

## The 21st Century Cures Act

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### Introduction

Following a multi-year, bipartisan, and bicameral effort to accelerate the pace of the discovery, development, and delivery of new treatments and cures, H.R. 34, the 21st Century Cures Act (Cures Act), was signed into law by President Obama on December 13, 2016. The House of Representatives passed the legislation by a vote of 392-26 on November 30, 2016, and the Senate approved the bill on December 7, 2016 by a 94-5 vote, with Vice President Joe Biden presiding over the chamber as his former colleagues renamed the “Cancer Moonshot” provision of the Cures Act in honor of his late son Beau Biden.

The Cures Act includes President Obama’s proposals for the Precision Medicine and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiatives, as well as provisions intended to enhance and accelerate the Food and Drug Administration’s processes for reviewing and approving new drugs, biologics, and medical devices. Those provisions seek to expand the types of evidence manufacturers of such products may bring to the FDA to support approval, encourage patient-centered drug development, create greater transparency with regard to manufacturer expanded access programs, clarify the regulatory approach to combination products and medical software, and permit the agency to grant limited population approvals to certain antibiotics. The Cures Act also includes US\$1 billion in new funding to address the opioid crisis over two years; streamline administrative processes for the National Institutes of Health’s (NIH) funding of medical research; fund new NIH research on human genetics and neuroscience; and facilitate secure, interoperable exchange of electronic health record (EHRs) data while protecting patients’ privacy. The new law also included provisions backed by Senate Majority Leader Mitch McConnell (R-KY) to accelerate the development of regenerative medicine treatments. While the Cures Act institutes important changes in FDAMA 114, significantly liberalizing the communication of healthcare economic information to payers, it does not address drug manufacturers’ broader concerns about the FDA’s restrictive policies regarding the communication of scientific and medical developments regarding unapproved uses. The Cures Act also does not include a proposed section that would have amended the Physician Payments Sunshine Act to exclude certain payments or transfers of value related to: (1) peer-reviewed journals, journal reprints, journal supplements, medical conference reports, and medical textbooks; and (2) certain indirect payments for non-promotional educational programs or events. This provision was removed shortly before the bill passed Congress at the request of Senator Charles Grassley (RA-IA), the original architect of the Sunshine Act.

In addition to the medical innovation provisions, the Cures Act passed by Congress includes versions of House-passed H.R. 2646, “Helping Families in Mental Health Crisis Act,” and S. 2002, “Mental Health and Safe Communities Act,” as well as several Medicare reforms. The mental health provisions reform the delivery of mental health and substance abuse prevention and treatment, increase the use of treatment-based alternatives for mentally-ill offenders, and improve crisis response and prevention by local officials. The Medicare provisions reduce payments for the inpatient hospital setting, saving US\$760 million over the next decade, and permit hospitals that are in the midst of building off-campus outpatient departments to continue being paid under the hospital outpatient prospective payment system, rather than the physician fee schedule, at a cost of US\$760 million over the same period. Other provisions give Medicare Advantage plans, long-term acute care hospitals, and suppliers of durable medical equipment relief from certain future changes in payment policy. A bill containing several provisions regarding foster care, H. R. 5456, the “Investing in Prevention and Family Services Act,” was included in the Nov. 25 package, but removed by a Manager’s Amendment prior to floor consideration.

Companies will want to closely analyze the new Cures Act, which ultimately could have a significant impact on several fields, including pharmaceutical and device manufacturers, clinical researchers, and healthcare providers. Below we describe the key provisions of the legislation.

**Division A — 21st Century Cures**

**Title I — Innovation Projects and State Responses to Opioid Abuse Crisis**

<b>Cures Act Section</b>	<b>Summary of Cures Act Provision</b>
Section 1001; Beau Biden Cancer Moonshot and NIH innovation projects	Provides over US\$4.8 billion over 10 years to the National Institutes of Health (NIH) for the Precision Medicine Initiative, the Brain Research Through Advancing Innovative Neurotechnologies Initiative, cancer research, and regenerative medicine using adult stem cells. A work plan and annual report related to this funding is also required.
Section 1002; Food and Drug Administration Innovation Projects	Provides US\$500 million to the Food and Drug Administration (FDA) over 10 years to implement provisions in Title III of Subdivision A to move drugs and medical devices to patients more quickly, while maintaining the same standard for safety and effectiveness.
Section 1003; Account for the State Response to the Opioid Abuse Crisis	Provides US\$1 billion over two years for grants to states to supplement opioid abuse prevention and treatment activities, such as improving prescription drug monitoring programs, implementing prevention activities, training for health care providers, and expanding access to opioid treatment programs.  Ensures accountability without increase in burden on states by requiring grantees to report on activities funded by the grant in the substance abuse block grant report.

**Title II — Discovery**

**Subtitle A — National Institute of Health Reauthorization**

Section 2001; National Institutes of Health Reauthorization	Reauthorizes the NIH for FY 2018 through 2020 at the following levels: US\$34.85 billion for FY 2018; US\$35.56 billion for FY 2019; and US\$36.47 billion for FY 2020.
Section 2002; EUREKA Prize Competitions	Requires the NIH Director to support prize competitions, pursuant to its authorities under the Stevenson-Wydler Technology Innovation Act, for one or both of the following goals: (1) identifying and funding areas of biomedical science that could realize significant advancements through a prize competition; and/or (2) improving health outcomes for which investment in research is disproportionately smaller than federal government expenditures to prevent or treat such disease, or for diseases that are serious and represent a significant disease burden, or where there is potential for a significant return on investment. The NIH Director would be required to track the effect of innovations funded by such prize competitions and include such information in the Triennial Reports, mandated under this Act.

**Subtitle B — Advancing Precision Medicine**

Section 2011; Precision Medicine Initiative	Amends the Public Health Service Act to encourage the Secretary to carry out the Precision Medicine Initiative to augment efforts to address disease prevention, diagnosis, and treatment. The Initiative may include: (1) developing a network of scientists; (2) developing new approaches for addressing scientific, medical, public health, and regulatory issues; (3) applying genomic technologies; and (4) collecting information voluntarily provided by a diverse cohort of individuals. In implementing this Initiative, the Secretary must ensure collaboration among the NIH, FDA, the Office of the National Coordinator for Health Information Technology, and the HHS Office of Civil Rights. The Secretary must also implement data access and privacy policies and procedures, and submit a report to Congress on such policies and procedures not later than one year after enactment.
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<p>Section 2011; Precision Medicine Initiative</p>	<p>Amends the Public Health Service Act to encourage the Secretary to carry out the Precision Medicine Initiative to augment efforts to address disease prevention, diagnosis, and treatment. The Initiative may include:</p> <ol style="list-style-type: none"> <li>(1) developing a network of scientists;</li> <li>(2) developing new approaches for addressing scientific, medical, public health, and regulatory issues;</li> <li>(3) applying genomic technologies; and</li> <li>(4) collecting information voluntarily provided by a diverse cohort of individuals.</li> </ol> <p>In implementing this Initiative, the Secretary must ensure collaboration among the NIH, FDA, the Office of the National Coordinator for Health Information Technology, and the HHS Office of Civil Rights. The Secretary must also implement data access and privacy policies and procedures, and submit a report to Congress on such policies and procedures not later than one year after enactment.</p>
<p>Section 2012; Privacy Protection for Human Research Subjects</p>	<p>Significantly expands upon HHS’s existing privacy protection policy for human research subjects. Effective 180 days after the date of enactment, the Secretary must issue to researchers engaged in federally-funded research, in which identifiable sensitive information is collected, a certificate of confidentiality to protect the privacy of human subjects. For research that is not federally-funded, the Secretary may issue a certificate of confidentiality upon application by the researcher. Researchers who receive such certificates may not disclose to persons not connected with the research any identifiable or sensitive information about the human subject, absent consent from the data subject.</p>
<p>Section 2013; Protection of Identifiable and Sensitive Information</p>	<p>Exempts from disclosure under the Freedom of Information Act individually identifiable biomedical information, as well as information that reasonably could be used to identify an individual, gathered or used in biomedical research. Agency determinations to grant such exemptions would have to be made in writing and be available to the public.</p>
<p>Section 2014; Data Sharing</p>	<p>Permits NIH to require recipients of NIH awards to share scientific data generated from research conducted using such awards, provided the disclosure of the data is consistent with applicable law regarding human subject protection, proprietary interests, trade secrets, and confidentiality privileges.</p>
<p><b>Subtitle C — Supporting Young Emerging Scientists</b></p>	
<p>Section 2021; Investing in the Next Generation of Researchers</p>	<p>Establishes the Next Generation of Researchers Initiative, which requires the Director of NIH to coordinate all policies and programs within the NIH that are focused on promoting and providing opportunities for new researchers and earlier research independence.</p>
<p>Section 2022; Improvement of Loan Repayment Program</p>	<p>Replaces NIH’s existing loan repayment programs for researchers who conduct research on acquired immune deficiency syndrome or contraception and infertility, with a four-part loan repayment program for intramural researchers and a separate loan repayment program for extramural researchers.</p>
<p><b>Subtitle D — National Institutes of Health Planning and Administration</b></p>	
<p>Section 2031; National Institutes of Health Strategic Plan</p>	<p>Requires the NIH Director to develop a NIH Strategic Plan at least every six years, with the first Strategic Plan issued not later than two years after enactment. The Strategic Plan must include a coordinated strategy to provide direction to the biomedical research investments made by the NIH, and it must identify strategic research priorities and objectives.</p>

