other requested EHI (that applicable law allows the actor to share).

Infeasibility Exception —
Third Party Modification Use Condition Update

PROPOSAL

Revise the condition so it would not apply when third party modification use is sought:

- By any HIPAA covered entity or business associate from an actor that is their business associate

- By any health care provider who is not a HIPAA covered entity from an actor whose activities **would** make the actor a business associate of that same health care provider if that health care provider were a HIPAA covered entity.

BENEFITS

- Recognizes the need of covered entities and their business associates to regularly modify EHI held by other business associates of the same covered entity.

- Recognizes that health care providers who are not HIPAA covered entities often have similar relationships with actors who provide services that would make the actor a business associate if the health care provider were a HIPAA covered entity, and that these providers may need or want a third party to modify EHI held by such actors on their behalf.

Information Blocking — Proposed New Exceptions

New Protecting Care Access Exception

PROPOSAL

Under its specified conditions, the exception would apply to practices likely to interfere with EHI access, exchange, or use an actor believes in good faith could result in a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought:
- under law in effect at the time the actor engages in the practice;
- against patients, health care providers, or those who help make providing or receiving care possible;
- for the mere fact that
  - a person sought, obtained, provided, or facilitated reproductive care that was lawful under the conditions in which it was provided; or
  - (where the patient protection condition applies) a patient has health conditions or history for which reproductive health care is often sought, obtained, or medically indicated.

BENEFITS

- Offers actors certainty that practices satisfying the exception will not be considered "information blocking"
- Assures patients that the information blocking regulations support actors limiting EHI sharing in response to risks that arise over time, while also continuing to support patients' own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that fosters better patient care.
- Supports continued advances in digitization, interoperability, and public confidence in the nationwide health information technology infrastructure.

New Protecting Care Access Exception

OVERVIEW

An actor's practice implemented to reduce the risk of potential exposure to legal action would not be information blocking when the actor's practice satisfies at least 2 conditions:

Threshold

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Patient Protection	‹ OR ›	Care Access

- **Threshold Condition Requirements:**
  1) Belief (an actor holds in good faith)
  2) Tailoring (of practice)
  3) Implementation (of practice) based on actor's
     - organizational policy – or –
     - case-by-case determination

- **Patient Protection Condition** – applicable to practices actor believes could reduce the patient's risk of potential exposure to legal action based on mere fact reproductive health care sought/received or a health history or condition for which reproductive health care often sought, received, or medically indicated

- **Care Access Condition** – applicable to practices actor believes could reduce potential exposure to legal action of health care providers or other persons who provide care or are otherwise involved in facilitating reproductive health care that is lawful under circumstances provided

Proposed New Requestor Preferences Exception

New Requestor Preferences Exception

PROPOSAL

A proposed Requestor Preferences Exception (to be codified in 45 CFR 171). This exception would apply where an actor honors a requestor's preference(s) expressed or confirmed in writing for:

1. Limitations on the amount of EHI made available to the requestor;

2. The conditions under which EHI is made available to the requestor;

3. When EHI is made available to the requestor for access, exchange, or use.

BENEFITS

- The exception would offer actors certainty that, under the exception's specified conditions, an actor's honoring these requestor preferences would not constitute information blocking.

- Would apply to honoring preferences of any requestor, including individuals, health care providers, and any other requestor of access, exchange, or use (for permissible purposes) of EHI the actor has.

- Flexible to accommodate, to the extent the actor may be able and willing to do so, the considerable variety of unique preferences it is possible for a requestor to have in comparison even to similarly situated requestors.

New and Revised Standards and Certification Criteria

New Imaging Requirements for Health IT Modules

PROPOSAL

- ONC proposes to revise the certification criteria found at § 170.315(b)(1) "transitions of care", § 170.315(e)(1) "view, download, and transmit", § 170.315(g)(9) "application access—all data request", and § 170.315(g)(10) "standardized API for patient and population services" to include certification requirements to support access, exchange, and use of diagnostic images via imaging links.

- ONC is not proposing a specific standard associated with the support of this functionality, and notes that this requirement can be met with a context-sensitive link to an external application which provides access to images and their associated narrative.

