



Introduction to Presenter:

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Overview: 21st Century CURES

- Patients: Right of Access to their Chart, Supporting Patient Privacy and Security, the Ability to Shop for Care and Avoid Bankruptcy
- ✓ **Doctors and Hospitals**: Making Patient's Chart Data Requests Easy and Inexpensive, Allowing Choice of Software, Implementation
- Patients, Doctors, and Hospitals: Improving Patient Safety
- Health IT Developers: Minimizing API Development and Maintenance Costs, Protecting Intellectual Property
- ✓ American Public: Maximizing Innovation, Transparency in Health Care

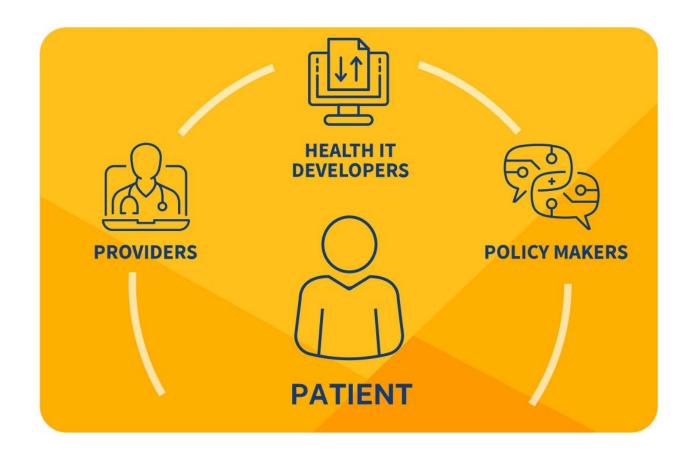








Spurring Innovation









Key Principle: Access

"We have finalized the definition of "access" as "the ability or means necessary to make EHI available for exchange, use, or both" (§ 171.102).

 Makes clear that "access" is the ability or means necessary to make EHI available not only for "use," but also for "exchange" or both (the proposed definition only included "for use").





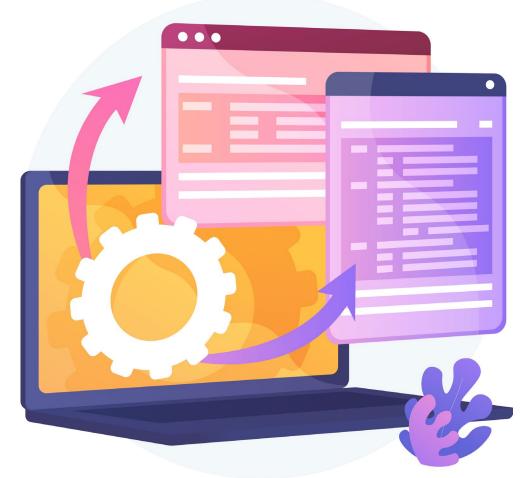




Key Principle: Exchange

"We have finalized the definition of "exchange" as "the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks."

 Emphasize that "transmitted" within the definition is not limited to a one-way transmission, but instead is inclusive of all forms of transmission such as bi- directional and network-based transmission.









Key Principle: Use

"We have finalized "use" to mean "the ability for EHI, once accessed or exchanged, to be understood and acted upon." Put another way, "use" is an individual or entity's ability to do something with the EHI once it has been accessed or exchanged.

 IT to access relevant EHI; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose









New: Open Notes

Good news about open notes

Open notes have positive impacts on patient engagement and understanding. Patients report that reading notes is a way to better understand and feel more in control of their health care. They also say it builds trust with their provider

Bad news about open notes

Concerns about open notes mainly revolve around the potential for conflicts with patients and potential time conflicts.

- **Timing**: Many providers and practices are still feeling the pandemic's effects, leading to the question: "Will new demands never end?"
- Uncertainty about the documentation process: Providers are wondering: "How can I make my notes comprehensible to patients while still writing them quickly?"
- Technology: Some EHR vendors are still racing to provide services that allow practices to remain in compliance with the Cures Act. It may be necessary for a provider to call their EHR vendor and say: "What are you doing to ensure my interoperability compliance?" Meanwhile, secure drop box options for records requests provide a workaround.









New: Application Programming Interface (API) 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







FHIR APIS

The biggest challenges to EHR interoperability are: Lack of standardization across many EHRs to communicate and Expense and time involved in creating needed interfaces between EHRs.

- Enables EHR Vendor App Marketplace
- Several improvements over HL7 >



Why FHIR?

