The Office of the National Coordinator for Health Information Technology

Physician–Computer Connection Symposium 2022: ONC Federal Priorities Update

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U.S. Department of Health and Human Services

The Office of the National Coordinator for Health Information Technology

ONC'S MISSION

Improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

HITECH Act : Catalyst for Transformation

HITECH Act

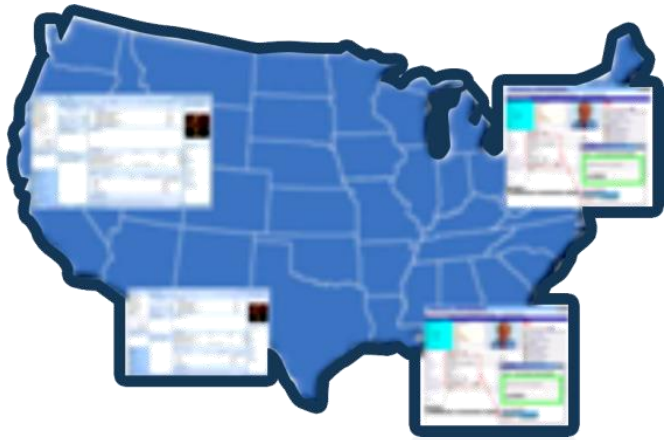
2009

EHR Incentive Program and 62 Regional Extension Centers

Current State

2022

Widespread adoption & use of EHRs



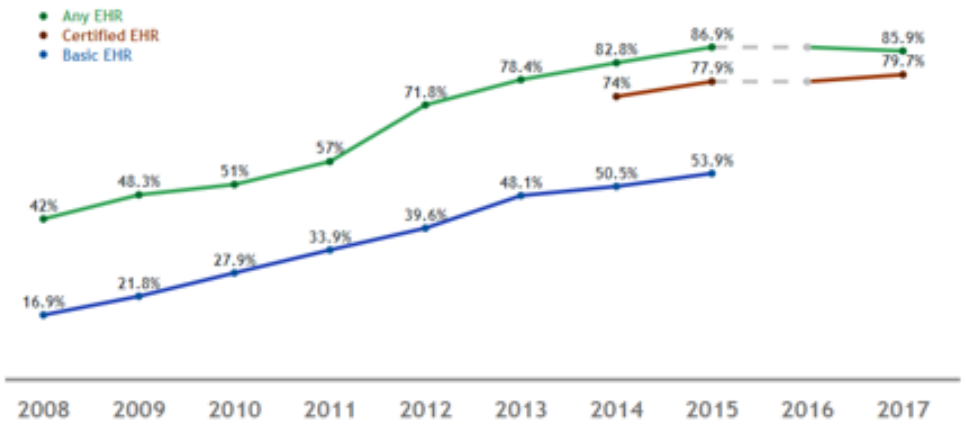
Promoting Interoperability Payment Data:

- More than $34.6 billion in Medicare and Medicaid EHR Incentive Program (PI) payments have been made.

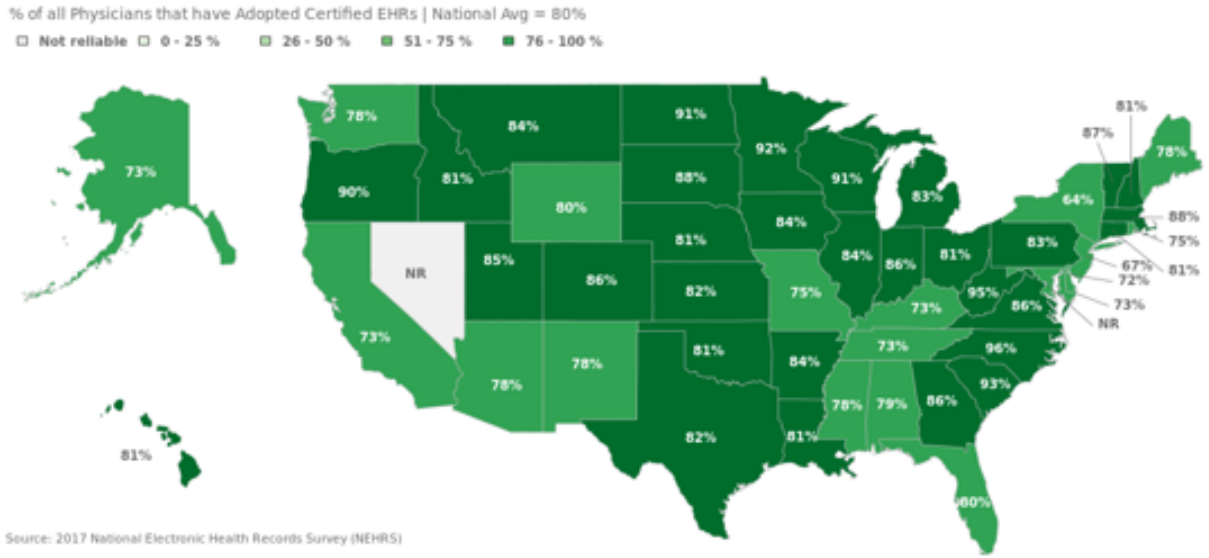
Reference: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/May2016_SummaryReport.pdf

