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21st Century CURES Act

Legislation Overview

December 13, 2016

Overview

H.R.34 - 21st Century Cures Act was signed into law on 12/13/2016. According to the FDA's website, the act was designed to "help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently".

Major provisions include:

- $4.8 billion in new funding for the National Institutes of Health
  - $1.8 billion is reserved for the "cancer moonshot" research program
- $1.6 billion for brain diseases including Alzheimer's
- $500 million in new funding for the Food and Drug Administration
- $1 billion in grants to help states deal with opioid abuse

FDA Funding

The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances our ability to modernize clinical trial designs, including the use of real-world evidence, and clinical outcome assessments, which will speed the development and review of novel medical products, including medical countermeasures.

It also provides new authority to help FDA improve our ability to recruit and retain scientific, technical, and professional experts and it establishes new expedited product development programs, including:

- The Regenerative Medicine Advanced Therapy, or RMAT, that offers a new expedited option for certain eligible biologics products.
- The Breakthrough Devices program, designed to speed the review of certain innovative medical devices.

In addition, the Cures Act directs FDA to create one or more intercenter institutes to help coordinate activities in major disease areas between the drug, biologics and device centers and improves the regulation of combination products.

On 6/7/2017, The FDA submitted their full allocation plan to Congress.

NIH Funding

According to NIH's website, the Cures Act provides NIH with the flexibility and resources needed to accomplish its mission to improve the health of Americans. Most notably, the Cures Act implements measures to:

- Alleviate administrative burdens that can prolong the start of clinical trials
- Allow researchers to more easily attend scientific conferences where in-person collaboration can often lead to scientific breakthroughs
- Enhance data sharing among NIH-supported researchers
- Improve privacy protections for research volunteers
- Encourage inclusion of diverse populations represented in clinical research
- Open up new NIH funding opportunities for young investigators

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Additionally, the Cures Act provides multiyear funding to four highly innovative scientific initiatives:

1. The *All of Us* Research Program, formerly known as the PMI Cohort Program,
2. The *Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative* seeks to better understand how the brain encodes, stores, and retrieves information, which will transform the ability to diagnose and treat neurological/mental disorders.
3. The *Cancer Moonshot℠*
4. The *Regenerative Medicine Innovation Project* will support clinical research in coordination with the FDA using adult stem cells to further the field of regenerative medicine.

The Cures Act allocates funding to NIH over each of the next 10 years, for a total of $4.8 billion. However, funding must be appropriated each year.

NIH's full implementation plan can be found here.

IT-Related Provisions

The Cures Act language also aims to promote the seamless exchange of health information:

- **SEC. 4002. Transparent reporting on usability, security, and functionality.**
  - Requires vendors to provide open patient data through a national application program interface (API).
- **SEC. 3009A. Electronic health record reporting program.**
  - Tasks ONC with creating an EHR Reporting Program with reporting criteria for security, usability, interoperability, and conformance.
- **SEC. 4003. Interoperability**
  - Defines interoperability.
  - Tasks ONC, NIST, and HHS with ensuring full network-to-network exchange of health information and supporting a trusted exchange framework common agreement.
- **SEC. 4004. Information blocking.**
  - Institutes penalties for violations in blocking the exchange and access of electronic health information.
- **SEC. 4006. Empowering patients and improving patient access to their electronic health information.**
  - Encourages the availability of health information to patients through a user friendly/electronic access point.
- **SEC. 4007. GAO study on patient matching.**
  - Directs the GAO to evaluate the current state of patient matching to EHRs and determine corrective steps to promote the privacy and security of patient information and reduce matchings errors.

ONC's CURES Act Final Rule

On November 4th, 2020, the Office of the National Coordinator for Health Information Technology (ONC) released a final ruling that outlines the requirements for health-related organizations to improve interoperability and prevent information blocking.

Specifically, it called for:

- The healthcare industry to adopt standardized application programming interfaces (APIs), which will help allow individuals to securely and easily access structured electronic health information using smartphone applications.
- And the rule includes a provision requiring that patients can electronically access all of their electronic health information (EHI), structured and/or unstructured, at no cost.
- Finally, to further support access and exchange of EHI, the rule implements the information blocking provisions of the Cures Act. The rule outlines eight exceptions to the definition of information blocking.

Full text of the rule can be found here.

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Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule:

On December 13th, 2023, the Office of the National Coordinator for Health Information Technology (ONC) released another finalized ruling, titled Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule.

Major provisions in the ruling include:

- **USCDI v3**: Established the United States Core Data for Interoperability (USCDI) Version 3 as the new standard, starting January 1st, 2026.
- **Algorithm Transparency**: Updated Decision Support Interventions certification criteria to include transparency requirements around the use of predictive algorithms in healthcare.
- **Information Blocking Rule Enhancements**: Added two reasons for the infeasibility rule (TEFCEA and Manner exception exhausted) and revised the uncontrollable events condition to be more specific on what qualifies as "uncontrollable".
- **Patient Requested Restrictions**: Patients now have the ability to electronically request that all or some of their information not be shared.
- **Insights Condition and Maintenance of Certification:** Sets criteria of who is considered a "health IT developer" and the transparency reporting requirements they are subject to.

Full text of the rule can be found here.

What Does This Mean for The Healthcare Industry?

Healthcare providers, spanning all ownership types (Federal, SLG, Non-profit etc.) must:

- Enable app-based patient access to health data via FHIR APIs
- Adopt the USCDI v3 interoperability framework by January 1st, 2026.
- Avoid information blocking penalties by training staff on sharing exemptions and audit tooling
- Build EHR apps that enable e-prior authorization and embed them into the workflow
- Plan for algorithm transparency in clinical decision support and build training and governance around use cases

What Does This Mean for Contractors?

Healthcare IT vendors must:

- Adopt USCDI v3 standards and SMART App Launch 2.0
- Support Bulk FHIR API data transfers
- Begin to adopt the TEFCA framework for interoperability

Contact Us:

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