<p>Section 2033; Increasing Accountability at the National Institutes of Health</p>	<p>Amends the current requirements for appointing Directors of the national research institutes and national centers. Notably, it establishes a five-year term limit for the directors of such institutes and centers; though, there is no limit on the number terms that a Director may serve. Directors who are serving on the date of enactment shall be deemed to be appointed for a five-year term. Additionally, this section requires the Director of the national research institute or national center to review and make the final decision on awarding certain R-series grants.</p> <p>Also requires the Secretary to submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes within two years after enactment.</p>
<p>Section 2034; Reducing Administrative Burden for Researchers</p>	<p>Requires the Secretary to: (1) review the agency’s financial conflict of interest policies and regulations, and to harmonize existing policies to reduce administrative burden on researchers while maintaining integrity and credibility of research findings and protections of human participants; (2) evaluate financial expenditure reporting procedures and requirements for recipients of NIH grants, and take appropriate actions to avoid duplication between agency procedures and requirements and to minimize burden to funding recipients; and (3) clarify the applicability of certain Office of Management and Budget requirements related to documentation of personal expenses for recipients of HHS-funded grants.</p> <p>Additionally, the Director of NIH must: (1) implement measures to reduce administrative burdens related to monitoring sub-recipients of grants by primary awardees; (2) review current laboratory animal regulations and policies and revise to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals; and (3) establish a Research Policy Board to provide federal officials with information on the effects of regulations related to federal research requirements.</p>
<p>Section 2036; High-Risk, High-Reward Research</p>	<p>Authorizes the NIH Director to approve requests by national research institutes and centers to engage in transactions (other than contracts, grants, or cooperative agreements) for projects that carry out the Precision Medicine Initiative, up to 50 percent of funds available in the NIH Common Fund. Such projects must conduct or support “high impact cutting-edge research.”</p>
<p>Section 2037; National Center for Advancing Translational Sciences</p>	<p>Authorizes the National Center for Advancing Translational Sciences (NCATS) to support clinical trials through the end of phase IIB (currently phase IIA). Additionally, this section authorizes NCATS to support clinical trial activities through the end of phase III for treatment of a rare disease or condition, provided certain conditions are satisfied.</p> <p>This section also requires the NCATS’s biennial report to include the methods and tools that have been developed since the last biennial report was prepared, as well as the methods and tools that have been developed and are being used by the FDA to support medical product reviews.</p>
<p>Section 2038; Collaboration and Coordination to Enhance Research</p>	<p>Requires the Director of NIH to assemble accurate data to assess research priorities, including information to evaluate scientific opportunity, public health burdens, and progress in reducing health disparities, as well as data on study populations of clinical research (including women, minority groups, age categories). Such data must be publicly available on the NIH website. This section also requires the Director of NIH to foster collaboration between clinical research projects funded by national research institutes and centers that conduct research involving human subjects and collect similar data.</p> <p>This section also requires the Director of NIH to encourage efforts to improve research related to the health of sexual and gender minority populations, including by facilitating increased participation of such populations in NIH-funded research. Additionally, this section requires the Director of NIH to convene a workshop of experts on pediatric and older populations to provide input on the appropriate age groups that should be included in human research and acceptable justifications for excluding participants from a range of age groups.</p>

Section 2039; Enhancing the Rigor and Reproducibility of Scientific Research	Requires the Secretary to convene a working group, within one year after enactment, to develop and issue recommendations for a formal policy to enhance rigor and reproducibility of scientific research funded by the NIH. Additionally, the Director of NIH must consider the recommendations and develop and update policies, as appropriate, within 18 months of enactment.
Section 2040; Improving Medical Rehabilitation Research at the National Institutes of Health	Requires the Director of the National Center for Medical Rehabilitation Research to develop a comprehensive Research Plan for the conduct, support, and coordination of medical rehabilitation research. Such plan must be revised and updated not less than every five years. This section defines “medical rehabilitation research as “the science of mechanisms and interventions and prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.”
Section 2041; Task Force on Research Specific to Pregnant Women and Lactating Women	Requires the Secretary to establish a Task Force on Research Specific to Pregnant Women and Lactating Women, which would provide advice and guidance to the Secretary on federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for such women. Not later than two years after enactment, the Secretary is required to consider any Task Force recommendations and consult with the heads of HHS sub-agencies to update regulations and guidance, as applicable.
Section 2042; Streamlining National Institutes of Health Reporting Requirements	Requires the head of each national research institute or national center to submit to the NIH Director the amount made available by the institute or center for conducting or supporting research that involved collaboration with another national research institute or national center. This section also repeals the requirement that the Secretary periodically review and submit to Congress reports on the centers of excellence.
Section 2043; Reimbursement for Research Substances and Living Organisms	Authorizes the Secretary to direct contractors, who provide to individuals and entities substances and living organisms for biomedical research, to collect payments on behalf of the Secretary for costs incurred to make available such substances and living organisms and to forward the payments to the Secretary. Under this section, the payments would be credited to the appropriations account that incurred the costs to make available the research substances and living organisms.
Section 2044; Sense of Congress on Increased Inclusion of Underrepresented Populations in Clinical Trials	Expresses the sense of Congress that the National Institute of Minority Health and Health Disparities should include in its strategic plan ways to increase representation of underrepresented populations in clinical trials.
<b>Subtitle E — Advancement of the National Institutes of Health Research and Data</b>	
Section 2051; Technical Updates to Clinical Trials Database	Authorizes the NIH Director to post on the Clinical Trials Database clinical trial data about a device prior to the date of clearance or approval, upon request by the responsible party. This section also clarifies the circumstances under which a clinical trial for a combination product (i.e., combination of drug, device, or biological) is considered a clinical trial for a drug or device, for purposes of this section.
Section 2053; Updates to Policies to Improve Data	Establishes reporting requirements for clinical trials in which women or members of minority groups are included as subjects, and directs the Director of NIH to consider whether the entity complied with the reporting requirements in awarding future grants to the entity.
Section 2054; Consultation	Requires the Secretary to consult with relevant federal agencies and stakeholders to receive recommendations regarding enhancements to the Clinical Trials Database.