Ambulatory Physician EHR Adoption
Increase in Adoption Nationwide

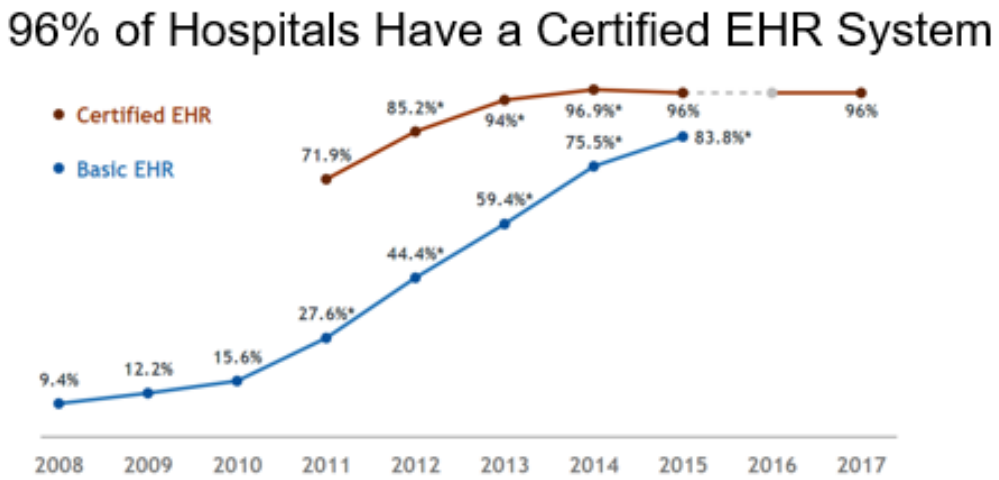
86% of Physicians Have an EHR System



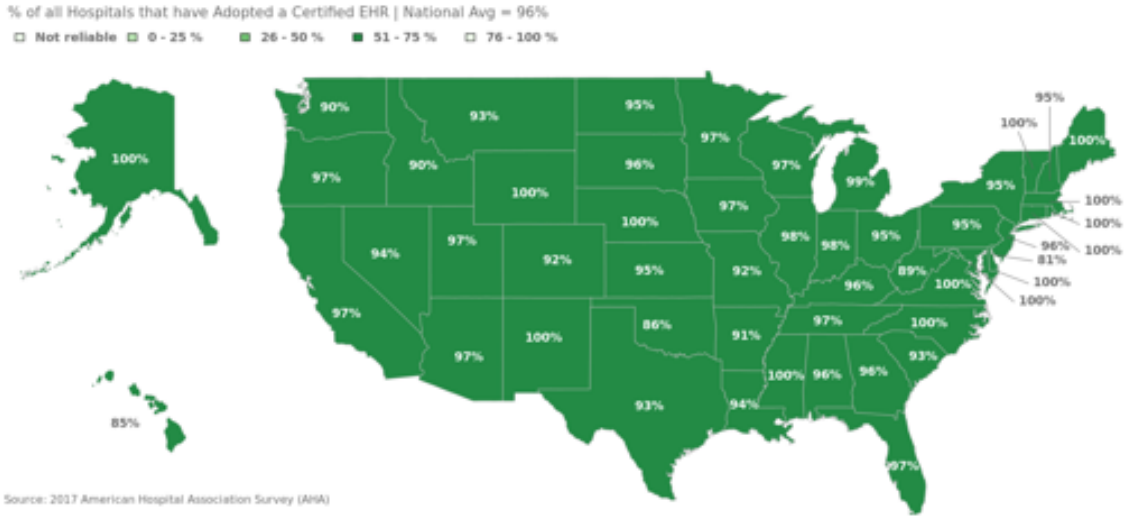
Source: Office of the National Coordinator for Health Information Technology. 'Office-based Physician Electronic Health Record Adoption,' Health IT Quick-Stat #50. dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php. January 2019.