- ONC proposes by January 1, 2028, a health IT developer of a Health IT Module certified to any of the aforementioned certification criteria must update their Health IT Module and provide the updated version to their customers to maintain certification of that Health IT Module.

BENEFITS

Diagnostic images are often stored in systems external to an EHR, such as picture archiving and communication systems (PACS) and vendor neutral archives (VNA). ONC believes that promoting access to and the exchange of images via ONC Certification Program requirements may encourage more widespread adoption and integration of these already existing pathways and reduce burdens caused by physical media exchange (e.g., CD-ROMs).

Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.

→ General Overview

→ USCDI v4

→ Electronic Prescription

→ Information Blocking (Exceptions)

→ Information Blocking (Definitions)

→ Public Health Reporting

→ TEFCA

→ Modular API

→ Patient, Provider, and Payer API

→ Key Compliance Dates
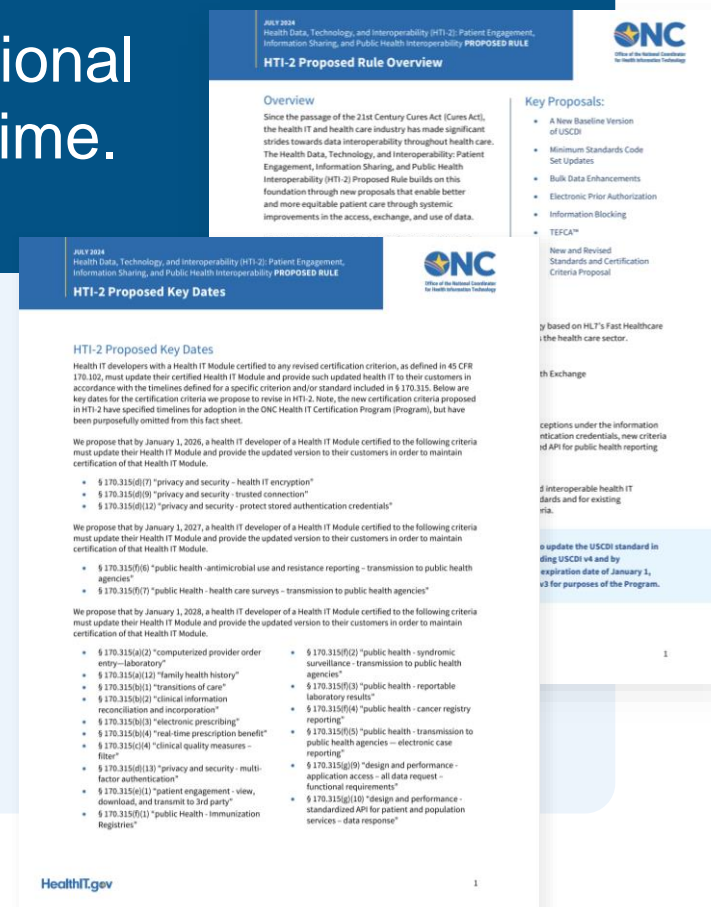
How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA06, through http://www.regulations.gov. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.

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PAST and UPCOMING WEBINARS

Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.

HTI-2 Proposed Rule Overview Information Session
Wednesday July 17, 2024. at 2pm ET
View Recording
Presentation Slides [PDF - 2.2 MB]

HTI-2 Proposed Rule Patient, Payer, Provider API Information Session
Thursday, August 15, 2024, at 2pm ET
View Recording