**Subtitle F — Facilitating Collaborative Research**

<p>Section 2061; National Neurological Conditions Surveillance System</p>	<p>Requires the Secretary to enhance and expand the tracking of the epidemiology of neurological diseases, and to incorporate such information in the National Neurological Conditions Surveillance System. The information may include the incidence and prevalence of neurological diseases, demographics, genetic and environmental risk factors, and diagnosis and progression markers. In carrying out this section, the Secretary is required to consult with individuals with the appropriate expertise as well as federal, state, and local agencies. The National Neurological Conditions Surveillance System must be made publicly available, while ensuring that personal privacy is protected. The law authorizes \$5 million per year for FY 2018 through 2022 to implement this section.</p>
<p>Section 2062; Tick-Borne Diseases</p>	<p>Requires the Secretary to continue conducting and supporting epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. Additionally, this section requires the Secretary to establish the Tick-Borne Disease Working Group to provide expertise and to review all efforts within HHS related to tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The authorization for the Working Group terminates six years after the date of enactment.</p>
<p>Section 2063; Accessing, Sharing, and Using Health Data for Research Purposes</p>	<p>Requires HHS to issue guidance clarifying that, under the HIPAA Privacy Rule, researchers who are granted access to “protected health information” (PHI) to conduct reviews preparatory to research without authorizations from the individuals to whom the PHI pertains must keep the PHI secure and may not copy or otherwise retain it. This will essentially confirm HHS’s existing interpretation of the HIPAA Privacy Rule.</p> <p>Section 2063 also requires HHS to clarify its current position that an individual may authorize the use of his or her PHI for future research only if the research is sufficiently described in the authorization so that the individual reasonably understands the likely research use of the PHI. HHS must also clarify whether and when entities obtaining individual authorizations for future research must provide annual notices to individuals of their right to revoke the authorizations.</p> <p>Section 2063 also requires HHS to convene a working group to study and report to HHS, within one year, on the use of PHI for research purposes within the constraints of the HIPAA Privacy Rule.</p>

**Subtitle G — Promoting Pediatric Research**

<p>Section 2071; National Pediatric Research Network</p>	<p>Requires the NIH Director to award funding to public or private nonprofit entities to support pediatric research consortia.</p>
<p>Section 2072; Global Pediatric Clinical Study Network</p>	<p>Expresses the sense of Congress that the NIH should facilitate a global pediatric clinical study network, by providing grants, contracts, or cooperative agreements to support new and early stage investigators.</p>



Title III — Development

Subtitle A — Patient-Focused Drug Development

<p>Section 3001; Patient Experience Data</p>	<p>Following FDA approval of a drug or biologic, this section requires the Secretary to make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application, at least 180 days after the date of enactment. This would include: (1) patient experience data; (2) information on patient-focused drug development tools; and (3) other information determined relevant by the Secretary.</p> <p>Defines “patient experience data” to include data that: “(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and (2) are intended to provide information about patients’ experiences with a disease or condition, including (A) the impact of such disease or condition, or a related therapy, on patients’ lives; and (B) patient preferences with respect to treatment of such disease or condition.”</p>
<p>Section 3002; Patient-focused Drug Development Guidance</p>	<p>Provides that no later than 180 days after enactment, the Secretary, acting through FDA, must develop a plan to issue draft and final versions of one or more guidance documents, over a period of five years, regarding the collection of patient experience data (as defined above), and the use of such data and related information in drug development. The draft guidance must be issued within 18 months of enactment and must be finalized not later than 18 months after the public comment period on the draft guidance.</p> <p>The guidance must address the following areas: (1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decision-making may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis; (2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease; (3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials; (4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decision-making; (5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary; (6) the format and content required for submissions under this section to the Secretary, including with respect to the information described above; (7) how the Secretary intends to respond to submissions of information described above, if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and (8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described above.</p>
<p>Section 3003; Streamlining Patient Input</p>	<p>Exempts from the Paperwork Reduction Act of 1995 the collection of patient experience data (defined above) to which a response is voluntary and initiated by the Secretary under Section 569C of the FDCA (21 U.S.C. § 360bbb-8c, as amended by section 3001).</p>
<p>Section 3004; Report on Patient Experience Drug Development</p>	<p>Requires the FDA to issue a report assessing the use of patient experience data in regulatory decision-making, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part of approved drugs not later than June 1 of 2021, 2026, and 2031.</p>

### Subtitle B — Advancing New Drug Therapies

#### Section 3011; Qualification of Drug Development Tools

Requires the Secretary (likely delegated to FDA) to establish a process for the qualification<sup>1</sup> of drug development tools, initiated by request (letter of intent), for use in supporting or obtaining FDA approval for or investigational use of a drug or biologic. Drug development tools are defined broadly to include: (1) a biomarker;<sup>2</sup> (2) clinical outcomes assessments,<sup>3</sup> and “any other method, material, or measure that the Secretary determines aid[s] drug development and regulatory review for purposes of this section.”

If the Secretary accepts the letter of intent, the requestor<sup>4</sup> must submit a “qualification plan”; if accepted, the requestor must then submit a full “qualification package.” The Secretary must determine to accept qualification submissions “based on factors which may include the scientific merit of the qualification submission.”<sup>5</sup> The Secretary may prioritize the review of a full qualification package based on factors determined appropriate by the Secretary including: (1) “as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and (2) the identification, by the Secretary or by biomedical research consortia<sup>6</sup> and other expert stakeholders, of such a drug development tool and its proposed context of use<sup>7</sup> as a public health priority.” The Secretary may also engage or consult with external experts for purposes of the review of qualification submissions.

Drug development tools determined to be qualified by the Secretary may be used by any person under the context for which they have been qualified. Specifically, a qualified drug development tool may be used for: (1) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or (2) supporting the investigational use of a drug or biological product.

The Secretary may rescind or modify determinations under this section if the Secretary determines that the tool is not appropriate for the proposed context of use specified by the requestor. This determination “may be based on new information that calls into question the basis for such qualification.”<sup>8</sup>

The Secretary must make publicly available, and update on least a biannual basis, on FDA’s website certain information outline in this section regarding the qualification tools (e.g., number of requests, the Secretary’s determinations, etc.).

Requires the Secretary, in consultation with the “biomedical research consortia” and other interested parties, to issue guidance on the implementation and regulatory framework of these provisions. Draft guidance must be issued not later than 3 years after enactment, with final guidance not later than 6 months after the date the comment period for the draft guidance closes.

Also requires the Secretary to consult with the biomedical research consortia and other interested parties through a “collaborative public process,” to establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development. Not later than 2 years after enactment, the Secretary must make such taxonomy publicly available in draft form for public comment, and must finalize the taxonomy not later than 1 year after the close of the public comment period.

The Secretary must also convene a public meeting within 2 years of enactment, and must issue a report not later than 5 years after enactment, regarding the qualification process.