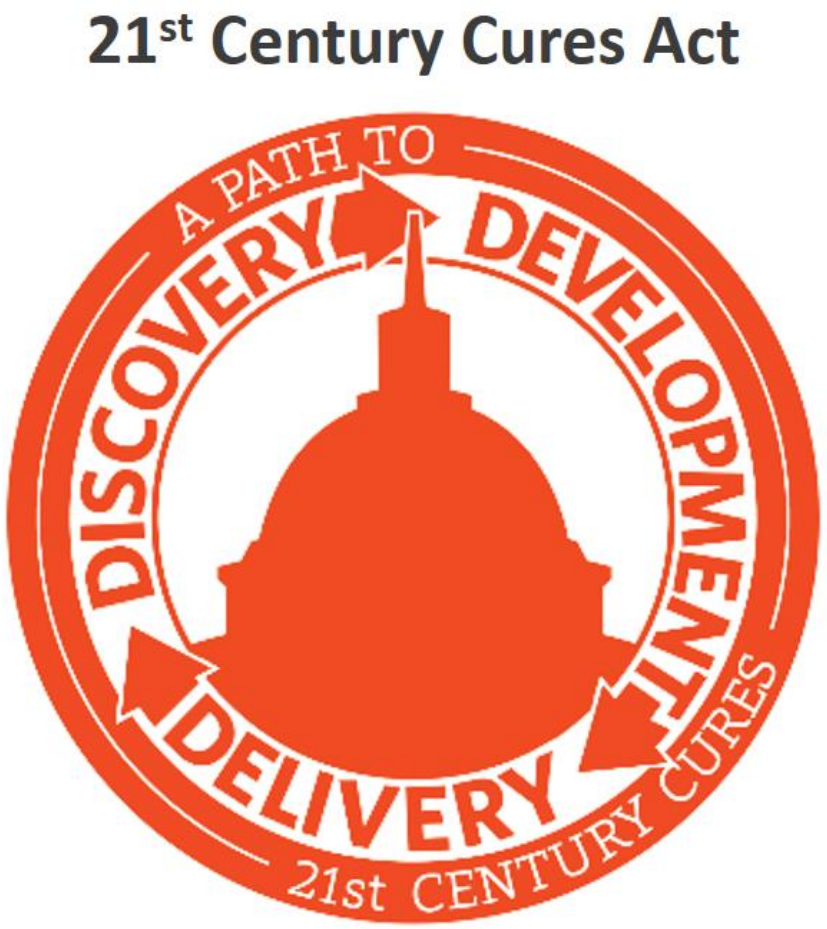
Hospital EHR Adoption
Increase in Adoption Nationwide



Source: Office of the National Coordinator for Health Information Technology. 'Non-federal Acute Care Hospital Electronic Health Record Adoption,' Health IT Quick-Stat #47. dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php. September 2017.



Health IT and the 21st Century Cures Act



ONCs Levers

- **Legislation**
- **Regulation**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 170 and 171

RIN 0955–AA01

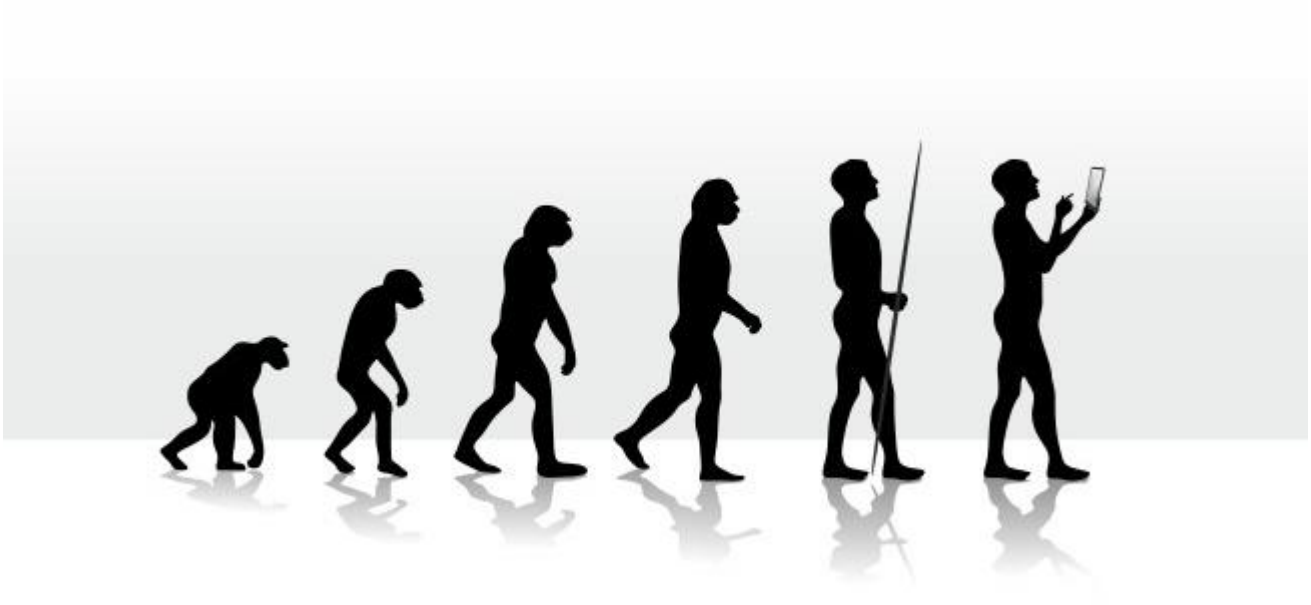
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

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

ACTION: Final rule.

