

21st Century Cures Act – Health Information Highlights
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President Obama signed the 21st Century Cures Act (H.R. 34) into law on December 13, 2016. The bill received bipartisan support in the House of Representatives and the Senate, passing with votes of 344-77 and 94-5, respectively. At 996 pages long, it addresses a wide array of healthcare-related issues and initiatives. The Act includes provisions for funding the [National Institutes of Health \(NIH\)](#), allocates money for state grants to address opioid abuse and addiction, creates new pathways for prescription drug approval through the [Food and Drug Administration \(FDA\)](#), and more. The Act also expands the federal government’s involvement in health information exchange and health information technology. Below are summaries of those provisions relevant to health information that may be of most interest to policymakers and other stakeholders.

Health Information Exchange

The Act requires recipients of NIH grants to share scientific data, consistent with all federal laws and regulations that govern the privacy and security of health information,¹ unless it is privileged or confidential.² Prior to the passage of the 21st Century Cures Act, NIH was constrained in its ability to require NIH-funded investigators to share their data to support other research opportunities. The Act supports greater access to data collected or generated through NIH-funded research to advance biomedical research as rapidly as possible while still ensuring the privacy of individual health information.

In an effort to curb information blocking, the Inspector General of the [Department of Health and Human Services \(HHS\)](#) is authorized to investigate claims that health information technology (HIT) developers are not offering certified HIT that meets interoperability requirements or that healthcare providers, health information exchanges, or health information networks are engaging in information blocking.³ “Information blocking” is defined as anything that is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

To expand registry capture of health information, electronic health records (EHRs) must be capable of transmitting, receiving, and accepting data to and from registries in accordance with standards set by the [Office of the National Coordinator for Health Information Technology \(ONC\)](#).

¹ As outlined in the 21st Century Cures Act § 2014, such federal laws and regulations include considerations for privacy, security, informed consent, protected health information, proprietary interests, and intellectual property rights. Additional information about federal laws and regulations that govern health information may be found on at healthinfolaw.org.

² § 21st Century Cures Act, H.R. 34, 114th Cong. § 2014 (2016).

³ § 4004.

The Act defines “clinician-led clinical data registries” as data repositories established and operated by a clinician-led or controlled tax-exempt organization devoted to the care of a population defined by a particular disease, condition, exposure, or therapy. These registries are designed to collect detailed and standardized data on an ongoing basis.⁴

Health Information Technology – Encouraging Interoperability

“Interoperable health IT” is defined as technology that allows secure transfer of health information, allows complete access to protected health information⁵ (PHI) for authorized users without special effort, and is not configured to block information.

The Act requires ONC to coordinate with the [National Institute of Standards and Technology \(NIST\)](#) and HHS to convene public-private and public-public partnerships to develop or support a trusted exchange framework, including a common agreement about health information networks internationally. This common agreement could include methods for authenticating trusted health information network participants, common set of rules for trusted exchange, organization and operational policies to enable exchange, and a process for adjudicating non-compliance. The Act does not require health information networks to adopt this trusted exchange framework or common agreement.

The Act further requires the HHS Secretary to establish a healthcare provider digital contact information index to provide digital contact information at both the healthcare professional and healthcare facility levels. Additionally, the Act establishes the HIT Advisory Committee, which will unify the roles of and replace the HIT Policy Committee and the HIT Standards Committee. This Advisory Committee will recommend a policy framework for adoption by the HHS Secretary. The Committee is to recommend priorities for developing these standards, specifications, and certification criteria. The Act specifically prioritizes the following target areas:

- Achieving national and local health IT infrastructure to allow for electronic access, exchange, and use of PHI;
- Promotion and protection of privacy in health IT;
- Facilitating secure access by an individual to his/her own PHI;
- Encouraging use of health IT to improve quality of health care through promoting care coordination, reducing medical errors, advancing research;
- Using health IT to address needs of children and vulnerable populations;
- Comprehensive collection of patient demographic data through electronic systems,
- Promoting telemedicine;
- Supporting data exchange for use in quality and public reporting programs, public health, and drug safety; and
- Ensuring that PHI is rendered unusable or unreadable when accessed by unauthorized individuals.⁶

⁴ § 4005.