<p>Section 3012; Targeted Drugs for Rare Diseases</p>	<p>Clarifies the authority of the FDA with regard to “genetically targeted drugs”<sup>9</sup> and “variant protein targeted drugs”<sup>10</sup> to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening. Also clarifies that FDA “maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.”</p> <p>Permits the Secretary (discretionary) to allow the sponsor of a drug or biologic application for a genetically targeted drug or variant protein targeted drug “to rely upon data and information (1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and (2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications” submitted to FDA “for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).”</p>
<p>Section 3013; Reauthorization of Program to Encourage Treatments for Rare Pediatric Diseases</p>	<p>Reauthorizes the pediatric rare disease priority review voucher program until 2020. However, if a drug is designated before October 1, 2020, it can continue to receive a voucher if approved before October 1, 2022.</p>
<p>Section 3014; GAO Study of Priority Review Voucher Programs</p>	<p>Requires the Government Accountability Office(GAO) to report by January 31, 2020 with respect to: (1) the neglected tropical disease voucher program; (2) the rare pediatric disease voucher program; and (3) the medical countermeasure priority review voucher program. This section outlines the specific information that the GAO report must contain.</p>
<p>Section 3015; Amendments to the Orphan Drug Grants</p>	<p>Updates the orphan drug grant program to clarify that grants may be used for “prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to: (1) develop or validate a drug development tool related to a rare disease or condition; or (2) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.”</p>
<p>Section 3016; Grants for Studying Continuous Drug Manufacturing</p>	<p>Allows the Secretary to issue grants to “institutions of higher education<sup>11</sup> and nonprofit organizations” for purposes of studying and recommending improvements to the process of continuous manufacturing for drugs and biological products and similar innovative monitoring and control techniques.</p>
<p><b>Subtitle C — Modern Trial Design and Evidence Development</b></p>	
<p>Section 3021; Novel Clinical Trial Designs</p>	<p>Requires the Secretary to conduct a public meeting (within 18 months of enactment) and issue guidance for purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs and biologics. The guidance must address: (1) the use of complex adaptive and other novel trial designs, including how such clinical trials proposed or submitted help to satisfy the substantial evidence standard; (2) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to: (i) completion of such modeling or simulations; or (ii) the submission of resulting information to the Secretary; (3) the types of quantitative and qualitative information that should be submitted for review; and (4) recommended analysis methodologies. The draft guidance must be issued not later than 18 months after the public meeting, and finalized not later than 1 year after the date public comment for the draft guidance closes.</p>

<p>Section 3022; Real World Evidence</p>	<p>Requires the Secretary to “establish a program to evaluate the potential use of real world evidence: (1) to help to support the approval of a new indication for a drug approved under section 505(c); and (2) to help to support or satisfy post-approval study requirements.</p> <p>For purposes of this section, “real world evidence” means “data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.”</p> <p>Not later than 2 years after enactment, the Secretary must establish a “draft framework for implementation” of the real world evidence program. The “framework” must include information describing: “(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities; (B) the gaps in data collection activities; (C) the standards and methodologies for collection and analysis of real world evidence; and (D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.”</p> <p>The Secretary must consult with “regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties” in developing the framework. This consultation may be carried out through public-private partnerships; contracts, grants, or other arrangements as the Secretary determines appropriate, such as a partnership or an independent research organization; or public workshops with the entities described above.</p> <p>The Secretary must implement the real world evidence program not later than 2 years after enactment to “evaluate the potential use of real world evidence.”</p> <p>In addition, the Secretary must utilize the program and activities or pilots noted above to “inform” a guidance for industry on: (A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence to help support a new indication of an approved drug or to help support or satisfy post-approval study requirements; and (B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes. The Secretary must issue a draft guidance on these topics not later than 5 years after enactment, and must finalize such guidance not later than 18 months after the close of public comment.</p> <p>This section also explicitly provides that nothing “prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such nonspecified use.”<sup>12</sup></p>
<p>Section 3023; Protection of Human Research Subjects</p>	<p>Requires the Secretary, “to the extent practicable and consistent with other statutory provisions, [to] harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations. Specifically, the Secretary must, as appropriate, make modifications to these regulations and the vulnerable population rules to: “(A) reduce regulatory duplication and unnecessary delays; (B) modernize such provisions in the context of multisite and cooperative research projects; and (C) protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs. In harmonizing or modifying the regulations, the Secretary must consult with relevant stakeholders and must complete the harmonization not later than 3 years after enactment.</p>
<p>Section 3024; Informed Consent Waiver or Alteration for Clinical Investigations</p>	<p>Provides FDA the flexibility to waive or alter informed consent requirements for clinical trials with minimal risk, similar to existing flexibility for HHS and NIH under the Common Rule.</p>

**Subtitle D — Patient Access to Therapies and Information**

<p>Section 3031; Summary Level Review</p>	<p>Provides that the Secretary “may rely upon qualified data summaries<sup>13</sup> to support the approval of a supplemental application, with respect to a qualified indication<sup>14</sup> for” an already approved drug, as well as biologics approved under the PHSa. This section would permit a supplemental application to have such review “only if (i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and (ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.</p> <p>Also requires the Secretary to post on FDA’s website, and to update annually, the number of applications reviewed under this section, as well as other information (e.g., time for completion of review, use of full data sets).</p>
<p>Section 3032; Expanded Access Policy</p>	<p>This section requires a manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions to “make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) [of the FDCA] for provision of such a drug.”</p> <p>The policies under this section “may be generally applicable to all investigational drugs of such manufacturer or distributor” and must be made public and readily available, such as by posting the policy on a publicly available website.</p> <p>Specifically requires the policies to include: (1) contact information for the manufacturer or distributor to facilitate communication about expanded access requests; (2) procedures for making such requests; (3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests; (4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and (5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act.</p> <p>Section 3032 expressly acknowledges that the “posting of policies by manufacturers and distributors ... shall not serve as a guarantee of access to any specific investigational drug by any individual patient.” The section also does not “prevent a manufacturer or distributor from revising a policy required under this section at any time.”</p> <p>These provisions become effective beginning on the later of: (1) 60 calendar days after enactment; or (2) the first initiation of a phase 2 or phase 3 study with respect to such investigational drug.</p>

<p>Section 3033; Accelerated Approval for Regenerative Advanced Therapies</p>	<p>While earlier versions of the legislation would have largely deregulated certain regenerative medicine therapies, that provision was replaced with provision focusing on FDA acceleration of approval of important new regenerative medicines. The section as enacted requires the Secretary, at the request of a sponsor, to facilitate an efficient development program for, and expedite review of, a drug if it qualifies as a “regenerative advanced therapy” under specified criteria. A drug is eligible for designation as a regenerative advanced therapy if: (1) the drug is a regenerative medicine therapy;<sup>15</sup> (2) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.</p> <p>The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug.</p> <p>Not later than 60 calendar days after the receipt of a request, the Secretary must determine whether the drug meets these criteria. If the Secretary determines that the drug meets the criteria, the Secretary must designate the drug as a regenerative advanced therapy. If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary must include with the determination a written description of the rationale for such determination.</p> <p>The sponsor of a regenerative advanced therapy is also eligible for the actions to expedite development and review of such therapy, including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).</p> <p>In addition, an application for a regenerative advanced therapy may be: (1) eligible for priority review; (2) eligible for accelerated approval, through, as appropriate: (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or (2) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.</p> <p>The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the post-approval requirements may, as appropriate, fulfill such requirements, as the Secretary may require, through: (A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; (B) the collection of larger confirmatory data sets, as agreed upon; or (C) post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.</p>
<p>Section 3034; Guidance Regarding Devices Used in the Recovery, Isolation or Delivery of Regenerative Advanced Therapies</p>	<p>Requires the FDA, not later than 1 year after enactment, to issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the guidance must specifically address: (1) how FDA intends to simplify and streamline regulatory requirements for combination device and cell or tissue products; (2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device; (3) when FDA considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and (4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type. FDA must finalize this guidance not later than 12 months after the public comment period.</p>
<p>Section 3035; Report on Regenerative Advanced Therapies</p>	<p>Provides that, before March 1 of each calendar year, Section 3035 requires the Secretary to submit a report to Congress on the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed, withdrawn, or denied, and how many of such applications or therapies were granted accelerated approval or priority review.</p>