SUMMARY: This final rule implements 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 will

Next Phase of Evolution



- Improved Interoperability
- Increased Patient Access to EHI
- Decreasing Clinician Regulatory an Administrative Burden

Application Programming Interfaces and the 21st Century Cures Act

conditions and requirements under this title, that the health information technology developer or entity—

"(i) does not take any action that constitutes information blocking as defined in section 3022(a);

"(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

"(iii) does not prohibit or restrict communication regarding—

"(I) the usability of the health information technology;

"(II) the interoperability of the health information technology;

"(III) the security of the health information technology;

"(IV) relevant information regarding users' experiences when using the health information technology;

"(V) the business practices of developers of health information technology related to exchanging electronic health information; and

"(VI) the manner in which a user of the health information technology has used such technology;

"(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

Cures Act Final Rule: Application Programming Interface Criterion

- Established a new application programming interface (API) certification criterion that requires health IT developers to support standardized APIs for single patient and population services.
- Certification criterion is limited to API-enabled "read" services using the HL7® Fast Healthcare Interoperability Resources (FHIR) Release 4 standard.
- The use of the FHIR standard and a set of implementation specifications provides known technical requirements against which third-party apps can be developed.

Supports two types of API-enabled services:

» Services for which a **single patient's data** is the focus

» Services for which **multiple patients' data** are the focus

USCDI

USCDI Version 1

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment

Care Team Member(s)
- Care Team Members

Clinical Notes
- Consultation Note
- Discharge Summary Note
- History & Physical
- Imaging Narrative
- Laboratory Report Narrative
- Pathology Report Narrative
- Procedure Note
- Progress Note

Goals
- Patient Goals

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results

Medications
- Medications

Patient Demographics
- First Name
- Last Name
- Middle Name (Including middle initial)
- Suffix
- Previous Name
- Birth Sex
- Date of Birth
- Race
- Ethnicity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems

Procedures
- Procedures

Provenance
- Author Organization
- Author Time Stamp

Smoking Status
- Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- Diastolic blood pressure
- Heart Rate
- Respiratory rate
- Body temperature
- Body height
- Body weight
- Pulse oximetry
- Inhaled oxygen concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

The 21st Century Cures Act

Section 4004: Information Blocking

- Defines “information blocking”
- Authorizes the Secretary to identify reasonable and necessary activities that do **not** constitute information blocking
- Tasks ***ONC*** to implement a standardized process for reporting information blocking claims
- Tasks the HHS Office of Inspector General (***OIG***) with investigating claims of information blocking
- Prescribes sanctions for information blocking

21st Century Cures Act and Information Blocking (Section 4004) (Information Sharing)

- Information blocking is a practice by a health IT developer, health care provider, health information exchange, or health information network that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI)
  - » May be policies, business, technical or organizational practices.
  - » Section 4004 of the Cures Act authorizes the Secretary of Health and Human Services to identify reasonable and necessary activities that do not constitute information blocking

> "(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this title, that the health information technology developer or entity—
>
> "(i) does not take any action that constitutes information blocking as defined in section 3022(a);

21st Century Cures Act and Information Blocking (Section 4004)

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the 'Inspector General') may investigate any claim that—

"(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

"(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

"(ii) engaged in information blocking;

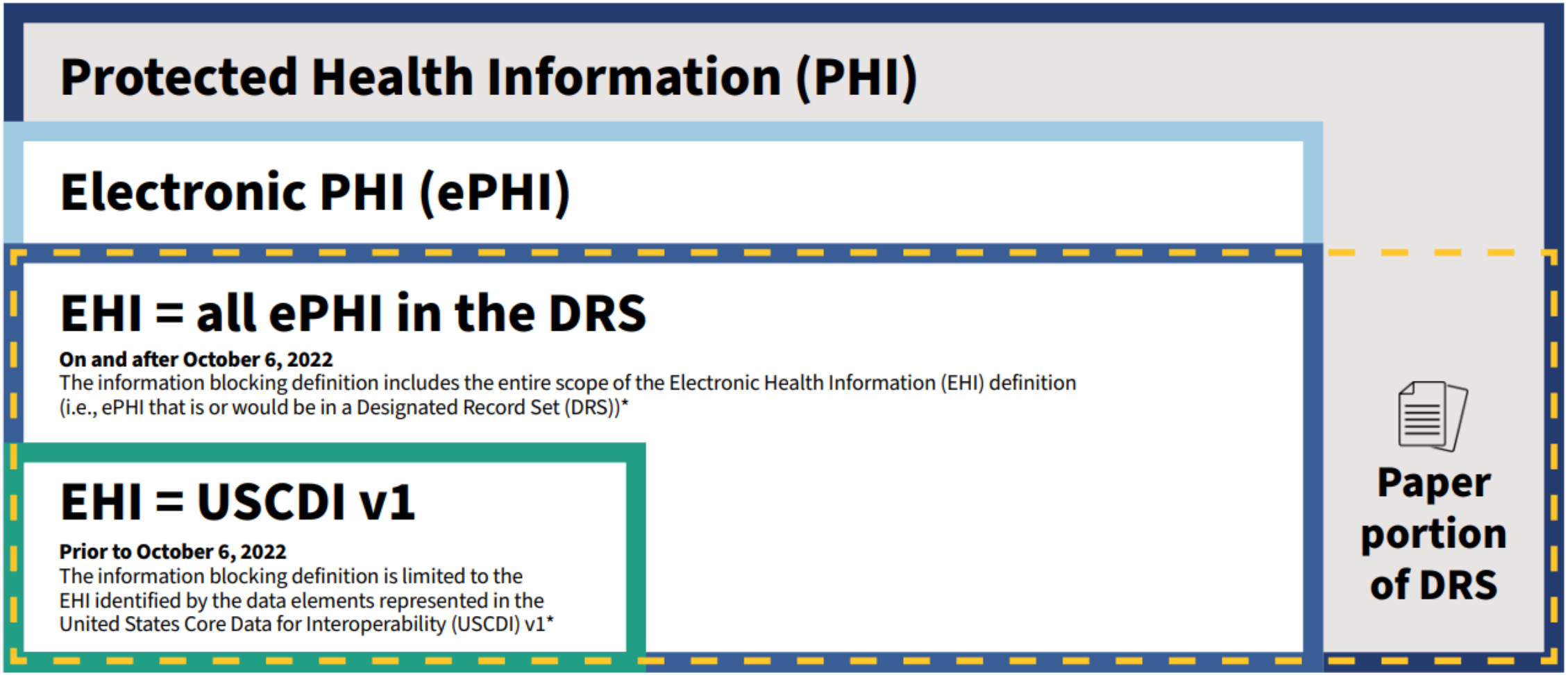
"(B) a health care provider engaged in information blocking; or

