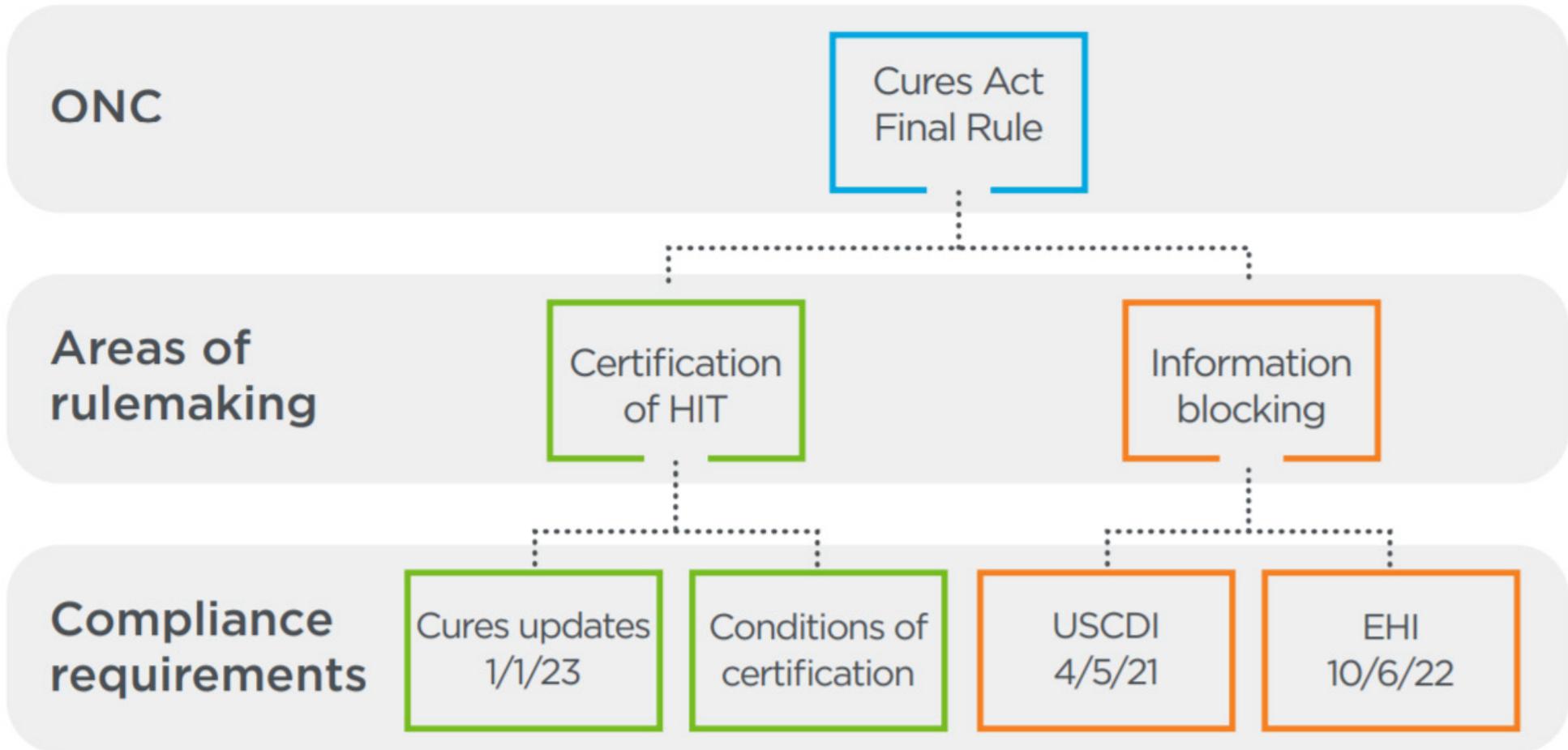


# Information Blocking (+Tackling)

Final Rule >> Starting Whistle

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2021

# Context: 21<sup>st</sup> Century Cures Act



# Information Blocking

## Meaning:

- (A) a *practice* that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI); and
- (B) (i) if conducted by a HIT developer, exchange, or network, such [actor] knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of EHI; or  
(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

# Information Blocking

## Examples:

- (A) practices that restrict authorized access, exchange, or use under applicable laws of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies (HIT);
- (B) implementation of HIT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI; and
- (C) implementation of HIT in ways that are likely to (i) restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between HIT systems; or (ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by HIT.