<p>Section 3036. Standards for Regenerative Medicine and Advanced Therapies</p>	<p>This section states not later than 2 years after enactment, the Secretary must, in consultation with NIST and various stakeholders, “facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.”</p> <p>Not later than 1 year after the development of these standards, the Secretary must review relevant regulations and guidance, through a public process, and update such regulations and guidance as the Secretary determines appropriate.</p>
<p>Section 3037; Health Care Economic Information</p>	<p>Amends Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (21 U.S.C. § 352(a)) to help clarify and facilitate the dissemination of health care economic information (HCEI):</p> <ol style="list-style-type: none"> <li>1. Broadens the current definition of HCEI to expand the types of HCEI materials and analyses firms could prepare and use with payors or formulary committees to include “any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug.”             <ul style="list-style-type: none"> <li>• The expanded definition would explicitly allow HCEI to be “comparative to the use of another drug, to another health care intervention, or to no intervention.” FDA officials had previously suggested that a healthcare economic claim comparing drug products could only be disseminated when there are underlying clinical studies supporting a clinical comparison between the products. These provisions reject that FDA stance and provide significant flexibility in framing HCEI analyses based on specific or general economic endpoints and comparative clinical assumptions. Of course, the claims must still utilize an appropriate methodology and should be truthful and non-misleading.</li> </ul> </li> <li>2. Extends the dissemination of HCEI explicitly to “payors” as well as formulary committees or other similar entities with knowledge and expertise in the area of health care economic analysis and the selection of drugs for “coverage or reimbursement.” The provision drops the need for an ongoing formulary deliberative process, as long as the payor’s interest is in coverage and reimbursement, and they have the requisite expertise.</li> <li>3. Clarifies that HCEI must only “relate” to an FDA-approved indication of a drug, rather than be “directly” related to such approved indication. This clarification will allow firms to disseminate health care economic studies and other HCEI that contain data on both approved and unapproved uses of a product (e.g., a database broader than just on-label patients, or an analysis focused on a patient subgroup that was not specifically studied as part of the clinical trials supporting FDA approval). However, the amendment explicitly does not protect HCEI that “relates only” to an unapproved indication.</li> <li>4. Requires manufacturers to, “where applicable,” affix to HCEI materials and communications “a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug.”</li> </ol>

<p>Section 3038; Combination Product Innovation</p>	<p>Requires the Secretary to assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product. Such combination products will be subject to premarket review under a single application, based on the Secretary’s determination of the “primary mode of action” of the combination product. For example, if the Secretary determines that the primary mode of action of the combination product is that of a device, then the agency center charged with premarket review of devices will have primary jurisdiction. If a sponsor disagrees with the Secretary’s determination of the primary mode of action, the sponsor will have an opportunity to request a substantive rationale and to propose additional studies. Sponsors also will have an opportunity to request a meeting with the agency to address the standards and requirements for market approval or clearance, other issues relevant to such combination product, and to identify subjects for future discussion. Agreements between the sponsor and the Secretary must be in writing and made part of the administrative record.</p> <p>Also provides direction to the FDA regarding coordinating communication between the primary agency center and any consulting centers involved in premarket review of the combination product.</p> <p>Additionally requires the Secretary to issue final guidance, within four years, that describes the structured process of managing pre-submission interactions with sponsors developing combination products, best practices for ensuring that feedback in the pre-submission interactions represents the Agency’s best advice, and information on meetings between the sponsor and FDA.</p> <p>Directs the Secretary to identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing processes may be adopted that vary from the regulations. After soliciting public comments on the list, this section requires the final list to be published in the Federal Register.</p>
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**Subtitle E — Antimicrobial Innovation and Stewardship**

<p>Section 3041; Antimicrobial Resistance Monitoring</p>	<p>Requires the Secretary of the U.S. Department of Health and Human Services (HHS) to “encourage reporting on aggregate antimicrobial<sup>16</sup> drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service.”<sup>17</sup></p> <p>Requires the Secretary to prepare and make publicly available certain data and information on antimicrobial drug resistance and use of antimicrobial drugs not later than 1 year after enactment of the legislation, including the following: (1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act (FDCA); (2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and (3) coordination between the Director of the Centers for Disease Control and Prevention (CDC) and FDA with respect to the monitoring of: (i) any applicable resistance from national or regional trends; and (ii) drugs approved under section 506(h)(discussed below).<sup>18</sup></p> <p>Requires the Secretary, “as appropriate,” to disseminate guidance and educational materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.</p> <p>The Secretary also must “continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance.”<sup>19</sup></p> <p>Additionally, the Secretary must: (1) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities; and (2) evaluate: (i) antimicrobial resistance data using a standardized approach; and (ii) trends in the utilization of drugs approved under section 506(h).<sup>20</sup></p>
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<p>Section 3042; Limited Population Pathway</p>	<p>Amends Section 506 of the FDCA (21 U.S.C. § 356) by adding a new provision<sup>21</sup> that would allow FDA to “approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug” if the following conditions are met: (1) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs; (2) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the PHSA, as applicable, are met; and (3) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.</p> <p>Would require FDA’s determination of safety and effectiveness to reflect the “benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population.”<sup>22</sup></p> <p>Imposes other requirements on drugs approved under section 506(h).</p> <ul style="list-style-type: none"> <li>■ <b>Labeling:</b> all labeling and advertising of antibacterial or antifungal drugs approved under this section must contain the statement “Limited Population” in a “prominent manner and adjacent to, and not more prominent than” the proprietary name of such drug or the established name of the drug, or in the case of a biological product, the proper name. The prescribing information must also include the following statement: “This drug is indicated for use in a limited and specific population of patients.”</li> <li>■ <b>Promotional Materials:</b> sponsors of drugs under this section must submit to FDA “copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.”</li> <li>■ Under the legislation, an antimicrobial drug would be misbranded if its labeling did not comply with the requirements noted above (adding 21 U.S.C. § 352(dd)).</li> </ul> <p>Allows sponsors of such drugs to also seek designation or approval under other applicable sections or subsections of the FDCA or PHSA (e.g., accelerated approval).</p> <p>Not later than 18 months after enactment, FDA must issue “draft guidance describing the criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs” and must publish the final guidance within 18 months of the close of the public comment period on the draft guidance. FDA may approve antibacterial and antifungal drugs under this subsection prior to issuing this guidance.</p> <p>Requires FDA to “provide prompt advice to the sponsor of a drug” under this subsection “to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in broader population.”</p> <p>If, after approval of a drug under this subsection, FDA “approves a broader indication for such drug under section 505(b) or section 351(a) ..., the Secretary may remove any post-marketing conditions, including requirements with respect to labeling and review of promotional materials ... applicable to the approval of the drug.”</p> <p>Requires the Secretary to report to Congress every two years on the number of requests for approval and the number of approvals of antibacterial or antifungal drugs under this subsection.</p> <p>In addition, GAO must issue a report no later than December 2021 to review the activities included in the approval of these drugs.<sup>23</sup></p>
<p>Section 3043; Prescribing Authority</p>	<p>Clarifies and reiterates that nothing in this section will restrict the prescribing authority of antimicrobial drugs or limit the practice of health care providers.</p>