"(C) a health information exchange or network engaged in information blocking.

"(2) PENALTIES.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking

Information Blocking and the definition of Electronic Health Information (EHI)



21st Century Cures Act and Interoperability - TEFCA

"(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

Trusted Exchange Framework and Common Agreement

GOAL 1

Provide a single "on-ramp" to nationwide connectivity

GOAL 2

Electronic Health Information (EHI) securely follows you when and where it is needed

GOAL 3

Support nationwide scalability

21st Century Cures Act 4001 (a) Reduce Clinician Buren

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111–5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

"SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

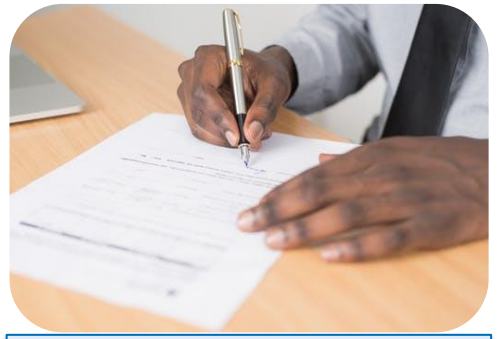
21st Century Cures Act - Section 4001. (a)
Clinician Burden Reduction Report to Congress

- **Reduction in Burdens Goal**--The Secretary of Health and Human Services shall establish a goal, strategy and recommendations with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records
- In consultation with providers of health services, health care payers, health professional societies, health information technology developers, public health entities, States, and other appropriate entities.

CMS and ONC collaborated to gain stakeholder feedback

Chief burdens reported by stakeholders

Billing-related documentation “note bloat”



Prior authorization

Quality measurement

Poor user experience with health IT and clinical workflow

Too much time outside of patient care spent on electronic records

PDMPs poorly integrated into EHRs

21st Century Cures Act - Section 4001. (a) Clinician Burden Reduction Report to Congress

Address the effects of rapid digitalization of healthcare

- **Clinical Burden Reduction**

MENU AMA Join Renew Enter Search Term

CPT®

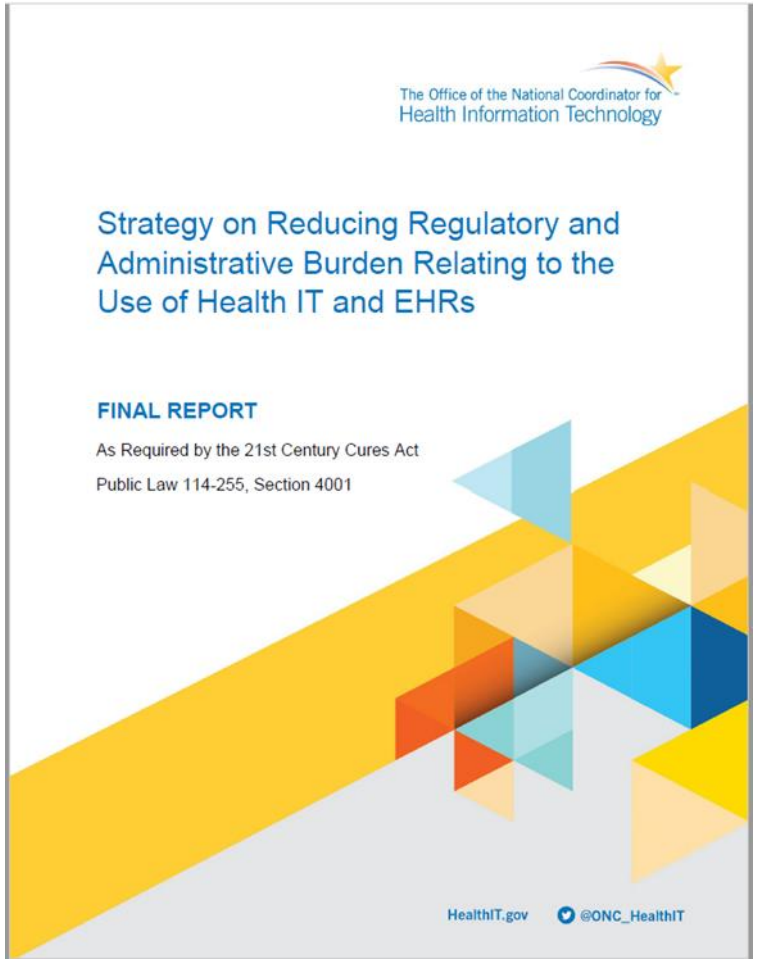
How 2021 E/M guidelines could ease physicians' documentation burdens

