

[21st Century Cures Act \(Public Law 114-255\)](#)

Provides new and renewed funding for medical research and certain signature programs, institutes new protections for medical research subjects, requires sharing of certain research data, tracks diseases and the scientific responses to them, and expedites the novel drug testing and approval process, among numerous other activities.

Updated last **December 15, 2016**
for Public Law 114-255.

WHAT IT DOES

[Public Law 114-255](#), the 21st Century Cures Act, is a lengthy and multifaceted bill; its numerous components are ultimately intended to improve public health. This brief focuses primarily on the genomic and neuroscience aspects of the legislation, many of which are found in the following Titles.

[Title I: Innovation Projects and State Responses to Opioid Abuse](#)

[Title II: Discovery](#)

[Title III: Development](#)

Title I establishes new accounts within the National Institutes of Health (NIH) and Food and Drug Administration (FDA) to promote biomedical breakthroughs that will improve health outcomes. Specifically:

Section 1001 establishes the National Institutes of Health Innovation Account, appropriating nearly \$4.8 billion over the course of 10 years (fiscal years 2017 to 2026) to the following projects:

- Precision Medicine Initiative (\$1.4 billion);
- Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative (\$1.511 billion);
- Cancer research (\$1.8 billion); and
- Regenerative medicine research using adult stem cells (\$30 million).

Section 1002 establishes the FDA Innovation Account, appropriating \$500 million over the course of 10 years (fiscal years 2017 to 2026) to improve drug development.

Under Title II, Subtitle A ("National Institutes of Health Reauthorization"), Section 2001 appropriates to the NIH approximately \$107 million over three years; uses include the [NIH Common Fund](#). Section 2002 directs the NIH to establish "Eureka Prize Competitions" for:

- Identifying and funding biomedical science for which there are significant advancement opportunities; and/or
- Improving health outcomes.

Title II, Subtitle B ("Advancing Precision Medicine"), codifies the Precision Medicine Initiative (PMI), creates human research subject protections, and promotes data sharing. Specifically, Section 2011 encourages the [Department of Health and Human Services](#) (HHS) to establish the Precision Medicine Initiative to "augment efforts to address disease prevention, diagnosis and treatment."

Components of the PMI may include:

- Developing a network of scientists to carry out the Initiative;

- Developing new approaches for addressing scientific, medical, public health, and [regulatory science issues](#);
- Applying genomic technologies to contribute data on the molecular basis of diseases;
- Collecting data across a large and diverse volunteer cohort of research participants to contribute to the understanding of health and disease; and
- Performing other activities deemed relevant to support the Initiative.

To meet these objectives, HHS has the discretion to:

- Coordinate with the [Department of Energy](#), private industry, and others to identify and address supercomputing needs for the PMI;
- Cultivate public-private partnerships; and
- Leverage existing data sources.

According to the bill, HHS must:

- Collaborate with the NIH, FDA, [Office of the National Coordinator for Health Information Technology](#), and the [Office for Civil Rights](#);
- Comply with [laws and regulations](#) protecting human research subjects and their privacy;
- Implement policies and mechanisms for secure and private data sharing;
- Ensure inclusion of a diverse participant cohort that represents a range of biological, social and other determinants of health and health disparities;
- Ensure that only authorized individuals access identifiable biological materials and associated information that is related to the PMI; and
- Publish on the HHS website the identification of any entities accessing PMI information, providing the purpose, research summary, and description of biological materials and associated information to which the entity has access.

Sections 2012 and 2013 create new processes and standards to protect the privacy of research subjects. Section 301(d) ([42 U.S.C. 241](#)) of the Public Health Service Act ([42 U.S.C. 241 et seq.](#)) is amended by:

- Requiring the NIH to issue a Certificate of Confidentiality (CoC) to every federally funded researcher who collects research subjects' identifiable information (non-federally funded researchers may also apply and receive a CoC);
- Mandating researchers holding a CoC to protect the privacy of research subjects' identities (and sensitive information that could be used to deduce identity), except when such information is:
 - Required by federal, state or local laws, with the exception of civil, criminal, administrative, legislative, or other proceedings;
 - Necessary for medical treatment of the subject and made with the consent of the individual;
 - Consented to be released by the subject; or
 - Made available for other scientific research that is in compliance with applicable federal regulations governing human research subject protections.
- Affording privacy protections in perpetuity;
- Compelling the NIH to:
 - Minimize the administrative burden associated with compliance of this new section; and
 - Coordinate with other federal agencies to ensure that CoC policies are in place.
- Requiring all research subject to 301(d) to comply with this act, as amended, 180 days after the date of enactment.

The bill further:

- Authorizes HHS to exempt from disclosure requests made under the [Freedom of Information Act \(5 U.S.C. 552\)](#) if related to an individual biomedical research information that reveals individual identity, or indicates sensitive information that could be [used to deduce an identity](#); and
- Clarifies that modifications shall not be construed to limit research subjects' access to their own data.

Section 2014 adds to the NIH's duties and authority the discretion to require recipients of NIH awards to share scientific data in a manner that protects human research participants and proprietary interests.

Title II, Subtitle D ("National Institutes of Health Planning and Administration"), addresses NIH administration in 14 different sections. Section 2031 creates requirements for the NIH Strategic Plan, which must be developed, submitted to Congress, and published online every six years. The plan is intended to provide direction for NIH biomedical research investments, facilitate collaboration across institutes and centers, leverage scientific opportunity, and advance biomedicine. The strategy shall:

- Identify biomedical research priorities, including:
 - Assessment of the current state of research;
 - Priorities and objectives to advance the prevention, treatment, and cure of health conditions;
 - Emerging opportunities, health challenges and knowledge gaps; and
 - Identification of near and long-term needs.
- Consider U.S. disease burden, rare diseases and conditions, and other factors that contribute to health disparities;
- Include [multi-institute priorities](#), [NIH Common Fund](#) strategies, and [NIH biomedical workforce activities](#); and
- Describe collaboration opportunities with other agencies and departments.