Section 3044; Susceptibility Test Interpretive Criteria for Microorganisms	<p>Amends Section 511 (21 U.S.C. § 351) of the FDCA to add new Section 511A, which would clarify the Secretary’s authority to “efficiently update susceptibility test interpretive criteria<sup>24</sup> for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of organisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies.” The Secretary would also provide public notice of the recognized interpretive criteria and interpretive criteria standards.<sup>25</sup></p> <p>Defines “antimicrobial drug” to mean “a systemic antibacterial or antifungal drug that: (i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus; (ii) may include a qualified infectious disease product designated under section 505E(d); and (iii) is subject to section 503(b)(1).”<sup>26</sup></p> <p>Requires the Secretary to “clear under section 510(k), classify under section 513(f) (2), or approve under section 515, antimicrobial susceptibility testing devices<sup>27</sup> using updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.”</p> <p>This section requires the Secretary to identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs: (1) if such criteria are available on the date of approval of the drug, upon such approval or licensure; or (2) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.</p> <p>The Secretary must identify appropriate susceptibility test interpretive criteria based on a review, to the extent available and relevant, of the following: (1) preclinical and clinical data, including pharmacokinetic, pharmacodynamics, and epidemiological data; (2) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and (3) other evidence or information deemed appropriate by the Secretary.</p> <p>No later than one year after enactment, the Secretary must establish and maintain on FDA’s website a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria (referred to as the “Interpretive Criteria Website”).<sup>28</sup> The list would be required to include susceptibility test interpretive criteria standards that are: (1) established by a nationally or internationally recognized standard development organization that meets certain criteria;<sup>29</sup> and (2) is recognized by the Secretary (as described below).</p>
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**Subtitle F — Medical Device Innovations**

<p>Section 3051; Breakthrough Devices</p>	<p>Requires the Secretary to establish a pathway for the “efficient and flexible” review of “devices that represent breakthrough technologies.” Specifically, the Secretary must establish a program to expedite the development of, and provide for the priority review for, devices the Secretary determines: (1) provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and “(2) (A) that represent breakthrough technologies; (B) for which no approved or cleared alternatives exist; (C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or (D) the availability of which is in the best interest of patients.</p> <p>Sponsors may request the Secretary to designate such a device for expedited development and priority for review any time prior to the submission of a device application. Not later than 60 calendar days after the receipt of such request, the Secretary must make a determination. This section further outlines the process under which the Secretary would review and approve expedited or priority review device requests.</p> <p>Permits the Secretary, as appropriate, to: coordinate with the sponsor regarding early agreement on a data development plan; take steps to ensure that clinical trial designs are as efficient and as flexible as practicable, when scientifically appropriate; facilitate expedited and efficient development and review of the device through utilization of timely post-market data collection; and agree in writing to clinical protocols.</p> <p>Not later than 1 year after enactment, the Secretary must issue guidance on the implantation of this section, which also enumerates what specific information the guidance must address.</p> <p>The Secretary is also required to issue a report to Congress on or before January 1, 2019, regarding the expedited device program.</p>
<p>Section 3052; Humanitarian Device Exemption</p>	<p>Provides FDA with the authority to apply the humanitarian device exemption to devices that treat diseases and conditions that affect up to 8,000 individuals in the U.S. The current cap is 4,000.</p> <p>Also requires FDA to issue draft guidance that defines the criteria establishing “probable benefit” as that term is used in section 520(m)(2)(C) of the FDCA not later than 18 months after enactment.</p>
<p>Section 3053; Recognition of Standards</p>	<p>Establishes a clear process at FDA for the submission, review, and recognition of standards established by a nationally or internationally recognized standard organization for purposes of medical device review.</p>
<p>Section 3054; Certain Class I and Class II Devices</p>	<p>Requires the Secretary, not later than 120 calendar days after the date of enactment and at least once every 5 years thereafter, to identify, through publication in the Federal Register, any type of class I or class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness.</p>
<p>Section 3055; Classification Panels</p>	<p>Improves the medical device classification panel review process at FDA to ensure adequate expertise<sup>30</sup> among panel members to assess the device and allow for presentation by the device sponsor to the panel, among other things.</p>
<p>Section 3056; Institutional Review Board Flexibility</p>	<p>Eliminates the requirement that a sponsor of a medical device trial always use a local institutional review board. This change will allow the use of centralized models.</p>

Section 3057; CLIA Waiver Improvements	Requires that the FDA update its existing regulatory guidance to clarify the criteria for waiving CLIA requirements, which will expand patient access to point-of-care diagnostics. Specifically requires FDA to issue guidance not later than 1 year after enactment that revises “Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy” of the guidance entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” and dated January 30, 2008; and (2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy. The guidance must be finalized not later than 1 year after public comment on the draft guidance closes.
Section 3058. Least Burdensome Device Review	<p>Requires each relevant employee at FDA to receive training regarding the meaning and implementation of the least burdensome requirements.</p> <p>Requires an audit by the FDA ombudsman and an assessment of the measurements used to track the implementation of the least burdensome requirements.</p> <p>Clarifies that FDA reviewers shall consider the least burdensome appropriate means necessary for demonstrating a reasonable assurance of safety and effectiveness when requesting additional information from manufacturers during the pre-market approval process.</p> <p>Requires that when requesting additional information regarding a premarket application, the Secretary must “consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness. The term “necessary” means “the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.”</p>
Section 3059; Cleaning Instructions and Validation Data Requirement	The Secretary must, not later than 180 days after enactment, identify and publish a list of reusable device types for which reports under subsection (k) are required to include: (A) instructions for use, which have been validated in a manner specified by the Secretary; and (B) validation data, the types of which shall be specified by the Secretary regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based. The Secretary may update or revise this list as appropriate, with notice in the Federal Register.

## Section 3060; Clarifying Medical Software Regulation

Clarifies that the term “device,” as defined in section 201(h) of the FDCA, “shall not include a software function that is intended:

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as: (i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals; (ii) such records are part of health information technology that is certified under section 3001(c)(5) of the PHSA; and (iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of: (i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); (ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and (iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

provides that in the case of a product “with multiple functions” that contains: (A) at least one software function that meets the criteria noted above or that otherwise does not meet the definition of device; and (B) at least one function that does not meet the criteria noted above and that otherwise meets the definition of device, the Secretary “shall not regulate the software function of such product ... as a device. However, the Secretary “may assess the impact that the software function or functions ... have on such device function or functions” in assessing the safety and effectiveness of the device function or functions.

Establishes that a software function shall not be excluded from the definition of device if: (i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and (ii) the software function has been identified in a final order issued by the Secretary, which must be published in the Federal Register. The Secretary must issue a public notification of the proposed order, which must include the Secretary’s finding, including the rationale and identification of the evidence on which such finding was based. The Secretary must give the public at least 30 calendar days to comment before issuing the final order.

<p>Section 3060; Clarifying Medical Software Regulation (cont'd)</p>	<p>Directs the Secretary to, in making a determination regarding the issuance of a final order, consider: (1) the likelihood and severity of patient harm if the software function were to not perform as intended; (2) the extent to which the software function is intended to support the clinical judgment of a health care professional; (3) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and (4) the intended user and user environment, such as whether a health care professional will use a software function of a type described above.</p> <p>Specifies that nothing in this section shall be construed as limited the authority of the Secretary to: (1) exercise enforcement discretion as to any device subject to regulation under the FDCA; (2) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or (3) regulate software as a device under the FDCA if such software meets the criteria under section 513(a)(1)(C).”</p> <p>Not later than 2 years after enactment, the Secretary, with input from relevant stakeholders, must publish a report that examines information available on any risks and benefits to health associated with the software functions described above and summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.</p> <p>The Secretary must classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.”</p>
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**Subtitle G — Improving Scientific Expertise and Outreach at FDA**