FEB 13, 2020 • 4 MIN READ

Andis Robeznieks
Senior News Writer

PRINT PAGE

Physicians will potentially have a lighter documentation burden and more time to spend with patients in 2021 thanks to an overhaul of Medicare coding guidelines for outpatient evaluation and management (E/M) services.



Health Equity By Design

- **What is it?**
  - Equity considerations identified and incorporated as early as possible in the health IT design, build and implementation process
  - Health IT products and capabilities are designed to be foundationally equity enforcing
  - Micky Tripathi's vision of injecting equity into the design principals of the health IT ecosystem
  - A portfolio of projects assembled from SMEs, stakeholders, and research literature to advance health equity

USCDI Version 2

The Office of the National Coordinator for Health Information Technology

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Reaction

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment ★

Care Team Member(s)
- Care Team Member Name ★
- Care Team Member Identifier ★
- Care Team Member Role ★
- Care Team Member Location ★
- Care Team Member Telecom ★

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- Procedure Note
- Progress Note

Clinical Tests ★
- Clinical Test ★
- Clinical Test Result/Report ★

Diagnostic Imaging ★
- Diagnostic Imaging Test ★
- Diagnostic Imaging Report ★

Encounter Information ★
- Encounter Type ★
- Encounter Diagnosis ★
- Encounter Time ★
- Encounter Location ★
- Encounter Disposition ★

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- Patient Goals
- SDOH Goals ★

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- Suffix
- Previous Name
- Date of Birth
- Race
- Ethnicity
- Sex (Assigned at Birth)
- Sexual Orientation ★
- Gender Identity ★
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Problems
- Problems
- SDOH Problems/Health Concerns ★
- Date of Diagnosis ★
- Date of Resolution ★

Procedures
- Procedures
- SDOH Interventions ★

Provenance
- Author Organization
- Author Time Stamp

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★ New Data Classes and Elements

Health IT Playbook

Goal: Help to resolve key issues and challenges clinicians are experiencing as it relates to health IT optimization and workflow

