#### JULY 2024

Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability **PROPOSED RULE** 

## **Information Blocking Exceptions**



# Information Blocking Exceptions

This rule proposes to revise certain existing <u>information blocking exceptions</u> and to establish two new exceptions. The new exceptions are designed to offer actors certainty that they can, if they choose, restrict information sharing in certain circumstances where the restrictions would protect patients' access to care or honor an information sharing partner's preferences for how much electronic health information (EHI) is made available to the partner when and under what circumstances.

# ONC Proposes the Following in HTI-2 Proposed Rule

### **Privacy Exception**

- Make the Privacy Exception's <u>§ 171.202(d)</u> sub-exception available to all actors, regardless of whether they are otherwise required to comply with, and regardless of whether the individual specifically invokes, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule right of access provision (45 CFR 164.524).
- Update the header of § 171.202(d) to "**Sub-exception interfering with individual access on unreviewable grounds**" to align with broadening its availability and for readability.
- Revise the §171.202(e) sub-exception applicable to an actor's respecting an individual's request for
  restriction on access, exchange, or use of their EHI. The proposal would remove the existing limitation of
  the sub-exception to restrictions that are permitted by other applicable law. Under the proposed
  revision, any practice that met the requirements specified in § 171.202(e) would simply not be
  considered information blocking under 45 CFR part 171, regardless of whether other valid law compels
  the actor to disclose EHI against the individual's expressed wishes. Although the revised § 171.202(e)
  sub-exception would no more change obligations an actor may have under another valid law to disclose
  EHI than does the current sub-exception, the revision would simplify actors' analyses of whether the
  sub-exception is applicable in each case where the actor is inclined to agree to the individual's
  requested restrictions.

### **Infeasibility Exception**

- Revise the *third party seeking modification use* condition by changing the words "health care provider" to "covered entity as defined in 45 CFR 160.103" in the exclusion from applicability of this condition. ONC also proposes to extend the exclusion so that the *third party seeking modification use* condition would not apply where a <u>health care provider</u> who is not a <u>HIPAA covered entity</u> requests modification use from an actor who would be the provider's business associate if the provider were a HIPAA covered entity.
- Revise the *responding to requests* condition (§ 171.204(b)) to offer actors a more flexible response timeframe where the reason(s) for infeasibility are consistent with the exception's *manner exception exhausted* (§ 171.204(a)(4)) or *infeasible under the circumstances* (§ 171.204(a)(5)) conditions. Under the proposal, the actor could satisfy the *responding to requests* condition by:
  - First, initiating within 10 business days of the actor receiving request good-faith collaborative engagement with the requestor to discuss the potential infeasibility of the request as received and potentially feasible alternative ways to achieve information sharing.
  - Second, where discussions and negotiations reach a result other than successful fulfillment of access, exchange, or use of EHI for the requestor, providing the requestor a written response indicating the reason for infeasibility within 10 business days of the actor's determination of infeasibility or the discontinuation of discussions (as described in proposed revised § 171.204(b)(2)(iii)).

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- ONC includes an alternative proposal that would establish maximum timeframe(s) within which good faith discussions and negotiations must reach a plan to proceed or an actor's determination that a particular requested access, exchange, or use of EHI is not feasible. Under the alternative proposal, the maximum amount of time would be: 3, 5, 10, 20, or 30 business days after the date the actor receives any initial request; or one of those timeframes for any request that does not implicate the HIPAA Privacy Rule's individual right of access (45 CFR 164.524) and the maximum timeframe allowed under 45 CFR 164.524 for those requests that do also implicate it.
- For infeasibility consistent with the § 171.204(a) *uncontrollable events, segmentation,* and *third party seeking modification use* conditions, the proposal would retain the § 171.204(b) *responding to requests* condition's existing requirement to respond within 10 business days of the actor receiving the request. However, ONC proposes to revise wording of the condition so it is more immediately clear when the 10 business day timeframe starts in certain circumstances.

#### **Protecting Care Access**

• The proposed **Protecting Care Access Exception (to be codified in 45 CFR 171.206)** would, under specified conditions, cover actors' limiting EHI sharing in order to reduce a risk of potentially exposing patients, providers, or persons who facilitate care to legal action based on the mere fact that they sought, obtained, provided, or facilitated lawful reproductive health care. The exception would also apply where an actor limits sharing of a patient's EHI potentially related to reproductive health care in order to protect that patient from potential exposure to legal action.

#### **Requestor Preferences Exception**

- A proposed **Requestor Preferences Exception (to be codified in 45 CFR 171.304)**. 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.

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.



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Disclaimer: This fact sheet describes select proposals in the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule. While every effort has been made to ensure the accuracy of this fact sheet, it is not a legal document. Please refer to the HTI-2 Proposed Rule for full details of each proposal.