<p>Section 3073; Establishment of Food and Drug Administration Intercenter Institutes</p>	<p>Requires the Secretary to establish one or more Intercenter Institutes (“Institute”) within FDA for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute must develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the FDA Centers (CDER, CBER, and CDRH). Such activities may include:</p> <ol style="list-style-type: none"> <li>(1) coordination of staff with diverse product expertise;</li> <li>(2) streamlining, where appropriate, the review of medical products;</li> <li>(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;</li> <li>(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;</li> <li>(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and</li> <li>(6) facilitation of the collaborative relationships of the Centers with other agencies within HHS regarding the major disease area of focus of the Institute.</li> </ol> <p>The Secretary must provide a period of public comment during the time that each Institute is being implement, and must establish at least one institute within 1 year after enactment. The Secretary may terminate any Institute if the Secretary determines it is no longer benefitting the public health.</p>
<p>Section 3074; Scientific Engagement</p>	<p>Improves FDA and NIH scientists’ ability to attend scientific conferences so they can keep up with the newest advancements in science and collaborate with one another, among other things.</p>
<p>Section 3075; Drug Surveillance</p>	<p>This section makes targeted edits to FDA’s drug surveillance program to allow FDA to focus on risk.</p>



**Subtitle H — Medical Countermeasures Innovation**

<p>Section 3081; Medical Countermeasure Guidelines</p>	<p>Requires timely and accurate recommended utilization guidelines for qualified Medical Countermeasures (MCMs), including for products in the Strategic National Stockpile. Also requires HHS to report to the appropriate committees of Congress when funding in the BioShield Special Reserve Fund (SRF) available for procurement of MCMs falls below \$1.5 billion and how the amount of funding will impact identified MCM priorities.</p> <p>Clarifies the reporting requirement’s annual deadline and that the report must be submitted to the Congressional committees of jurisdiction.</p>
<p>Section 3082; Clarifying BARDA Contracting Authority</p>	<p>Ensures coordinated, timely, and efficient processes for executing MCM development and procurement programs by clarifying that the Director of the Biomedical Advanced Research Development Authority (BARDA) has authority to carry out the programs funded by the Special Reserve Fund, as well as the procurement contracts, grants, and cooperative agreements under BARDA.</p>
<p>Section 3083; Countermeasure Budget Plan</p>	<p>Requires HHS to annually develop a five-year budget plan based on identified MCM priorities. Also clarifies that in addressing agents that present a national threat, the plan will include those that are novel or emerging infectious diseases, and the efforts to develop MCMs for such threats, including qualified pandemic and epidemic products. Also clarifies when this plan is required to be submitted to Congress and that it will be made publicly available.</p>
<p>Section 3084; Medical Countermeasures Innovation</p>	<p>Provides BARDA with targeted authority to enter into an agreement with a Medical Countermeasure Innovation Partner to foster and accelerate the development and innovation of MCMs, including promising technologies that also address unmet public health needs in addition to MCM needs, such as multi-use platform technologies. The provision sunsets after September 30, 2022.</p>
<p>Section 3085; Streamlining Project BioShield Procurement</p>	<p>Removes unnecessary steps that no longer reflect current BioShield SRF practices, .</p>
<p>Section 3086; Encouraging Treatments for Agents that Present a National Security Threat</p>	<p>Establishes a priority review voucher to encourage the development of drugs and vaccines for agents that present national security threats.</p> <p>Requires the HHS Secretary to award a priority review voucher to the sponsor of a “material threat MCM application” upon approval.</p> <p>Consistent with the targeted priority review vouchers under current law, the priority review voucher can be transferred and used to receive priority review of another drug application at a later date.</p> <p>The provision sunsets after October 1, 2023.</p>
<p>Section 3088; Clarifying Food and Drug Administration Emergency Use Authorization</p>	<p>Clarifies that FDA’s authorities with respect to emergency use authorizations applies to animal drugs.</p>

**Subtitle I — Vaccine Access, Certainty, and Innovation**

<p>Section 3091; Predictable Review Timelines of Vaccines by the Advisory Committee on Immunization Practices</p>	<p>Provides that upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (ACIP) must, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.</p> <p>In the event the vaccine is not considered at the first scheduled meeting, the ACIP will provide an update on the committees review.</p> <p>Requires the ACIP to make recommendations regarding the use of certain vaccines in a timely manner, including vaccines designated as a breakthrough therapy or those that could be used in a public health emergency.</p>
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<p>Section 3092; Review of Processes and Consistency of Advisory Committee on Immunization Practices Recommendations</p>	<p>Requires the Director of the CDC to conduct a review of the process used by ACIP in formulating and issuing recommendations pertaining to vaccines, including consistency in doing so. Following such review, the CDC Director must publish a report on the results of the review, including recommendations on improving the consistency of the process.</p>
<p>Section 3093. Encouraging Vaccine Innovation</p>	<p>Requires the CDC Director to coordinate appropriate staff with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization.</p> <p>Requires the Secretary, within one year of enactment to issue a report to Congress on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease. The report must review the current status of vaccine development and: (1) consider the optimal process to determine which vaccines would be beneficial and how to share that information to key stakeholders; (2) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and (3) make recommendations on how to remove any obstacles identified in order to promote and incentivize vaccine innovation and development.</p> <p>In preparing this report the Secretary may consult with: relevant federal agencies, academic researchers, developers and manufacturers of vaccines, medical and public health practitioners, representatives of patient, policy, and advocacy organizations, and others as determined appropriate.</p> <p>Requires the Secretary to revise the Vaccine Injury Table to include vaccines recommended by CDC for routine administration in pregnant women.</p> <p>Clarifies that “both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.”</p>

## Title IV — Delivery

<p>Section 4001; Assisting Doctors And Hospitals In Improving Quality Of Care For Patients.</p>	<p>Includes several provisions of S. 2511, sponsored by HELP Committee Chair Lamar Alexander (R-TN), which was reported by the Committee in February.</p> <p>Requires the Secretary, within one year of enactment, to consult with stakeholders to establish goals and a strategy for reducing regulatory and administrative burdens, such as documentation requirements, of electronic health records (EHRs). The recommendations must address the requirements of the Medicare EHR Incentive Program, the Medicaid EHR Incentive Program, the Hospital Value-Based Purchasing Program, and Medicare’s new payment systems for physicians, the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs). The Secretary may apply the recommendations to other value-based purchasing programs. The recommendations must address health information technology (HIT) standards and specifications, the certification process, patient access, privacy and security, clinical research, and alignment and simplification of quality measures, among others. FACA does not apply to the activities of the group.</p> <p>Provides that, to the extent consistent with state law, physicians, as defined in § 1866(r) (1) of the Social Security Act, may delegate EHR documentation requirements of CMS regulations to a “person performing a scribe function who is not such physician” if the physician has “signed and verified” the documentation.</p> <p>Requires the Secretary to use existing authorities to encourage voluntary certification of HIT for medical specialties and sites of service “for which no such technology is available or where more technological advancement or integration is needed.” Requires the Secretary to recommend, within 18 months of enactment, and adopt, within 2 years of enactment, a voluntary certification process and standards for the practice of pediatrics and health care for children. It establishes periodic public reporting of meaningful use attestation statistics for the EHR Incentive Program and flexibility for the Secretary to adapt them for the MIPS.</p>
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Section 4002; Transparent Reporting On Usability, Security, And Functionality.

Expands authority for the Secretary to grant significant hardship exceptions for hospitals and health care professionals whose EHRs lose their certification, and extends the significant hardship exception for healthcare professionals to apply to the MIPS.