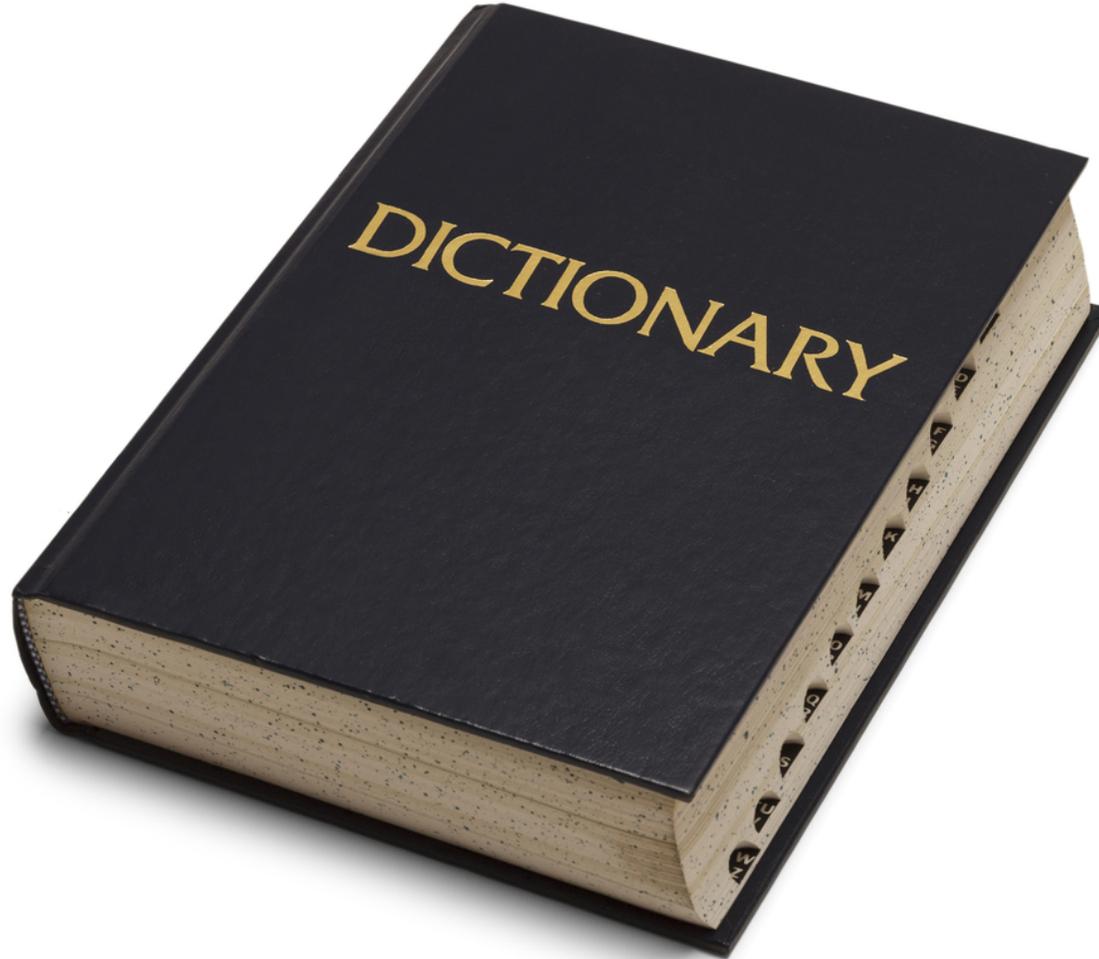
# New Rigor: Interop Priority + Exceptions

access:

exchange:

use:

practices:



unreasonable:

materially:

likely:

discourage:

should:

# Enforcement

## Estimated for 2023:

- By HHS OIG
- Potential *referral* to CMS for healthcare providers;  
OCR: HIPAA Privacy Rule
- \$1mm/violation for HIT developers and networks
- False/incorrect attestations
- Yet to be determined: “appropriate disincentives”

# 21st Century Cures Act vs. HIPAA

## **Alignment:**

- Patient rights to access and sharing
- Patient consent
- Confidentiality, integrity, and availability

## **Tension:**

- Request-response cycle time
- Accuracy/currency: documentation, BAA, NPP
- Workforce culture, awareness

