A short history of Cures

- 21st Century Cures Act of 2016 passed both the House (392-26) and Senate (94-5) December 7, 2016
- President Obama signed Public Law No: 114-255 Dec 13, 2016

Health IT and Cures

- A dozen sections under Title IV, 9 of which have health IT focus
  - Address provider burden
    - Strategy, Certification for specialties and sites of service, provider directory
  - Transparent reporting on usability, security, and functionality
    - Conditions & Maintenance of Certification
      - Real-world testing, EHR Reporting Program (Usability, Interoperability, Security, Communications), Information Blocking, APIs
  - Interoperability
    - New definition
  - Information blocking
    - New "reasonable and necessary activities that do not constitute information blocking"
  - Trusted Exchange / Common Agreement
  - Empowering patients and improving patient access to their electronic health information

Policy Levers

- ONC manages the Certification Program, proving regulatory authority of Certified Health IT
  - Generally, this has been focused on certification criteria meant to dictate specific functionalities, using specific standards
    - CPOE, CDS, HL7 C-CDA, LOINC, etc.
- Cures provided a new policy tool for the Certification Program, known as Conditions & Maintenance of Certification Requirements
  - Initial and ongoing *technical* and *behavior* requirements

Intellectual and Spiritual Center of this Policy

- Cures defines interoperability in the context of health IT that:
  - (1) enables the secure exchange and use of **electronic health information without special effort** on the part of the user
  - (2) allows for **complete access, exchange, and use** of all electronically accessible health information for authorized use under applicable State or Federal law; and
  - (3) does not constitute **information blocking**

Defined in Section 4003 of the Cures Act

ONC's Finalized Definition of EHI

EHI means:

- (i) electronic protected health information (ePHI) as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:
  - (1) Psychotherapy notes as defined in 45 CFR 164.501; or
  - (2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

ONC Definition of EHI: § 171.102 Definitions

Without special effort

Certification Criterion

- Without Special Effort will be accomplished through:
  - Standardization & Functional Requirements
    - Standardized API for Patient and Population Services
      - FHIR R4 & US Core Implementation Guides; Bulk Data/Flat FHIR; USCDI; ARCH

- -

Certification Conditions

- Transparency condition
  - Business and technical documentation necessary to interact with the APIs in production freely and publicly accessible
- Permitted Fees condition
  - Certified API Developers can charge fees to health care organizations and API Users in specific instances or for specific services
- Openness and pro-competitiveness conditions
  - Positions health care organizations to independently permit an app developer to interact with the certified API technology
  - Non-discriminatory terms: objective, verifiable criteria that are uniformly applied

Complete Access

Certification Criterion

- Accomplished through:
  - Functional Requirements for EHI Export & USCDI Standard
    - EHI Export – 36 months to develop/deploy capability
      - Single Patient Export to Support Patient Access
      - Patient Population EHI Export for Transitions between Health IT Systems
    - USCDI Standard
      - API aka (g)(10)-API Standards incl. Bulk FHIR (Flat FHIR) standard
      - API Resource Collection in Health (ARCH) Version 1

Certification Conditions

- USCDI Data Policy
  - Proposed Expansion Process (January 5, 2018) https://www.healthit.gov/sites/default/files/draft-uscdi.pdf
- Information Blocking
  - Pertains to USCDI for 24 months, then to broader set of data encompassing EHI

Implications of ONC's Approach

Pros of USCDI + EHI Export Strategy

- USCDI
  - Enable continuous, persistent access to specified data
    - Fuel provider-facing and consumer-facing APIs and apps
  - Establish a process to prioritize additional FHIR resources
- EHI Export
  - Enable system-to-system transfer
    - Lower barriers to switch EHRs, possibly improving usability
  - Provide patients access to wide assortment of data in computable format
  - Improve providers' HIPAA compliance burdens by converging the HIPAA Right of Access to Certified Health IT
    - Fulfills a Joint AMIA and AHIMA recommendation from December 2018

Implications of ONC's Approach

Cons of USCDI + EHI Export Strategy

- USCDI
  - Codifies "structure first, share later" strategy
- EHI Export
  - Provides only a static snapshot in time of data
  - Danger of creating second-class digital citizens
    - Innovation will focus on FHIR-enabled data

Information Blocking

- Actors comply after six months
  - USCDI focus for 24 months
  - EHI focus after that period
- Narrowed definitions for HIE/HIN
- 8 Exceptions
  - New Content and Manner Exception
  - Several new clarifications
- Forthcoming OIG rule will discuss enforcement actions

Key Points to Remember

- Only through experience with the policy will all stakeholders become more familiar with the contours of what is and what is not information blocking.

- Next, it will be up to the OIG to finalize enforcement conditions that compel proper actions, dispel improper actions, and create an educational environment for all actors to learn the difference between the two

- Before HIPAA there were no HIPAA lawyers, the same was true before Information Blocking rules