- A strong focus on fast and easy implementation; developers have reported they
 experienced simple interfaces being implementable in a single day.
- Free to use with no restrictions.
- Support from major vendors including Apple, Microsoft, Google, Epic, Cerner, and most other EHR vendors.
- Many free, online, and downloadable tools, including reference servers and implementation libraries.
- Many public examples available to help kick-start development of new applications.
- Interoperability out-of-the-box base resources can be used as is, but can also be adapted for local requirements (the process of Profiling).
- An evolutionary development path from earlier HL7 healthcare standards, Version 2 and Clinical Document Architecture (CDA®), enabling them to co-exist and leverage each other.
- A strong foundation in web standards including XML, JSON, HTTP, and OAuth.
- Concise and easily-understood online specifications.
- A human-readable serialization format for ease of use by developers.
- A global community to assist implementers.

Source: https://www.healthit.gov/sites/default/files/2019-08/ONCFHIRFSWhatIsFHIR.pdf







Information Blocking

What is information blocking?

A <u>practice</u> by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the **Secretary as a reasonable and necessary activity**, is likely to interfere with access, exchange, or use of electronic health information.

What are the exceptions?

- Section 4004 of the Cures Act authorizes the Secretary to identify reasonable and necessary activities that do not constitute information blocking.
- In consultation with stakeholders, we have identified eight exceptions for practices that are reasonable and necessary, provided certain conditions are met.



Three categories of "Actors":



Health Care Providers



 Health IT Developers of Certified Health IT



 Health Information Exchanges and/or Health Information Networks



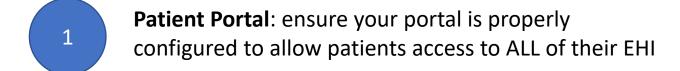


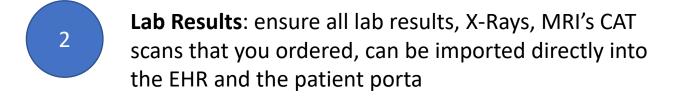


Practice Requirements

- Make sure to avoid Implementing Health IT in ways that are likely to—
 - Restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health IT systems; or
 - Lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health IT.

How does a practice comply with the Data Blocking requirements?





Note: complaints of non compliance are made on: https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6

Source: https://docadvocates.com/news/the-21st-century-cures-act-what-physicians-need-to-know/







Information Blocking Exceptions



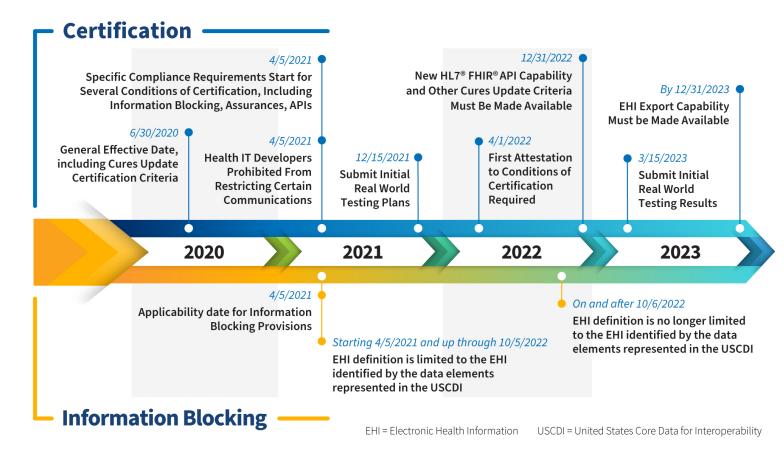






Compliance Timeline

- April 5th, 2021: This is when the ONC's Information Blocking provision goes into effect.
- October 6th, 2022: Regulatory compliance around information blocking will be expanded to include all ePHI instead of only <u>USCDI</u> data.
- December 31st, 2023: Various requirements for certified health IT vendors will extend into 2023.



Source: https://blog.pcc.com/what-does-21st-century-cures-act-mean-for-you







Conditions and Maintenance of Certification Requirements

The 21st Century Cures Act requires HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program.









Supporting New PHI Requirements

To support the PHI (Protected Health Information) requirements of the act, Health Centers can implement the following:

Patient Portal Implementation

Regular EHR
System updates

Data Sharing Agreements

Staff Training

Audit Trails

Data Request Workflow

Interoperability
Testing

Cybersecurity
Measures

Feedback Mechanisms







Performance Measurement



Patient Access Metrics

Portal Utilization
Data Request
Response Time

Feedback Surveys



Interoperability Metrics

Data Exchange Volume

Successful Integrations

Error Rates



Information Blocking Audits

Audit Trail Reviews Incident Reports



Staff Training Metrics

Training Completing Rates

Knowledge Assessments



Cyber Security Metrics

Security Incidents
Vulnerability
Assessments



Documentation Metrics

Policy Updates
Documentation
Accessibility



Financial Metrics

Investment in Technology

Penalties Avoided





