



# 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule

## *Information Blocking*

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The Office of the National Coordinator for  
Health Information Technology



## Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.
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## Information Blocking Definition in the Final Rule

**(a) Information blocking means a practice that—**

- (1) Except as required by law or covered by an exception, is likely to interfere with access, exchange, or use of electronic health information; and
- (2) **If conducted by a health information technology developer, health information network or health information exchange**, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, access, exchange, or use of EHI; or
- (3) **If conducted by a health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

**(b) Until 24 months after the publication date of the final rule**, EHI for purposes of paragraph (a) of this section is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.



## What Makes an Individual or Entity an Information Blocker?

### Elements of information blocking

- ☐ Actor regulated by the information blocking provision
- ☐ Involves electronic health information (EHI)
- ☐ Practice is likely to interfere with, 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**
  - Health IT developers of certified health IT, health information networks, and health information exchanges → Civil monetary penalties (CMPs) up to \$1 million per violation
  - Health care providers → Appropriate disincentives
- **Certification ban (§ 170.581) for health IT developers in violation of the Conditions of Certification**
  - Information blocking Condition of Certification (§ 170.401)
  - Public listing of certification bans and terminations

## Compliance Timeline

- Actors do **not** have to comply with the information blocking provision until **six months after publication** of the final rule.
- Enforcement of information blocking civil monetary penalties (CMPs) will not begin until established by future rulemaking by OIG. As a result, actors will not be subject to penalties until the CMP rule is final.
  - *At a minimum*, the timeframe for enforcement will **not** begin sooner than the compliance date of the ONC final rule and will depend on when the CMP rules are final.
  - Discretion will be exercised such that conduct that occurs before the CMP rule is final will not be subject to information blocking CMPs.

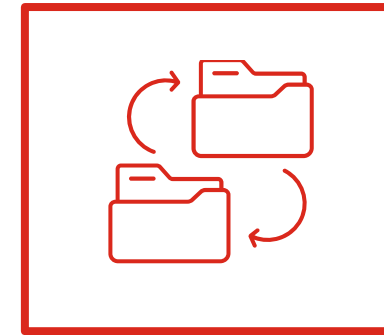
## “Actors” Regulated in the Final Rule



**Health Care  
Providers**



**Health IT  
Developers of  
Certified Health IT**



**Health Information  
Networks (HIN)/  
Health Information  
Exchanges (HIE)**

## Definition of Electronic Health Information (EHI)

- Focused the scope of EHI to mean **electronic protected health information (ePHI)** to the extent that the ePHI is included in a **designated record set** as these terms are defined for HIPAA.
- This is applicable whether the actor is a covered entity or not.





# Information Blocking Exceptions

## 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. Content and Manner Exception



7. Fees Exception



8. Licensing Exception

## Complaint Process

- The Cures Act directs the National Coordinator to implement a standardized process for the public to submit reports on claims of information blocking.
- We will **implement and evolve** the complaint process by building on existing mechanisms, including the process for providing feedback and expressing concerns about health IT that is currently available at <https://www.healthit.gov/curesrule/final-rule-policy/information-blocking/report>
- For additional information about submitting an information blocking complaint or about information blocking general, please see our final rule website and materials at [www.healthit.gov/curesrule](http://www.healthit.gov/curesrule).

# Protection from Disclosure of Information

Any information received by  
ONC in connection with a  
claim or suggestion of  
possible information  
blocking and that could  
reasonably be expected to  
facilitate identification of the  
source of the information  
would fall under protections  
in section 3022(d)(2) of the  
Public Health Service Act.

## Excerpt from 21<sup>st</sup> Century Cures Act

### **SEC. 4004. INFORMATION BLOCKING.**

Subtitle C of title XXX of the Public Health Service Act ([42 U.S.C. 300jj–51 et seq.](#)) is amended by adding at the end the following:

### **‘SEC. 3022. INFORMATION BLOCKING.**

“(d) ADDITIONAL PROVISIONS

...

(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

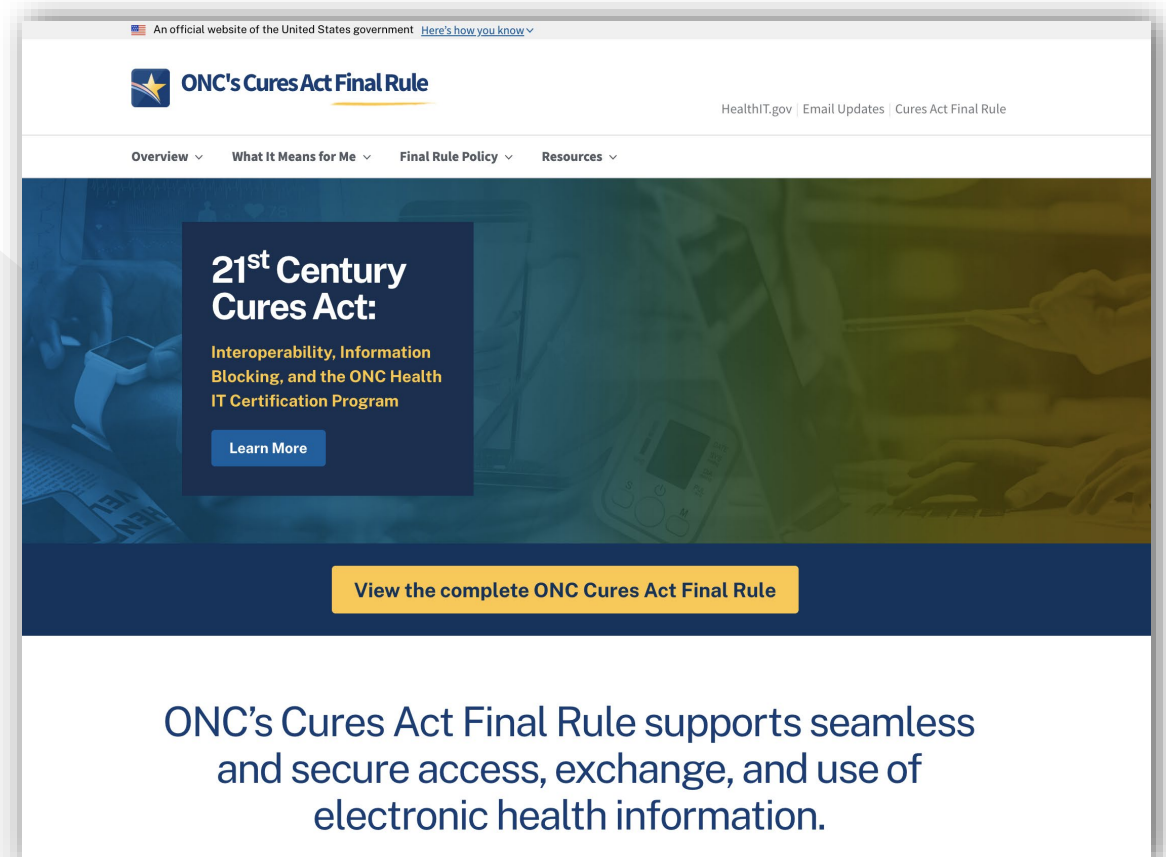
“(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

“(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

“(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

## Please visit [www.healthit.gov/curesrule](http://www.healthit.gov/curesrule)

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- Fact Sheets
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# Thank you

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