The Office of the National Coordinator for Health Information Technology

Key Considerations: HIPAA Security, Health IT, and the App Ecosystem

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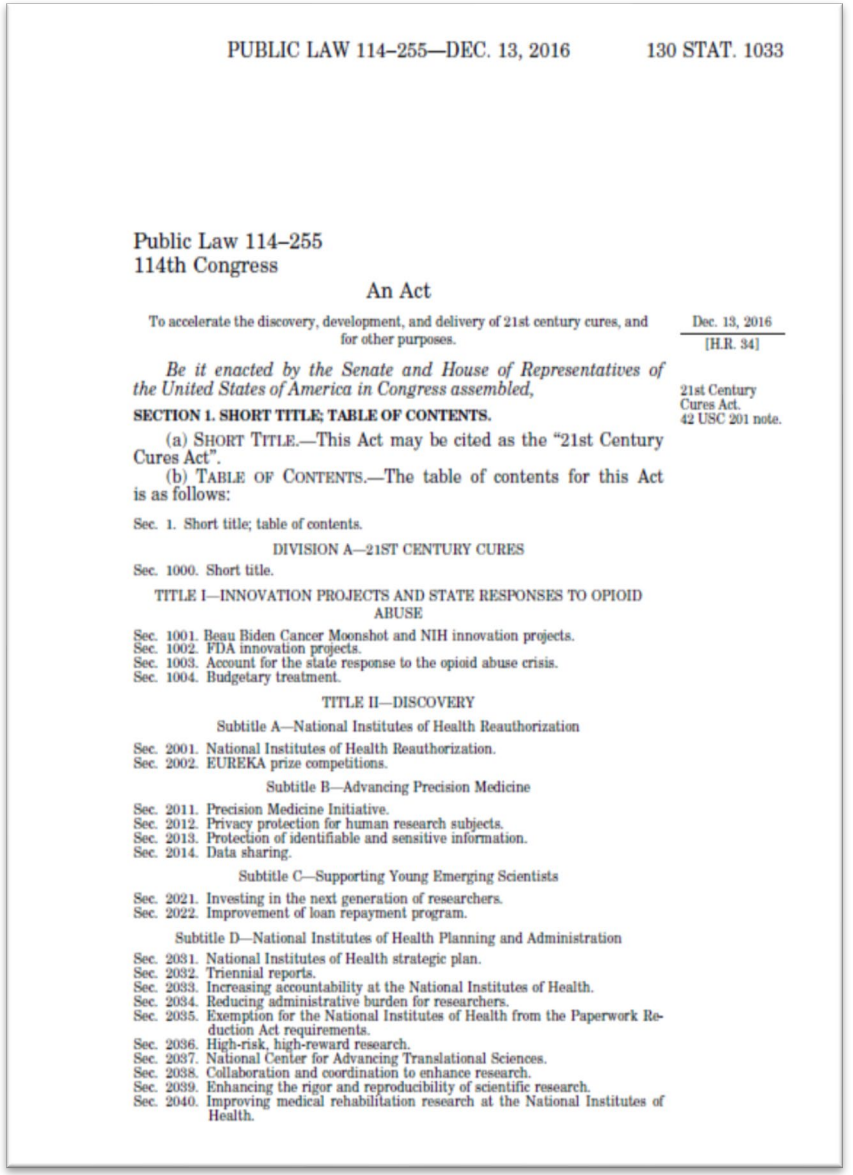
About ONC

- The Office of the National Coordinator for Health Information Technology
  - Sits within US Department of Health and Human Services
  - Created in 2004 under an Executive Order by President Bush
  - Codified in law in 2009 as part of the American Recovery and Reinvestment Act ("Recovery Act")
  - Substantial new authority as a result of the 21st Century Cures Act (2016)

Title IV of the 21st Century Cures Act

- **Sec. 4001. Assisting doctors and hospitals in improving quality of care for patients.**
- **Sec. 4002. Transparent reporting on usability, security, and functionality.**
- **Sec. 4003. Interoperability.**
- **Sec. 4004. Information blocking.**
- **Sec. 4005. Leveraging electronic health records to improve patient care.**
- **Sec. 4006. Empowering patients and improving patient access to their electronic health information.**