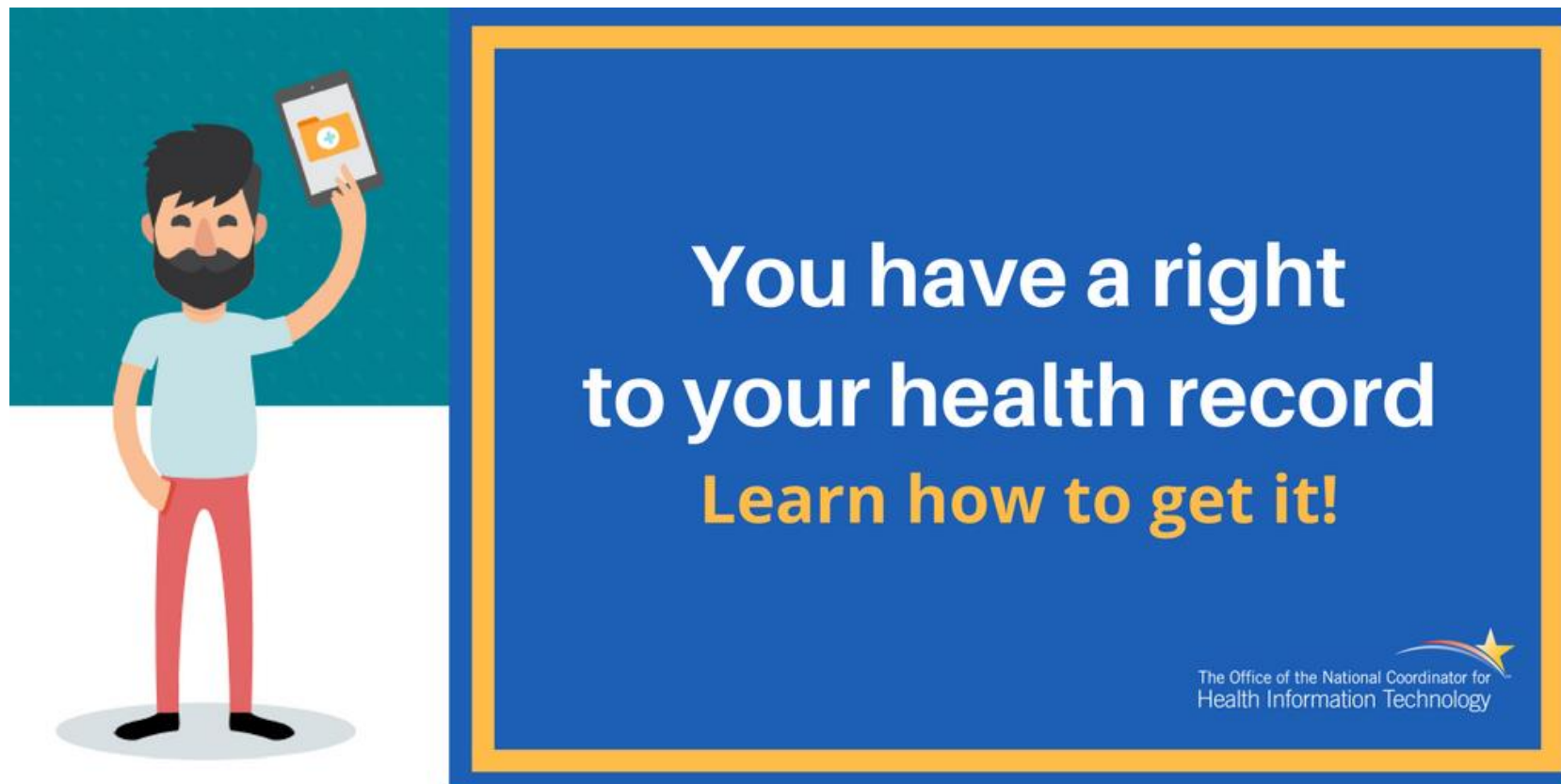**HTI-2 Proposed Rule Public Health Information Session**
Tuesday, July 30, 2024, at 2pm ET
View Recording
Presentation Slides [PDF - 1.9 MB]

ONC's Guide to Getting and Using Your Health Records

https://www.healthit.gov/how-to-get-your-health-record/

ONC and HHS Resources

- **Learn how to get, check, and use your records.** If the health information you need is not available through a patient portal, you can request it from the doctor's office. Visit the Guide to Getting & Using Your Health Records for practical tips to help you access, review, and make the most of your health records.

- Patient Access Information for Individuals: Get it, Check it, Use it!

- ONC Patient Engagement Playbook

- Guide to Privacy and Security of Electronic Health Information

- "Your Health Information, Your Rights" Infographic

- OCR Access Sub-Regulatory Guidance

- Patient Access Videos

- API Training Module

- Access Frequently Asked Questions (FAQs)

- Improving the Health Records Request Process for Patients Insights from User Experience Research [PDF- 2.7MB]

- ONC's Cures Act Final Rule

- Information Blocking

- Trusted Exchange Framework and Common Agreement (TEFCA)

Contact Us

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