# Exceptions, 1-5

## **For Denials:**

1. Preventing Harm
2. Privacy
3. Security
4. Infeasibility
5. Health IT Performance

# Exceptions, 6-8

## **For Potential Hindrance or Delays:**

6. Content and Manner
7. Fees
8. Licensing

# 1. Preventing Harm

Not fulfilling a request is not information blocking when:

- a) Actor holds a reasonable belief practice will substantially reduce a risk of harm to patient or another natural person; and
- b) The practice is no broader than necessary; and one of (c, d, or f)
- c) The risk of harm
  - Is determined by licensed health care professional with relationship to patient; or
  - Arises from data known to be bad or reasonably suspect of being bad
- d) Type of harm is one that could serve as grounds for covered entity to deny access under:
  - §164.524(a)(3)(iii) Access by legal representative
  - §164.524(a)(3)(ii) Information that references another natural person
  - §164.524(a)(3)(i) Patient's access is likely to risk life or physical safety
  - §164.524(a)(3)(i) Is likely to risk life or physical safety
- e) Based on an organizational policy or specific determination; and
  - Must be in writing, based on relevant expertise, consistently implemented and conforming
  - Determination made based on facts and expertise

# 1. Preventing Harm

Not fulfilling a request is not information blocking when:

- a) Actor holds a reasonable belief practice will substantially reduce a risk of harm to patient or another natural person; and
  - Objective:**
  - Protect the public interest to protect patients and others against unreasonable risks of harm**
- b) The practice is no broader than necessary, and one of (c, d, or f)
- c) The risk of harm
  - Is determined by licensed health care professional with relationship to patient; or
  - Arises from data known to be bad or reasonably suspect of being bad
- d) Type of harm is one that could serve as grounds for covered entity to deny access under:
  - § 164.522(a)(1)(ii) (i.e., death or serious harm)
  - § 164.522(a)(1)(iii) (i.e., financial harm)
  - § 164.522(a)(1)(iv) (i.e., harm to reputation)
  - § 164.522(a)(1)(v) (i.e., harm to privacy)
- e) Base
  - Must be in writing, based on relevant expertise, consistently implemented and conforming
  - Determination made based on facts and expertise

# 2. Privacy

Not fulfilling a request is not information blocking when:

- a) Unsatisfied pre-condition not met; and
  - 1) Practice tailored to precondition and consistently implemented; and either
  - 2) Relies on provision of consent and provided consent does not meet precondition; and
- b) Privacy policy of Certified Health IT Developer not covered by HIPAA does not permit; and
  - 1) Policy complies with State and Federal law
  - 2) Tailored to specific privacy risk addressed
  - 3) Implemented in consistent non-discriminatory manner
- c) Denial consistent with 45 CFR 164.524(a)(1) and (2) if requested from actor who must comply
- d) Respecting individual's request not to share information; and
  - 1) No improper encouragement or inducement
  - 2) Request documented within reasonable time period
  - 3) Implemented in consistent non-discriminatory manner

# 2. Privacy

Not fulfilling a request is not information blocking when:

- a) Unsatisfied precondition not met; and
  - 1) Practice tailored to precondition and consistently implemented; and either
  - 2) Relies on provision of consent and provided consent does not meet precondition, and
- b) Privacy policy of certified HIT Developer not covered by HIPAA does not permit; and
  - 1) Policy complies with State and Federal law
  - 2) Tailored to specific privacy risk
  - 3) Implemented in consistent non-discriminatory manner
- c) Denial consistent with 45 CFR 164.524(a) and (b) if requested from actor who must comply with 45 CFR 164.524(a) and (b)
- d) Response consistent with 45 CFR 164.524(a) and (b) if requested from actor who must comply with 45 CFR 164.524(a) and (b)
  - 1) No individual choice to not provide access, exchange or use
  - 2) Request documented within reasonable time period
  - 3) Implemented in consistent non-discriminatory manner

**Objective:**

**An actor will not be required to use/disclose EHI in a manner prohibited by state or federal law.**

**Key (pro-privacy) conditions:**

- Precondition not satisfied
- HIT dev of certified HIT not covered by HIPAA
- Denials consistent with 45 CFR 164.524(a)
- Individual choice to not provide access, exchange or use

# 3. Security

Not fulfilling a request is not information blocking when:

- a) Practice is directly related to protecting confidentiality, integrity, or availability of information;
- b) Tailored to specific security risk; and
- c) Implemented in a consistent non-discriminatory manner; and either
- d) If pursuant to policy
  - 1) In writing
  - 2) Responsive to identified risk
  - 3) Based on standards
  - 4) Timeframe for response to incident
- e) If not pursuant to policy, determination based on facts and circumstances that:
  - 1) Practice necessary to mitigate security risk to EHI; and
  - 2) No reasonable and appropriate alternative

# 3. Security

Not fulfilling a request is not information blocking when:

- a) Practically directly related to protecting confidentiality, integrity, or availability of information;
  - Objective:***  
**An actor will not be required to use/disclose EHI in a manner that compromises the legitimate security of the EHI.**
- b) Tailored to specific security risk; and
- c) Implemented in a consistent non-discriminatory manner; and either
- d) If pursuant to policy
  - Key (pro-security) conditions:***
    - **Direct relation to confidentiality, integrity, availability**
    - **Mitigation of specific risk**
    - **Consistent, non-discriminatory implementation**
    - **Supported by policy or specific risk assessment**
  - 1) If with
  - 2) F
  - 3) E
  - 4) T
- e) If no
  - 1) F
  - 2) No reasonable and appropriate alternative

# 4. Infeasibility

Not fulfilling a request is not information blocking when:

- a) When one of the following conditions is met:
  - 1) Uncontrollable event: disaster, public health emergency, public safety incident, war etc.
  - 2) Information cannot be unambiguously segmented
  - 3) Infeasible under the circumstances, in writing, through consideration of:
    - i. Type of EHI and purposes
    - ii. Cost of complying
    - iii. Financial and technical resources required
    - iv. Practice non-discriminatory
    - v. Ownership or control over technology
    - vi. Consistent with exception in §171.301
- b) Reasons why request is infeasible are provided in writing within **10** days of receipt of request.

# 4. Infeasibility

Not fulfilling a request is not information blocking when:

a) When **Objective:** following conditions is met:

- 1) Uncontrollable events, disasters, public health emergencies, public safety incidents, war etc.
- 2) Information cannot be unambiguously segmented
- 3) Infeasible under the circumstances, in writing, through consideration of:

i. Type of EHI and purposes

**Key conditions:**

- Uncontrollable events i.e. disasters, emergencies
- Inability to precisely segment requested EHI
- Non-discriminatory circumstances
- Written, reasoned response in 10 days or less

b) Reasonable response within 10 days of receipt of request.

# 5. Health IT Performance

Not fulfilling a request is not information blocking when one of conditions (a) (b) (c) or (d) are met :

- a) Practice due to temporary maintenance or improvement of IT
  - No longer than necessary
  - Consistent and non-discriminatory manner
  - If implemented by Certified health IT developer, Health Information Exchange or Network it is planned or within SLA
- b) Against a third-party application (causing negative impact) if:
  - No longer than necessary
  - Consistent and non-discriminatory manner
  - Consistent with SLAs
- c) If unavailability of Health IT is initiated in response to risk of harm
- d) If response to security risk to EHI

# 5. Health IT Performance

Not fulfilling a request is not information blocking when one of conditions (a) (b) (c) or (d) are met:

## ***Objective:***

- a) **Provide for reasonable and necessary maintenance windows in order to enhance or sustain health IT performance.**

- No longer than necessary
- Consistent and non-discriminatory manner
- If implemented by Certified health IT developer, Health Information Exchange or Network it is planned or with SLA

## ***Key conditions:***

- b) Against a third party application (causing negative impact) if:
- **Downtime no longer than necessary**
  - **Consistent, non-discriminatory**
  - **Consistent with SLAs, where applicable**

c) If un

d) If response to security risk to EHI

# 6. Content and Manner

Not fulfilling a request is not information blocking when (a) and (b) are met:

a) Response (content) includes:

- 1) Request before May 2, 2022 and includes at a minimum all EHI listed in USCDI v1
- 2) Request on or after May 2, 2022 all EHI defined in §171.102

b) Manner condition

- 1) In manner requested
  - i. Unless technically unable
  - ii. If request fulfilled: Any fees charged not required to fulfill exception §171.302, any license granted not required to satisfy §171.303
- 2) If technically unable and cannot reach agreement must, in the following order, if able:
  - i. Use certified technology
  - ii. Use recognized content and transport standards specified by requestor
  - iii. Use an alternative machine-readable format and any fees charged used to satisfy §171.302 and §171.303

