



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

HHS Proposes New Rule to Improve the Interoperability of Health Information

ONC REQUESTS PUBLIC COMMENT FOR PROPOSED RULE THAT PROMOTES PATIENT ACCESS AND EXCHANGE OF ELECTRONIC HEALTH INFORMATION

The U.S. Department of Health and Human Services' (HHS) Office of the National Coordinator for Health Information Technology (ONC) proposed a new rule that supports seamless and secure access to, exchange of, and use of electronic health information (EHI).

What is the proposed rule designed to do?

Increase innovation and competition



by giving patients and their healthcare providers safe and secure access to health information and to new tools, allowing for more choice in care and treatment;

Identify exceptions to the definition of information blocking



that the HHS Office of the Inspector General (OIG) would consider in their enforcement of the information blocking provisions in the 21st Century Cures Act (Cures Act); and

Adopt standardized application programming interfaces (APIs) in the healthcare industry



which would help allow individuals to securely and easily access structured EHI using smartphone applications;

Place a strong focus on a patient's ability to access their health information



through a provision requiring that patients can electronically access all of their electronic health information (structured and/or unstructured) at no cost.

What actions are being proposed?

- **The proposed rule would update the existing 2015 Edition certification criteria** to ensure certified health IT systems can
 - (1) send and receive EHI in a structured format,
 - (2) make that EHI available without special effort through the use of APIs, and
 - (3) export a single patient's or multiple patients' EHI from the health IT system to a location designated by the patient.
- **The proposed rule would implement the information blocking provisions of the Cures Act** by outlining seven proposed exceptions to the definition of information blocking under the law.
- **The proposed rule includes a request for information** on the parameters and implications of including price information within the scope of EHI and if that information would help the public see the prices they are paying for their healthcare.

What are the proposed exceptions to information blocking?

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Under the proposed rule, actions of a healthcare provider, health IT developer of certified health IT, health information network, or health information exchange that interfere with the access, exchange, or use of EHI — subject to certain conditions — would **not** be considered information blocking if the entity is:



- Engaging in practices to prevent **patient harm**



- Engaging in consistent, non-discriminatory practices **to protect the privacy of electronic health information**



- Implementing practices **to promote the security of electronic health information**



- **Performing maintenance or improvements to health IT performance** with the agreement of the user

- **Recovering reasonable costs** to allow for the access, exchange, and use of electronic health information



- Receiving a **request** to provide access, exchange, or use of electronic health information that is infeasible **because the request would impose a substantial burden** that is unreasonable under the circumstances



- Allowing for the **licensing of technical artifacts to support the interoperability of EHI on reasonable and non-discriminatory terms**



How does this proposed ONC rule intersect with the interoperability rule proposed by the Centers for Medicare & Medicaid Services?

CMS's efforts to improve interoperability and enhance patient's access to essential health information aligns with the proposed rule being issued by the HHS Office of the National Coordinator for Health Information Technology (ONC), the 21st Century Cures Act proposed rule. CMS proposes that entities must conform to the same advanced API standards as those adopted for certified health IT including an aligned set of content and vocabulary standards for common clinical data classes through the United States Core Data for Interoperability standard (USCDI). Together, these proposed rules address both technical factors and healthcare industry factors that cause barriers to interoperability and limit the ability of patients to access essential health information. Aligning these requirements for payers, health care providers, and health IT developers will help to drive an interoperable health IT infrastructure across systems ensuring providers and patients have access to health data when and where it is needed.

How do I comment on the proposed rule?



The proposed rule will be available for public comment for a period of **60 days**.



For additional information about the proposed rule, visit [HealthIT.gov/nprm](https://www.healthit.gov/nprm)