PUBLIC LAW 114–255—DEC. 13, 2016 130 STAT. 1033

Public Law 114–255
114th Congress

An Act

To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

Dec. 13, 2016
[H.R. 34]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

21st Century Cures Act.
42 USC 201 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Two Statutory Sections Implemented Together

45 CFR Part 170.4xx and Part 171.2xx

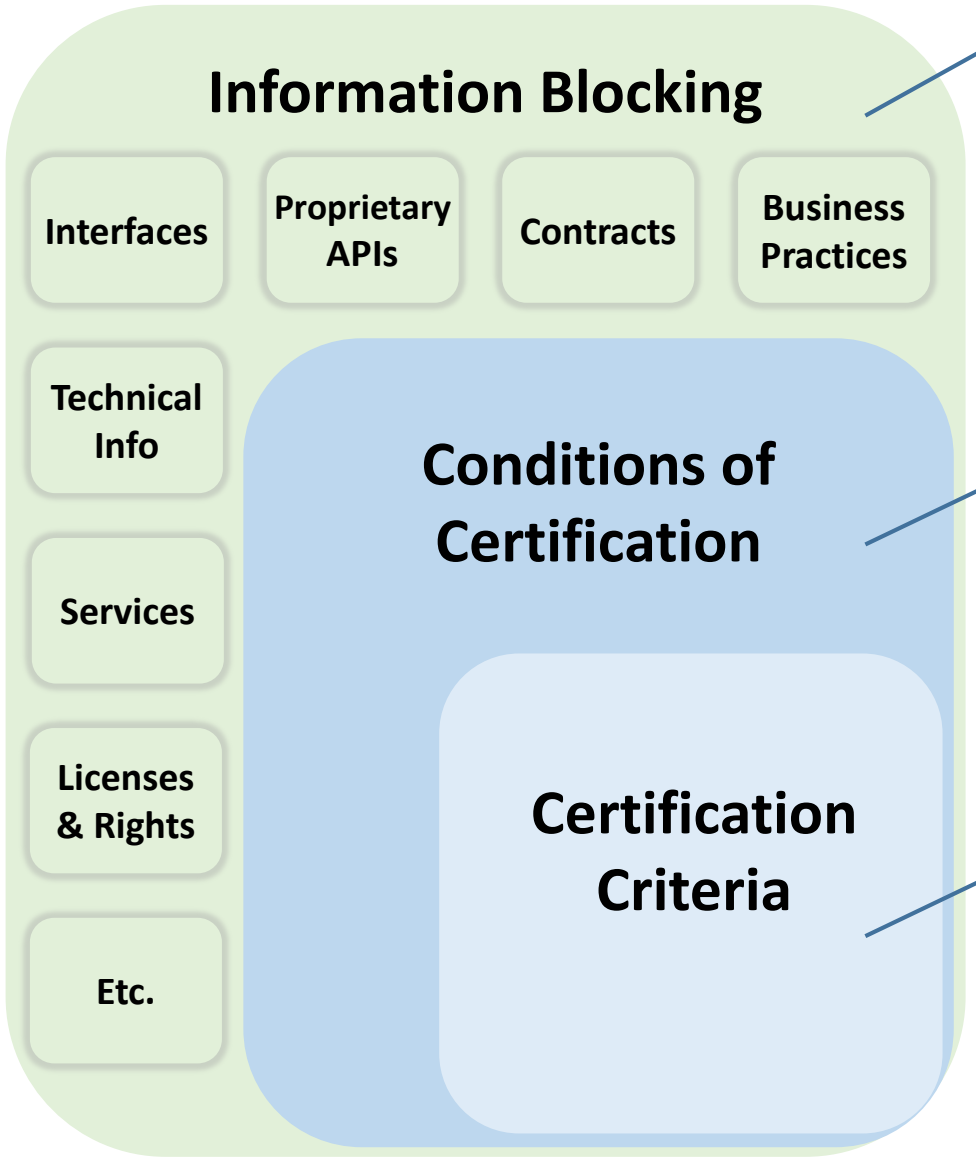
Conditions of Certification

- 170.401 Information blocking
- 170.402 Assurances
- 170.403 Communications
- 170.404 APIs (without special effort)
- 170.405 Real world testing
- 170.406 Attestations
- 170.40x EHR Reporting Program