Other sections within this Title address leadership appointments and reporting requirements, such as efforts to reduce duplicate federal biomedical research and administrative burden.

In an effort to facilitate further research, surveillance, and reporting on the epidemiology and progression of neurological diseases, Section 2061 will amend the [Public Health Service Act](#) to establish a National Neurological Diseases Surveillance System. The system will:

- Enhance and expand the current infrastructure and activities within the [Centers for Disease Control and Prevention](#) (CDC) to track neurological disease, create an integrated surveillance system, and facilitate further research; and
- Be created through consultation with 1) epidemiologists who have experience with disease surveillance or registries, 2) national voluntary health associations, 3) health information technology experts, 4) clinicians, and 5) research scientists who have experience in translational research or use of surveillance systems.

Within Title III, Subtitle A ("Patient-Focused Drug Development"), Section 3012 aims to expedite the development, review, and approval process for new genetically-targeted drugs that treat rare, serious, life-threatening diseases. A new section is added to the [Federal Food, Drug and Cosmetic Act \(21 U.S.C. 301 et seq.\)](#) which allows sponsors of new drugs to use information and data collected on other, already-approved and similarly-functioning drugs to support a new drug application. The data may be used if:

- The data and information was collected by the same sponsor that is submitting the new application; or
- The new sponsor has permission from the sponsor of an approved drug to use their data and information.

Sections 3013 reauthorizes the [Rare Pediatric Disease Priority Review Voucher Program](#) through September 30, 2020, with certain exceptions. Section 3014 directs the [Government Accountability Office](#) to study the effectiveness of all voucher programs; the report is due to Congress no later than January, 2020.

Other sections and titles 1) allocate funds for the opioid epidemic; 2) support emerging scientists, and 3) address clinical care, mental health, Medicare, and Medicaid.

STATUS

Public Law 114-255 was passed by Congress as [HR 34](#), which was originally introduced as [HR 6](#) on 05/19/2015. The House first passed HR 6 on 07/10/2015, but the Senate never passed this version of the bill.

Once the bill was re-introduced with amendments as HR 34, the House passed the bill on 11/30/2016 and the Senate on 12/07/2016. President Barack Obama signed the bill into law on 12/13/2016.

RELATED POLICIES

Components of many of the following bills were eventually absorbed into the text of HR 34:

- [HR 292](#): Advancing Research for Neurological Diseases Act of 2015
- [HR 1877](#): Mental Health First Aid Act of 2016
- [HR 2299](#): Amending title XVIII of the Social Security Act
- [HR 2426](#): Amending the Federal Food, Drug, and Cosmetic Act
- [HR 2428](#): Amending the Federal Food, Drug, and Cosmetic Act
- [HR 2435](#): Amending the Federal Food, Drug, and Cosmetic Act
- [HR 2439](#): Amending the Public Health Service Act
- [HR 2452](#): Amending the Federal Food, Drug, and Cosmetic Act
- [HR 2488](#): Medicare Beneficiary Preservation of Choice Act of 2015
- [HR 3291](#): Medicare Crosswalk Hospital Code Development Act of 2015
- [HR 3716](#): Ensuring Access to Quality Medicaid Providers Act
- [HR 3821](#): Medicaid Direcotry of Caregivers Act
- [HR 5210](#): Patient Access to Durable Medical Equipment Act of 2016
- [HR 5268](#): Medicare Beneficiary Enrollment Improvement Act
- [HR 5273](#): Helping Hospitals Improve Patient Care Act of 2016
- [HR 5414](#): FDA Cross-Center Collaboration Act of 2016
- [HR 5447](#): Small Business Health Care Relief Act of 2016
- [HR 5688](#): Amending title XVIII of the Social Security Act
- [HR 5713](#): Sustaining Healthcare Integrity and Fair Treatment Act of 2016
- [S 607](#): Rural Community Hospital Demonstration Extension Act of 2015
- [S 1077](#): Advancing Breakthrough Devices for Patients Act of 2016
- [S 1767](#): Combination Product Regulatory Fairness Act of 2016
- [S 2030](#): Advancing Targeted Therapies for Rare Diseases Act of 2016
- [S 2055](#): Medical Countermeasure Innovation Act of 2016
- [S 2188](#): Rare Disease Innovation Act
- [S 2261](#): Rural Accountable Care Organization Provider Equity Act of 2016
- [S 2669](#): Ensuring Removal of Terminated Providers from Medicaid and CHIP Act
- [S 2713](#): Advancing Precision Medicine Act of 2016
- [S 2744](#): Genetic Research Privacy Protection Act
- [S 2745](#): Advancing NIH Strategic Planning and Representation in Medical Research Act

POLICY HISTORY

[HR 6](#), also called the 21st Century Cures Act, was the original version of the bill as considered and passed by the House of Representatives.

SPONSORS

Sponsor: [Representative Suzanne Bonamici \(D-OR-1\)](#)

Cosponsors:

- [Representative Dana Rohrabacher \(R-CA-48\)](#)
- [Representative Eddie Bernice Johnson \(D-TX-30\)](#)
- [Representative Lamar Smith \(R-TX-21\)](#)
- [Representative Gregorio Kilili Camacho Sablan \(D-MP-at large\)](#)
- [Representative Peter A. DeFazio \(D-OR-4\)](#)
- [Representative Kurt Schrader \(D-OR-5\)](#)
- [Representative Jaime Herrera Beutler \(R-WA-3\)](#)

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RECOMMENDED CITATION

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