⁵ Protected health information (PHI) is individually identifiable health information, or health information in part or whole that can be linked to a specific person.

⁶ § 4003.

The Act requires the HIT Advisory Committee to develop a schedule for assessing their policy recommendations within thirty days of their first meeting. The Committee is further required to update this schedule annually, and the HHS Secretary must publish this schedule in the Federal Register. The Act also directs the Committee to submit an annual report to the HHS Secretary and Congress about the progress made in the preceding year.

One of the goals of the Act is to improve patient access to EHRs. It asserts that the Secretary must leverage partnerships between health information exchange organizations, networks, health care providers, health plans, and other entities with the goal of improving patient access to EHRs through a single, easy-to-understand format.⁷

In an effort to improve telehealth access, the [Centers for Medicare & Medicaid Services \(CMS\)](#) must submit to the House of Representatives and the Senate a list of eligible populations with chronic conditions whose care may be improved through the expansion of telehealth services.⁸

Protecting the Privacy of Health Information

The Act requires the HHS Secretary to issue a certificate of confidentiality to any person engaged in federally funded biomedical, clinical, behavioral, or other research where PHI is collected. A certificate of confidentiality allows researchers to refuse to disclose names and identifying characteristics of research subjects in response to certain legal proceedings.⁹ In the event an individual is engaged in such research, but the project is not federally funded, the HHS Secretary must issue a certificate of confidentiality when requested by that individual. The Act qualifies that a certificate of confidentiality does not apply if disclosure of PHI is required by federal, state, or local laws, is necessary for medical treatment of an individual, or if an individual seeks access to his/her own PHI. PHI collected in behavioral, clinical, or other research is not admissible in any action, suit, or other judicial, legislative, or administrative proceeding without consent of the individual.¹⁰

The HHS Secretary is required to exempt from disclosure biomedical information about an individual gathered during biomedical research in one of the following situations: 1) where an individual is identified and 2) where there is a small risk that some combination of the information could be used to deduce the identity of that individual.¹¹

The HHS Secretary is required to convene stakeholders in an effort to determine the effect of the final 42 CFR Part 2 regulations governing substance abuse information on patient care, health outcomes, and privacy.¹²

⁷ § 4006.

⁸ § 4013.

⁹ *Certificates of Confidentiality (COC)*. (2016, May 18). Retrieved from <https://humansubjects.nih.gov/coc/index>.

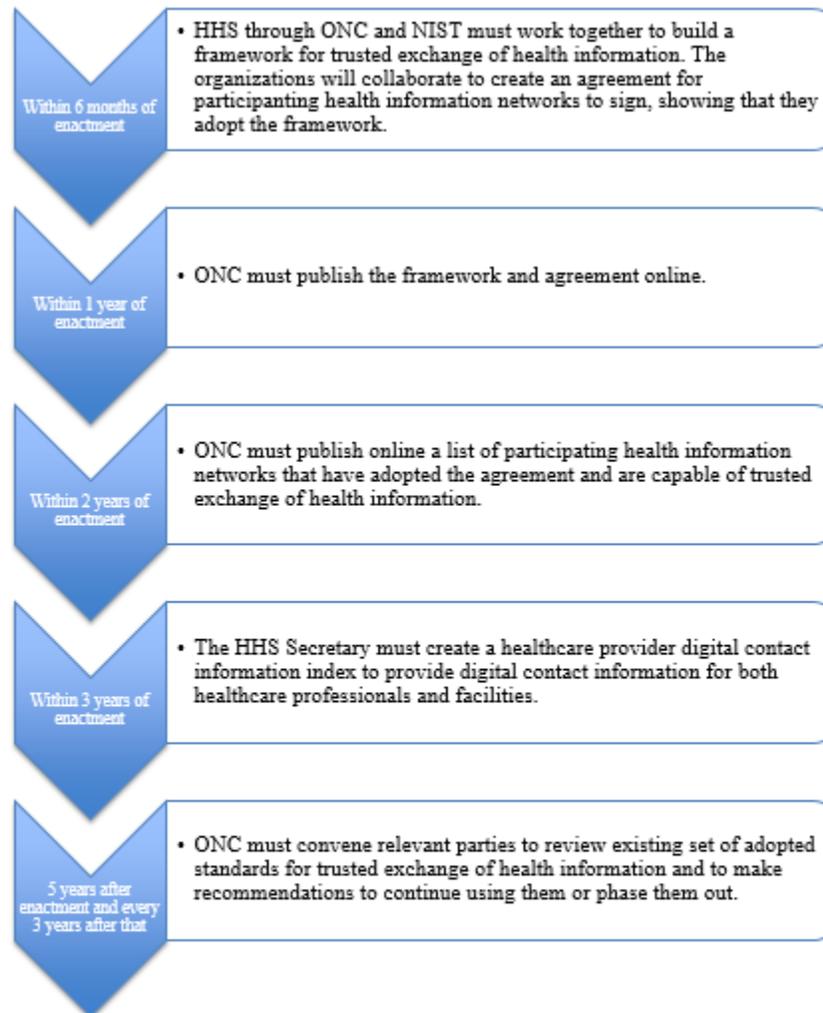
¹⁰ § 2012.