Information Blocking Exceptions

- 171.201 Preventing harm
- 171.202 Promoting the privacy of electronic health information
- 171.203 Promoting the security of electronic health information
- 171.204 Recovering costs reasonably incurred
- 171.205 Responding to requests that are infeasible
- 171.206 Licensing of interoperability elements on reasonable and non-discriminatory terms
- 171.207 Maintaining and improving health IT performance

The Really Big Picture
Scope and Applicability



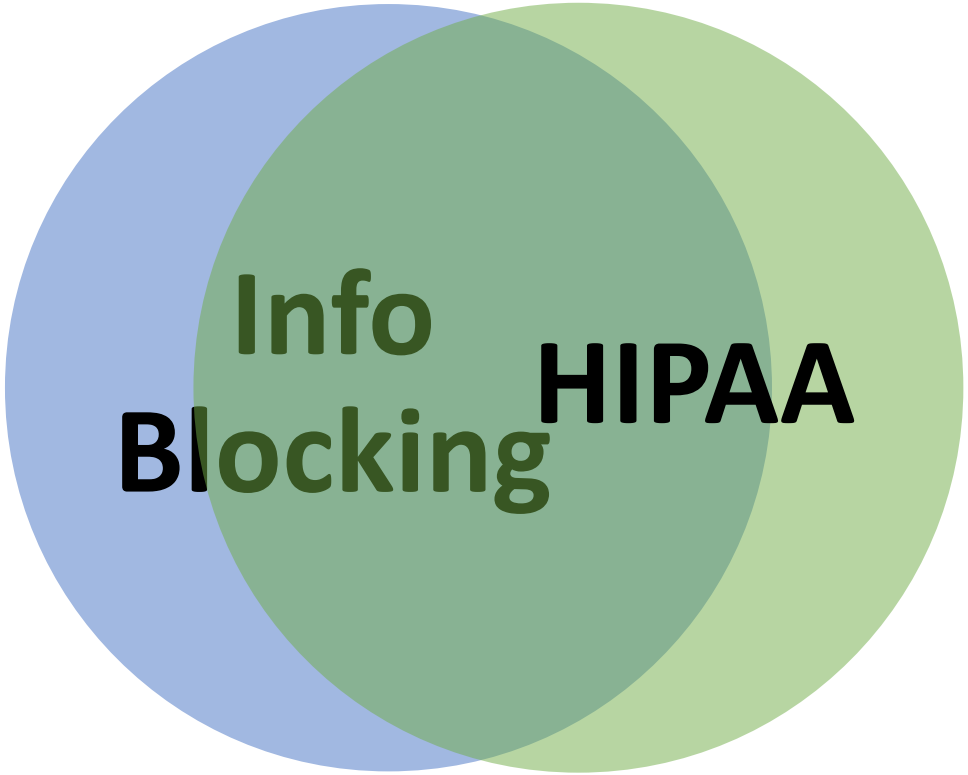
- Applies to certified health IT developers, health information exchanges, health information networks, & health care providers
- Electronic health information is expected to be accessible, exchangeable, & useable unless an "interference" is required by law or covered by an exception(s)
- An action(s) covered by an exception(s) would not be subject to penalties or disincentives

- Applies only to health IT developers
- Also include maintenance of certification requirements

- Specify the technical requirements that software products presented for certification need to meet.