www.healthit.gov/playbook

Where To Find More Information

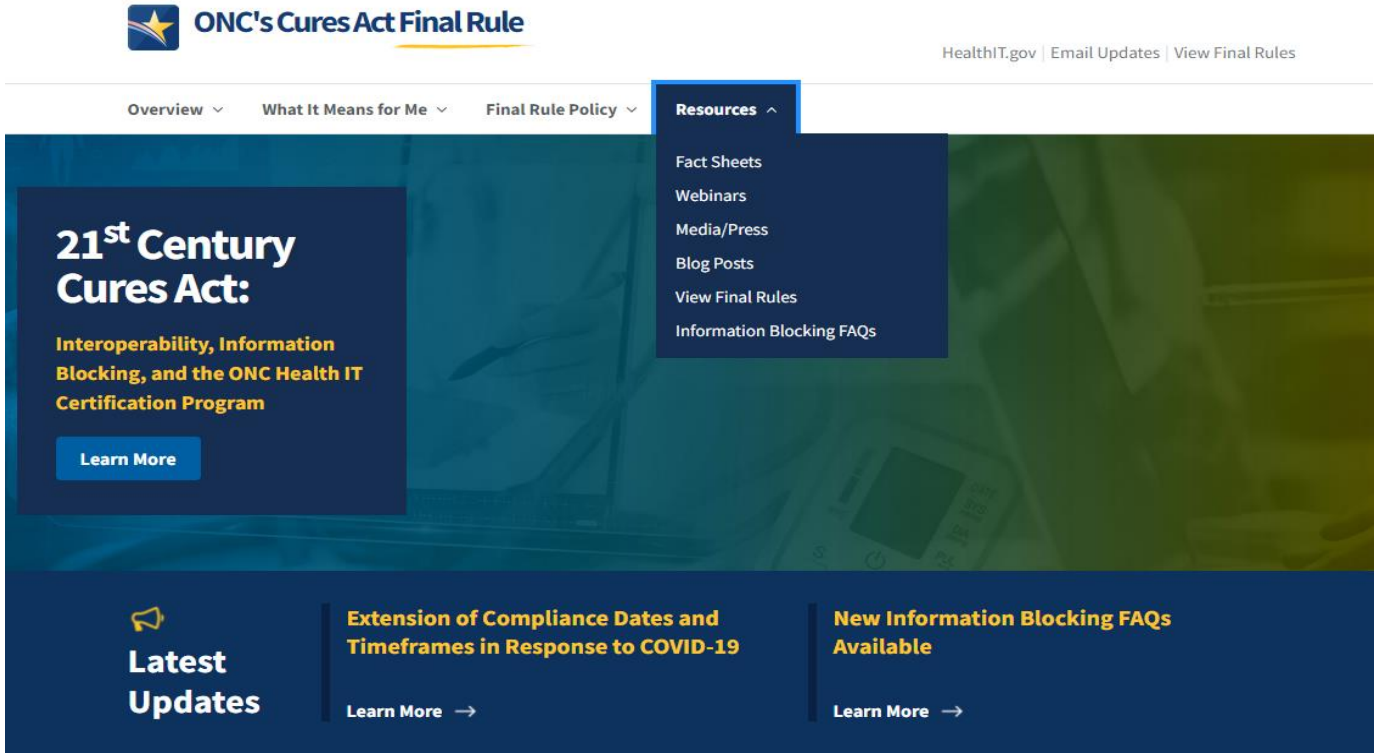
- **ONC Website Resources:** www.HealthIT.gov/CuresRule

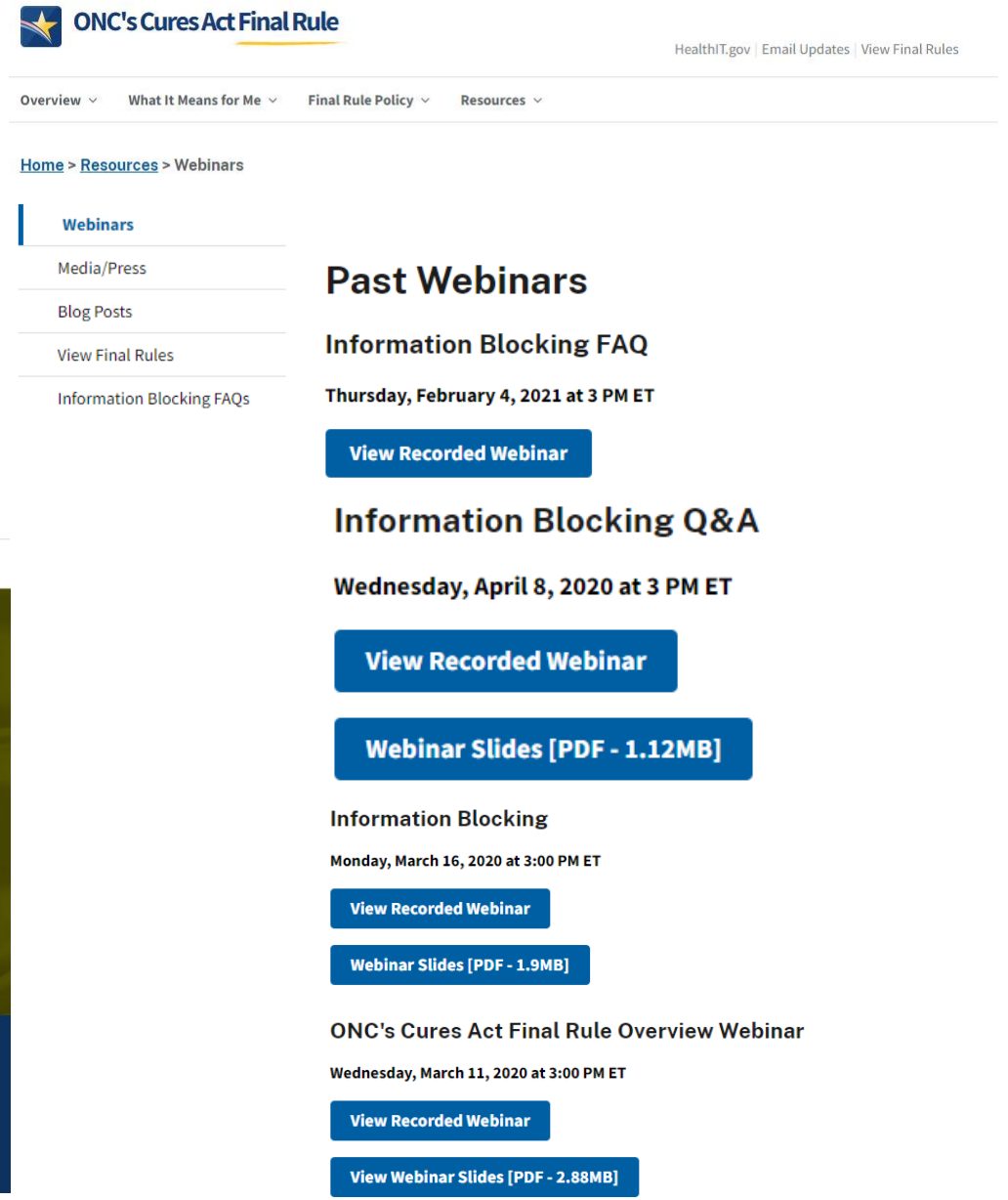
Factsheets: https://www.healthit.gov/curesrule/resources/fact-sheets

