

21ST CENTURY CURES ACT: INTEROPERABILITY, INFORMATION BLOCKING, AND THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE



Information Blocking Exception for Practices that Prevent Harm

OVERVIEW

Under the proposed exception, it will not be information blocking for an actor to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided certain conditions are met.

To qualify for this exception, an actor must:

Have a reasonable belief that the practice will directly and substantially reduce the likelihood of a recognized harm to a patient or another person

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Implement a Qualifying Organizational Policy

or

Implement a Qualifying Individualized Finding

Objective



The public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of electronic health information (EHI).

The exception focuses on risks of harm that are specific to access, exchange, or use of EHI.

“Actors” regulated by the information blocking provision:



- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Exchanges
- Health Information Networks

Recognized Categories of Harm

The actor must have a reasonable belief that the practice will directly and substantially reduce the risk to a patient or another person under one or more of the following categories of harm:

- Harm arising from corrupt or inaccurate data being recorded or incorporated in a patient’s electronic health record.
- Harm arising from misidentification of a patient or patient’s EHI.
- A determination by a licensed health care professional that disclosure is reasonably likely to endanger the life or physical safety of the patient or another person (provided that, if required by applicable federal or state law, the patient has been afforded any right of review of that determination).

The proposed exception does not recognize the risk of harm that might arise from the incompleteness of EHI, including because of a patient’s decision not to consent to the disclosure of EHI.

Qualifying Organizational Policy

If the practice implements an actor’s organizational policy, that policy must be:

- In writing;
- Based on relevant clinical, technical, and other appropriate expertise;
- Implemented in a consistent and non-discriminatory manner; and
- No broader than necessary to mitigate the risk of harm.

Qualifying Individualized Finding

If the practice does not implement an organizational policy, the actor must make a finding in each case, based on the particularized facts and circumstances and, as applicable, relevant clinical, technical, and other appropriate expertise, that the practice is necessary and no broader than necessary to mitigate the risk of harm.