Who's covered?
Information Blocking vs HIPAA

(Actors)
- Developers of certified health IT
- Health information exchanges
- Health information networks
- Healthcare providers



(Covered Entities)
- Healthcare providers
- Health plans
- Healthcare clearinghouses

(Business Associates)
- All shapes and sizes

Points to consider:
- Likelihood that most info blocking actors will be a covered entity or business associate
- Healthcare provider is a term shared between the two regulatory structures

The Trusted Exchange Framework and Common Agreement

21st Century Cures Act - Section 4003(b)

"[T]he 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—

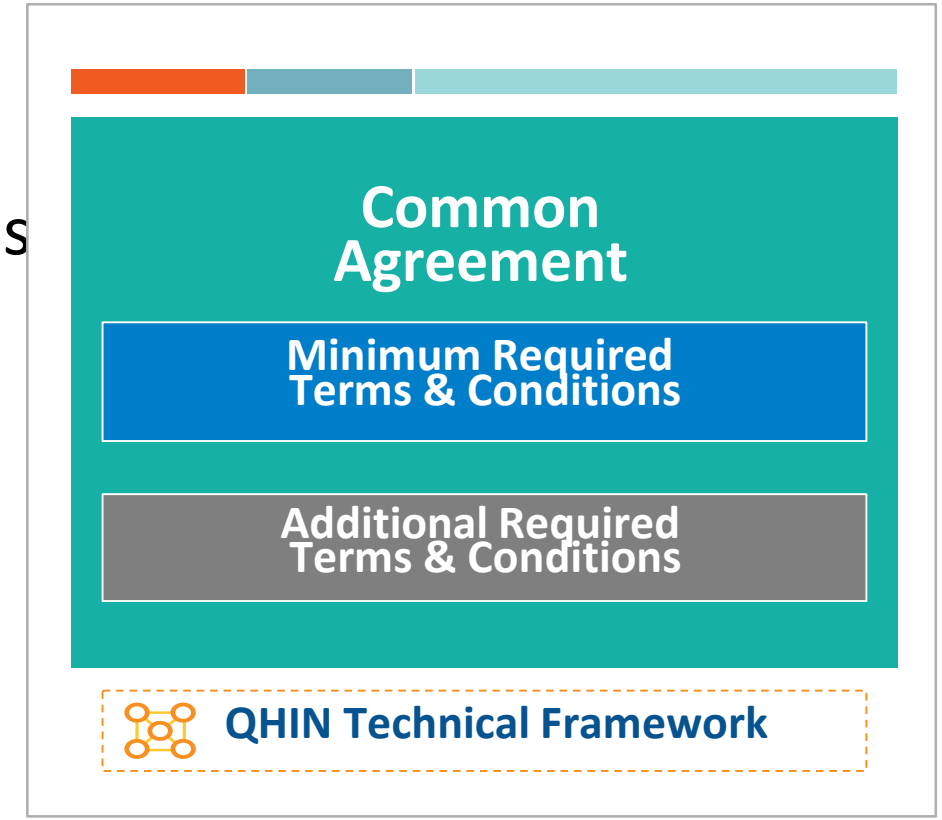
> *"(I) a common method for authenticating trusted health information network participants;*
>
> *"(II) a common set of rules for trusted exchange;*
>
> *"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and*
>
> *"(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement."*

"[T]he National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under paragraph B…"

Security Focus: TEFCA and ONC Proposed Rule

- ONC Proposed Rule with respect to APIs
  - App registration
  - Secure connection
  - User authentication
  - App authorization

- TEFCA: minimum required terms and conditions (MRTCs) provisions that address:
  - data integrity
  - identity proofing
  - access control
  - user authentication
  - auditing



Ways to Engage

- Health IT Feedback
  - https://www.healthit.gov/healthit-feedback
- Interoperability Standards Advisory
  - https://www.healthit.gov/isa/
- Guide to Getting & Using Your Health Records
  - https://www.healthit.gov/how-to-get-your-health-record/
- Interoperability Proving Ground
  - https://www.healthit.gov/techlab/ipg/
- Certified Health IT Product List
  - https://chpl.healthit.gov/

The Office of the National Coordinator for Health Information Technology

Thanks & Questions

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