¹¹ § 2013.

¹² § 11002. The Final 42 CFR Part 2 rule, “Confidentiality of Substance Use Disorder Patient Records,” was released on January 18, 2017 and can be found here: <https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records>.

Additionally, the HHS Secretary must issue guidance clarifying circumstances under which a provider or covered entity may use or disclose PHI pursuant to the Health Insurance Portability and Accountability Act (HIPAA).¹³ In an effort to improve public knowledge surrounding HIPAA, the Secretary must identify model programs and materials for training healthcare providers regarding permitted uses and disclosures, consistent with privacy and security standards, and work with the [Office for Civil Rights \(OCR\)](#) to generate materials for patients and families informing them of their rights to protect and obtain PHI.¹⁴

Timeline of Authorized Health Information-Related Activities



ONC – The Office of National Coordinator for Health Information Technology

NIST – National Institute of Standards and Technology

HHS – Department of Health and Human Services

Trusted exchange framework - A policy framework that allows for health information to be shared between and among healthcare providers, payers, patients/consumers, researchers and other stakeholders while appropriately protecting patient privacy.

Related Health Information and the Law Materials

¹³ § 11003.

¹⁴ § 11004.

- [Myth Buster: All Electronic Health Records \(EHRs\) are Interoperable¹⁵](#)
- [Fast Facts: What is Interoperability?¹⁶](#)
- [Myth Buster: Mental health information cannot be disclosed for research¹⁷](#)
- [Fast Facts: How Does the HIPAA Privacy Rule Apply to Research?¹⁸](#)
- [Myth Buster: HIPAA and the Common Rule regulate research in the same way¹⁹](#)
- [Fast Facts: How Does the HIPAA Privacy Rule Apply to Research?²⁰](#)

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¹⁵ [http://www.healthinfolaw.org/article/myth-buster-all-electronic-health-records-ehrs-are-interoperable.](http://www.healthinfolaw.org/article/myth-buster-all-electronic-health-records-ehrs-are-interoperable)

¹⁶ [http://www.healthinfolaw.org/search/apachesolr_search/interoperability.](http://www.healthinfolaw.org/search/apachesolr_search/interoperability)

¹⁷ [http://www.healthinfolaw.org/article/myth-buster-mental-health-information-cannot-be-disclosed-research.](http://www.healthinfolaw.org/article/myth-buster-mental-health-information-cannot-be-disclosed-research)

¹⁸ [http://www.healthinfolaw.org/article/fast-facts-how-does-hipaa-privacy-rule-apply-research.](http://www.healthinfolaw.org/article/fast-facts-how-does-hipaa-privacy-rule-apply-research)

¹⁹ [http://www.healthinfolaw.org/article/myth-buster-hipaa-and-common-rule-regulate-research-same-way.](http://www.healthinfolaw.org/article/myth-buster-hipaa-and-common-rule-regulate-research-same-way)

²⁰ [http://www.healthinfolaw.org/article/fast-facts-how-does-hipaa-privacy-rule-apply-research.](http://www.healthinfolaw.org/article/fast-facts-how-does-hipaa-privacy-rule-apply-research)