

## CURES ACT FINAL RULE

# Changes and Clarifications from the Proposed Rule to the Final Rule

## Changes and Clarifications Related to the ONC Health IT Certification Program



### Electronic Health Information (EHI) Export Certification Criterion

#### PROPOSED RULE

We proposed to adopt a new 2015 Edition certification criterion, referred to as “EHI Export,” in § 170.315(b)(10). The criterion’s proposed conformance requirements were intended to provide a means to export the entire EHI that a certified health IT product produces and electronically manages to support two contexts: (1) single patient EHI export; and (2) patient EHI export when a health care provider is switching health IT systems.

#### FINAL RULE

- The final certification criterion and scope of data that a Health IT Module certified to § 170.315(b)(10) must export is more specific (“at the time of certification”) and aligned to the definition of “EHI” finalized in § 171.102 (see the *EHI definition* section below).
- Consistent with the “Assurances” Condition of Certification, developers of certified health IT whose Health IT Modules need to be certified to § 170.315(b)(10) must do so and provide such capabilities to their customers within 36 months of the final rule’s publication date (compared to 24 months as proposed).



### FHIR Standard for Application Programming Interface (API) Certification Criterion

#### PROPOSED RULE

We proposed to adopt the HL7® Fast Healthcare Interoperability Resources® (FHIR®) standard as a foundational standard and requested comment on four options to determine the best version of FHIR® to adopt.

#### FINAL RULE

We have adopted FHIR Release 4.



### Communications Condition and Maintenance of Certification – Permitted Restrictions for Intellectual Property and Visual Communications

#### PROPOSED RULE

We proposed to prohibit health IT developers from restricting the sharing of screenshots of their health IT, except in limited circumstances. We also proposed that health IT developers would not be permitted to prohibit or restrict, or purport to prohibit or restrict, communications that would be a “fair use” of any copyright work comprised in the developer’s health IT.

## Changes and Clarifications Related to the ONC Health IT Certification Program



### FINAL RULE

- We clarified in the final rule that screenshots are only one form of visual communications protected under the Cures Act, and that the protections afforded to screenshots in the Communications Condition of Certification extend to video. Such visual communications are critical to addressing issues with health IT related to patient safety, usability, security, and interoperability.
- Developers may, under the permitted prohibitions and restrictions section of the condition, restrict communications that involve intellectual property, provided that -
  - » Any prohibition or restriction imposed by a developer must be no broader than necessary to protect the developer's intellectual property; and
  - » Are consistent with the other requirements of this section.
- Developers must not restrict or preclude a public display of a portion of a work subject to copyright protection (without regard to whether the copyright is registered) that would reasonably constitute a "fair use" of that work.
- Developers may limit the sharing of screenshots and video of their health IT products to only the relevant number of screenshots and amount of video needed to communicate about the certified health IT products regarding one or more of the six protected subject areas identified in the 21<sup>st</sup> Century Cures Act. Developers may limit the sharing of videos to only those videos that address temporal matters that cannot be communicated through screenshots or other forms of communication.

## Changes and Clarifications Related to Information Blocking



### Compliance Timeline

#### PROPOSED RULE

The information blocking provision did not specify any delays in implementation once finalized.

#### FINAL RULE

Health care providers, health IT developers of certified health IT, health information exchanges, and health information networks ("actors") do not have to comply with the information blocking provision until six months after publication of the final rule. ONC and OIG are also coordinating timing of the compliance date and the start of information blocking enforcement. Enforcement of information blocking civil monetary penalties (CMPs) in section 3022(b)(2)(A) of the PHSA will not begin until established by future notice and comment rulemaking by OIG. As a result, actors would not be subject to penalties until CMP rules are final. At a minimum, the timeframe for enforcement would 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 that time will not be subject to information blocking CMPs.

## Changes and Clarifications Related to Information Blocking



### EHI Definition

#### PROPOSED RULE

The information blocking provision applies to “EHI,” which is not defined in the Cures Act. We proposed a broad definition of EHI in the proposed rule.

#### FINAL RULE

- We focused the scope of EHI in § 171.102 in the final rule to mean electronic protected health information (ePHI) as the term is defined for HIPAA in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501 (other than psychotherapy notes as defined in 45 CFR 164.501 or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding), regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103.
- We also clarify that until 24 months after the publication date of the final rule, EHI for purposes of the information blocking definition is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.



### Access, Exchange, and Use Definitions

#### FINAL RULE

We clarified the definitions of **access, exchange, and use** in the final rule. For example, we finalized “use” to mean the ability for EHI, **once accessed or exchanged**, to be understood and acted upon. We also emphasized that “transmitted” within the definition of “exchange” is not limited to a one-way transmission, but instead is inclusive of all transmissions.



### What it Means to “Interfere with” Access, Exchange, or Use of EHI

#### FINAL RULE

- Provided certain criteria are met, we clarified in the final rule that it would **not** be considered an “interference with” the access, exchange, or use of EHI (and thus **not** “information blocking”) if an information blocking “actor” engaged in practices to educate patients about the privacy and security risks posed by the apps they choose to receive their EHI.
- For example, actors may establish processes where they notify a patient, call to a patient’s attention, or display in advance (as part of the app authorization process with certified API technology) whether the third-party developer of the app that the patient is about to authorize to receive their EHI has attested in the positive or negative as to whether the third party’s privacy policy and practices (including security practices) meet certain “best practices” set by the market for privacy policies and practices.
- We recommended that the privacy policies and practices of third-party apps should, at a minimum, adhere to the following:
  - › The privacy policy is made publicly accessible at all times, including updated versions;
  - › The privacy policy is shared with all individuals that use the technology prior to the technology’s receipt of EHI from an actor;
  - › The privacy policy is written in plain language and in a manner calculated to inform the individual who uses the technology;

## Changes and Clarifications Related to Information Blocking



- » The privacy policy includes a statement of whether and how the individual's EHI may be accessed, exchanged, or used by any other person or other entity, including whether the individual's EHI may be sold at any time (including in the future); and
- » The privacy policy includes a requirement for express consent from the individual before the individual's EHI is accessed, exchanged, or used, including receiving the individual's express consent before the individual's EHI is sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction).
- We clarified in the final rule that the information blocking provision does not require actors to violate business associate agreements or associated service level agreements. However, we also clarified that such agreements *could* constitute an interference if used in a discriminatory manner by an actor to limit or prohibit the access, exchange, or use of EHI for treatment purposes that otherwise would be permitted by the Privacy Rule.