FAQs: https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Blogs: https://www.healthit.gov/buzz-blog/category/21st-century-cures-act

Webinars: https://www.healthit.gov/curesrule/resources/webinars





Let’s Continue Building upon Progress Together

Thank you!!

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Additional Slides

Information Blocking Exceptions

§ 171.201 Exception | Preventing Harm

- An actor may engage in practices that are reasonable and necessary to prevent physical harm to a patient or another person.
- The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of physical harm to a patient or another person.
- The practice must implement an organizational policy that meets certain requirements or must be based on an individualized assessment of the risk in each case.

This proposed exception acknowledges that 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).

§ 171.202 Exception | Promoting the Privacy of Electronic Health Information

- An actor may engage in practices that protect the privacy of EHI.
- An actor must satisfy at least one of four discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices: (1) practices that satisfy preconditions prescribed by privacy laws; (2) certain practices not regulated by HIPAA but which implement documented and transparent privacy policies; (3) denial of access practices that are specifically permitted under HIPAA; (4) practices that give effect to an individual's privacy preferences.
- The information blocking provision will not require that actors provide access, exchange, or use of EHI in a manner that is not permitted under the HIPAA Privacy Rule.
- General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a consistent and non-discriminatory manner.

This proposed exception would advance the goal of preventing information blocking for improper or self-interested purposes while maintaining and upholding the privacy rights that patients now have.

Information Blocking Exceptions

§ 171.203 Exception | Promoting the Security of Electronic Health Information

- An actor may implement measures to promote the security of EHI.
- The practice must be directly related to safeguarding the confidentiality, integrity, and availability of EHI.
- The practice must be tailored to specific security risks and must be implemented in a consistent and non-discriminatory manner.
- The practice must implement an organizational security policy that meets certain requirements or must be based on an individualized determination regarding the risk and response in each case.

This proposed exception would protect actors who mitigate security risks and implement appropriate safeguards to secure the EHI they control.

§ 171.204 Exception | Recovering Costs Reasonably Incurred

- An actor may recover costs that it reasonably incurs, in providing access, exchange, or use of EHI.
- Fees must be: (1) charged on the basis of objective and verifiable criteria uniformly applied to all similarly situated persons and requests; (2) related to the costs of providing access, exchange, or use; and (3) reasonably allocated among all customers that use the product/service.
- Fees must not be based on anti-competitive or other impermissible criteria.
- Certain costs would be specifically excluded from coverage under this exception, such as costs that are speculative or subjective or costs associated with electronic access by an individual to their EHI.

This proposed exception acknowledges that actors should be able to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability and promote innovation, competition, and consumer welfare.

Information Blocking Exceptions

§ 171.205 Exception | Responding to Requests that are Infeasible

- An actor may decline to provide access, exchange, or use of EHI in a manner that is infeasible.
- Complying with the request must impose a substantial burden on the actor that is unreasonable under the circumstances (taking into account the cost to the actor,
- The actor must timely respond to infeasible requests and work with requestors to provide a reasonable alternative means of accessing the EHI.

This proposed exception acknowledges that there may be legitimate practical challenges beyond an actor's control that may limit its ability to comply with requests for access, exchange, or use of EHI.

§ 171.206 Exception | Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

- An actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on reasonable and non-discriminatory terms.
- The license can impose a reasonable royalty but must include appropriate rights so that the licensee can develop, market, and/or enable the use of interoperable products and services.
- The terms of the license must be based on objective and verifiable criteria that are uniformly applied and must not be based on impermissible criteria, such as whether the requestor is a potential competitor.

This proposed exception would allow actors to protect the value of their innovations and earn returns on the investments they have made to develop, maintain, and update those innovations.

Information Blocking Exceptions

- **§ 171.207 Exception** | Maintaining and Improving Health IT Performance

  - An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT.
  - An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements.
  - The practice must be implemented in a consistent and non-discriminatory manner.
  - In circumstances when health IT is supplied to an individual or entity, the individual or entity (e.g., customer) must agree to the unavailability of health IT.

The proposed exception recognizes that it may be reasonable and necessary for actors to make health IT, and in turn EHI, temporarily unavailable for the benefit of the overall performance of health IT.