

Intellectual Property and Regulation: A Case Study of the 2019 Health Record Interoperability Rulemaking

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Intellectual Property (IP) rights can be misused in ways that undermine the promotion of competition and innovation. The potential for abuse is heightened when the IP rights . . . are essential to enabling interoperability.



**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



Adopt standardized application



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955-AA01

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

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions

Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format on ONC's website (<http://www.healthit.gov>). We believe this version will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally a

birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Michael Lipinski, Office of Policy, Office of the National Coordinator for Health Information Technology, 202-690-7151.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

Outline

- Background and history of the rulemaking
- Components of NPRM and appearances of IP
- Reflections

HITECH Act of 2009

- Objective: Transition to electronic health records (EHR)
- Creates Office of the National Coordinator of Health Information Technology (ONC)
- Voluntary certification of health IT
- Incentive: \$35 billion

Information Blocking

- EHR vendors/hospitals/etc. inhibiting interoperability and information sharing
- ⇒ ONC report (2015)
- ⇒ 21st Century Cures Act (2016)
- ⇒ ONC rulemaking (2019)

Types of Information Blocking

- Fees
- Proprietary interfaces
- Refusals per privacy law
- IP assertion?

IP and Information Blocking

- Litigation: Not really
- Gag clauses on screenshots
- Data ownership
- FTC consultation

ONC Rulemaking Components

- Interoperability standards (APIs)
- Prohibition on communication restrictions (gag clauses)
- Define information blocking and exceptions

No contractual restrictions on communications allowed for:

- “communications with unqualified protection” (public safety, whistleblowing, etc.)
- screenshots, unaltered or with annotations only
- “communications that would be a ‘fair use’ of any copyright work comprised in the developer’s health IT”

Questions on Communications

- Fair use as standard for regulatory limiting of contracts
- Copyright or trade secrets?
- Copyright law's preemption of contracts?

Information Blocking

- Broad definition: “likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information” (plus scienter)
- Six exceptions, including “licensing of interoperability elements on reasonable and non-discriminatory terms”—a FRAND policy
 - Interoperability element: “Any functional element of a health information technology”
 - 10-day period to respond to licensing requests
 - Reasonable royalty factors drawn from SSO cases (*Innovatio*, *Microsoft*, *Realtek*)

Questions on Information Blocking

- What IP is at stake exactly?
- Why FRAND (as opposed to setting rates etc.)?
- What methodology for computing royalties?
- What about IP assignments?

Reflections

- Regulation versus IP (Narechania, *Patent Conflicts*)
- Enforcement mechanisms: regulator versus courts/competition agencies
- Tendency to latch onto existing IP doctrines
- IP discourse in the “real world”