## Health Information Network (HIN) and Health Information Exchange (HIE) Definitions

### PROPOSED RULE

The terms “network” and “exchange” are not defined in the Cures Act. ONC proposed functional definitions for these “actors” under the information blocking provision that focused on the role of the actors in the health information ecosystem.

### FINAL RULE

We focused the HIN and HIE definitions in four ways:

1. Combined the definitions of HIN and HIE to create one functional definition that applies to both statutory terms in order to clarify the types of individuals and entities that would be covered.
2. Limited the types of actions that would be necessary for an actor to meet the definition of HIN or HIE.
3. Revised the definition to specify that to be a HIN or HIE there must be more than two unaffiliated individuals or entities besides the HIN/HIE that are enabled to exchange with each other.
4. Focused the definition's scope to be about exchange related to treatment, payment, and health care operations, as each are defined in the HIPAA Rules.



## Structure of the Exceptions

### PROPOSED RULE

We proposed seven categories of practices that would be exceptions to the information blocking definition.

### FINAL RULE

We finalized eight information blocking exceptions, including the new Content and Manner Exception (discussed below). We restructured the exceptions into two categories:

- Exceptions that involve not fulfilling requests to access, exchange, or use EHI; and
- Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI.

## Changes and Clarifications Related to Information Blocking



### Promoting Privacy Exception

#### PROPOSED RULE

We proposed that to qualify for this exception when individual consent or authorization is a precondition to providing access, exchange, or use of EHI, an actor would need to do all things reasonably necessary within its control to provide the individual with a meaningful opportunity to provide the consent or authorization.

#### FINAL RULE

To qualify for this exception when individual consent or authorization is a precondition to providing access, exchange, or use of EHI, an actor must have used reasonable efforts within its control to provide the individual with a consent or authorization form that satisfies all applicable requirements or have provided other reasonable assistance with respect to the deficiencies. In effect, this places more of an obligation on the party requesting the EHI and the individual to attempt to satisfy the precondition by providing a consent or authorization.



### New Content and Manner Exception

#### FINAL RULE

The Content and Manner Exception was not explicitly proposed in the proposed rule though many of its principles were addressed in various ways. This new exception addresses a broad range of comments we received about the required content and manner of an actor's response to a request to access, exchange, or use EHI. Under the exception, it will not be information blocking for an actor to limit the content of its response to a request to access, exchange, or use EHI or the manner in which it fulfills a request to access, exchange, or use EHI, provided certain conditions are met. This exception supports innovation and competition by allowing actors to first attempt to reach and maintain market negotiated terms for the access, exchange, and, use of EHI.

- **Content Condition** establishes the content (EHI) an actor must provide in response to a request to access, exchange, or use EHI in order to satisfy the exception.
  1. Up to 24 months after the publication date of the Cures Act final rule, an actor must respond to a request to access, exchange, or use EHI with, at a minimum, the EHI identified by the data elements represented in the United States Core Data for Interoperability (USCDI) standard.
  2. On and after 24 months after the publication date of the Cures Act final rule, an actor must respond to a request to access, exchange, or use EHI with EHI as defined in § 171.102.
- **Manner Condition** establishes the manner in which an actor must fulfill a request to access, exchange, or use EHI in order to satisfy this exception.
  - › An actor may need to fulfill a request in an alternative manner when the actor is:
    - Technically unable to fulfill the request in any manner requested; **or**
    - Cannot reach agreeable terms with the requestor to fulfill the request.
  - › If an actor fulfills a request in an alternative manner, such fulfillment must comply with the order of priority described in the manner condition and must satisfy the Fees Exception and Licensing Exception, as applicable.

## Changes and Clarifications Related to Information Blocking



### Infeasibility Exception

#### FINAL RULE

- We restructured the exception to include:
  - » Two new discreet conditions concerning:
    - Uncontrollable events; and
    - Inability to unambiguously segment the requested EHI.
  - » A condition that describes factors that will be considered to determine whether a request is infeasible under the circumstances.
- We removed the “reasonable alternative” requirement from this exception and repurposed that concept in the new Content and Manner Exception (see above). The Content and Manner Exception improves on the “reasonable alternative” requirement in the proposed rule by clarifying actors’ obligations for providing access, exchange, or use of EHI in *all* situations, creating actionable technical procedures, and aligning the requirement for providing an alternative with the Fees Exception and Licensing Exception.



### Fees Exception – Profits

#### FINAL RULE

We reiterated and included in regulation text that actors may charge fees, **including fees that result in a reasonable profit margin**, for accessing, exchanging, or using EHI. We also clarified how the Fees Exception works with the Licensing Exception and Content and Manner Exception.



### Licensing Intellectual Property

#### FINAL RULE

We reiterated and clarified in the final rule that an actor does not need to license its interoperability elements if the actor is able to fulfill a request to access, exchange, or use EHI in an alternative manner without licensing its IP (see the Content and Manner Exception discussed above). We also clarified how the Licensing Exception works with the Fees Exception and Content and Manner Exception.