# 6. Content and Manner

Not fulfilling a request is not information blocking when (a) and (b) are met:

a) Response (*Objective:*) includes:

- 1) Specify required content scope and the manner by which to respond to requests.
- 2) Request on or after May 2, 2022 all EHI defined in §171.102

b) Manner condition

1) In manner requested  
*Key conditions:*

- EHI = USCDI, then all EHI
- Respond in manner requested
- Alternative manner requirements:
  - Actor is technically unable
  - Agreeable terms not attainable
  - Fees and Licensing exception conditions satisfied

# 7. Fees

Fees charged will not be considered information blocking when meeting all conditions in (a) does not include fees in (b) and all applicable conditions in (c) met:

## a) Basis of Fees

### 1) Fees charged must be:

- i. Based on objective and verifiable criteria uniformly applied,
- ii. Reasonably related to costs,
- iii. Reasonably allocated across all similarly situated classes, and
- iv. Based on costs not otherwise recovered for same service

### 2) Must not be:

- i. Whether requestor is competitor or potential competitor,
- ii. Sales, profit or revenue
- iii. Costs associated with non-standard implementation,
- iv. Costs associated with intangible assets other than implementation or acquisition costs,
- v. Opportunity costs unrelated to access, exchange or use,
- vi. Costs related to creation of intellectual property if actor charged royalty

# 7. Fees (continued)

Fees charged will not be considered information blocking when meeting all conditions in (a) does not include fees in (b) and all applicable conditions in (c) met:

b) Excluded Fees:

- i. Fee prohibited by 45 CFR 164.524(c)(4)
- ii. Fee based in any part on electronic access to EHI of individual
- iii. Fee for export related to switching health IT or to provide EHI to patients
- iv. Fee to export not agreed to in writing at time of purchase of Health IT

c) If Certified Health IT developer comply with conditions of certification

# 7. Fees

Fees charged will not be considered information blocking when meeting all conditions in (a) does not include fees in (b) and all applicable conditions in (c) met:

## ***Objective:***

**Enable actors to earn reasonable returns on technology development and service provisioning which enhances interoperability.**

## ***Key conditions:***

- **Objective, verifiable criteria**
- **Cost-based fees, direct relation to access, exchange, use**
- **No exclusionary practices, e.g. churn mitigation**

# 8. Licensing

Not fulfilling a request is not information blocking when all the following are met:

a) Timing:

- 1) Begin license negotiations within 10 days
- 2) Negotiate license, subject to (b), within 30 days

b) Terms requirements:

- 1) Provide all rights necessary to enable and achieve access, exchange and use of EHI
- 2) Any royalty charged is reasonable
- 3) Non-discriminatory terms
- 4) Prohibitions:
  - i. Non-compete
  - ii. Exclusivity
  - iii. Obtain unrelated licenses
  - iv. License, grant, assign or transfer intellectual property of licensee
  - v. Pay a fee other than in (b)(2)
- 5) May include reasonable non-disclosure agreement

# 8. Licensing (continued)

Not fulfilling a request is not information blocking when all the following are met:

- c) Must not engage in practice that impedes use of interoperability elements,
  - efficient development, distribution or deployment or use (of interoperability elements), or
  - degrades performance or interoperability unless necessary to improve technology and after reasonable opportunity to upgrade

# 8. Licensing

Not fulfilling a request is not information blocking when all the following are met:

- a) **Objective:**
- 1) Begin license negotiations within 10 days
  - 2) Negotiate license, subject to (b), within 30 days
- b) **Terms requirements:**
- 1) **Ensure actors retain legal means to protect and earn an economic return on their intellectual property, through licensing of interoperability elements.**
  - 2) Any royalty charged is reasonable
  - 3) Non-discriminatory terms
  - 4) **Key conditions:**
    - **Defined scope**
    - **Reasonable royalty**
    - **Non-discriminatory terms**
    - **Consistent with SLAs, where applicable**
  - 5) Non-exclusivity

# Operational Focus:

- Conforming Policies and Procedures
- Verify & Assess Risk: Current Delivery
- Value Chain for Response Logic
- Tabletop/Simulation e.g. Inquiry Response
- With Legal: Attestation Support