Requires the Secretary to enhance the EHR certification process, as modified by § 4001(b) to reduce documentation burdens on physicians, through notice-and-comment rulemaking. This enhanced certification process requires EHR developers, as a condition of EHR certification or the maintenance of certification, to attest to the Secretary that they have not taken any action that constitutes information blocking, as defined, and will not restrict interoperability, unless for a legitimate purpose authorized by the Secretary. EHR developers will also need to attest that they do not prohibit or restrict communications among healthcare professionals about the interoperability, security or user experience of the EHR, or the business practices of the HIT developer. Additional attestations involve developing application programming interfaces (APIs) (or successor technologies) to permit health information exchange of all data elements of a patient’s EHR (as permitted under privacy laws) “without special effort” on the part of the user. This responds to a common complaint of physicians that costly interfaces inhibit interoperability. Developers must also attest that their technology allows for health information to be exchanged, accessed, and used; that they have successfully tested the interoperability of technology in real-world use cases; and will submit reporting criteria in accordance with a new process, described further below.

A new provision establishes an EHR Reporting Program, which will publicly report information permitting healthcare providers and consumers to compare HIT products. The Secretary must, within one year of enactment, award a contract to an independent entity (which may not be a developer of certified HIT or a state or local government) to run a public, transparent process to obtain input on the reporting criteria. The contractor must develop a process to obtain and verify confidential information submitted by healthcare providers, patients, and HIT developers. Prior to publishing public reports summarizing this information, the contractor must permit the developer to comment on the portrayal of its product.

The process for developing the reporting criteria must include certain stakeholders, including healthcare providers, hospitals, HIT developers, patient advocates, health information exchange networks, authorized certification bodies and testing labs, “relevant” makers of medical devices, the National Quality Forum, and security and user design experts.

The reporting criteria must include measures of (i) security;(ii) usability and user-centered design;(iii) interoperability;(iv) conformance to certification testing; and other categories designated by the Secretary, and must be designed in a way that does not disadvantage small and startup HIT developers.

The reporting criteria may include measures of the usability of EHRs for ordering and viewing the results of diagnostic imaging and laboratory tests; measures for retrieving data from registries such as clinician-led clinical data registries; and measures on accessing and exchanging information among healthcare providers, including patient-generated information, through health information exchanges, from medical devices, and by Federal, State, and local agencies, among others. The Secretary may include measures of the ability of EHRs to provide the patient or an authorized designee with a complete copy of their EHR data in a compatible format.

The submitted data will be summarized by the contractor in a public report.

Provides that the Secretary may encourage compliance with the conditions of certification and take action to discourage noncompliance, but, unlike prior versions of this legislation, there is no other enforcement mechanism such as civil monetary penalties.

<p>Section 4003; Interoperability.</p>	<p>Establishes a definition of interoperability in federal law. Interoperability, as it relates to HIT, means technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking, as defined in the Cures Act.</p> <p>The provision also includes the “Trusted Exchange Framework” from S. 2511. It requires the National Coordinator for HIT to work with the National Institute of Standards and Technology (NIST) and other relevant agencies to convene public-private and public-public partnerships to build consensus around and develop a trusted exchange framework, including a common agreement among health information networks nationally. The common agreement may include a method for authenticating participants, rules for trusted exchange, enabling organizational and operational policies, and a process for adjudicating disagreements among parties to the agreement. Within two years of the convening event, and annually thereafter, the National Coordinator must publish a list of HIE networks that have adopted the common agreement. The Secretary must consider existing exchange networks to minimize disruption.</p> <p>Adoption of the common agreement and use of the trusted exchange framework is not mandatory for HIE networks, but federal agencies may require use of the trusted exchange network as a condition of grants to the networks.</p> <p>Requires that within three years of enactment, the Secretary must establish a provider digital contact information index for health professionals and health facilities to encourage the exchange of electronic health information. The Secretary must include “all health professionals and health facilities” to create the most useful, reliable, and comprehensive index of providers possible.</p> <p>Abolishes the HIT Standards Committee and the HIT Policy Committee that advise the National Coordinator for HIT, and instead establishes a HIT Advisory Committee that complies with the Federal Advisory Committee Act (FACA). The new Advisory Committee will be responsible for identifying standards that support interoperability, and may consider prior recommendations of the HIT Standards Committee but must prioritize standards and implementation specifications developed by consensus-based standards development organizations.</p>
<p>Section 4004; Information Blocking.</p>	<p>Establishes a new federal definition of information blocking and establishes a process for HHS OIG to investigate complaints concerning the practice. It defines information blocking as a practice that, except as required by law or specified by the Secretary, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. The standard for HIT developers, exchanges and networks is “knows, or should know” will interfere, while the standard for healthcare providers is, “knows is unreasonable.” The bill lists several types of “information blocking practices,” including restricting authorized access to information for treatment purposes such as transitions between certified HIT products; implementing HIT in nonstandard ways that are likely to substantially increase complexity or burden, and implementing HIT in ways that are likely to restrict export of data or lead to fraud and abuse.</p> <p>The Secretary must use notice-and-comment rulemaking to establish a list of exceptions for reasonable and necessary practices that do not constitute information blocking. However, enforcement of the new prohibitions begins 30 days after enactment of the Cures Act. The OIG may assess civil monetary penalties for HIT developers and exchange networks, not to exceed \$1 million per violation. The penalties for healthcare providers are limited to the payment disincentives in current law, such as the Medicare and Medicaid EHR Incentive Programs. The OIG may refer cases to the Federal Trade Commission or the HHS Office of Civil Rights (OCR), as appropriate. The National Coordinator must also, with OCR, issue guidance on common legal, governance, and security barriers that prevent trusted exchange, and establish a process for the public to submit complaints about information blocking and barriers to interoperability.</p>

<p>Section 4005; Leveraging Electronic Health Records To Improve Patient Care.</p>	<p>Requires that, as a condition of certification, EHRs must be capable of transmitting to, and receiving and accepting data from, registries, including clinician-led clinical data registries, in accordance with standards recognized by the Office of the National Coordinator for HIT.</p> <p>Adds HIT developers as “providers” who participate in the network of patient safety organizations.</p>
<p>Section 4006; Empowering Patients And Improving Patient Access To Their Electronic Health Information.</p>	<p>Directs the Secretary to use existing authorities to encourage partnerships between health information exchange networks and health care providers, health plans, and other entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.</p>
<p>Section 4007. GAO Study On Patient Matching.</p>	<p>Requires that GAO conduct a study of the current HIT policy landscape and activities of the National Coordinator for HIT and make recommendations to Congress, within two years of enactment, on ways to improve patient matching across the healthcare system, such as creating common minimum data sets for the exchange of patient data, to reduce duplication of data while continuing to protect patient privacy and security.</p>
<p>Section 4008; GAO Study On Patient Access To Health Information.</p>	<p>Requires that GAO conduct a study and report to Congress within 18 months of enactment to review patients’ access to their own PHI, including describing practices of charging patients, third parties, and health care providers, for EHR data, examples of the amounts and types of fees charged to individuals for record requests, instances in which third parties may request PHI through patients’ individual right of access to circumvent appropriate fees, and policies that enable providers to charge appropriate fees to third parties while providing patients access at low or no cost.</p>
<p>Section 4009; <b>Improving Medicare Local Coverage Determinations (Lcds).</b></p>	<p>This section, which requires the Secretary to establish additional transparency rules for Medicare Administrative Contractors (MACs) with respect to LCDs, is identical to the provision passed by the House in July 2015. While early drafts of the provision required a notice-and-comment process and explicitly required MACs to follow it when proposing to adopt an LCD from another MAC jurisdiction, this provision is unclear as to whether notice-and-comment is required. It requires MACs to post on their websites, at least 45 days before a new or revised LCD takes effect, (1) the LCD, (2) “[w]here and when the proposed [LCD] was first made public”; (3) “[l]inks to the proposed [LCD] and a response to comments submitted to the [MAC]” concerning the proposed LCD; and (4) a summary of the evidence the MAC considered in developing the LCD. This language suggests that the MAC was required to post the proposed LCD and seek comments on it. But at least arguably, this language could instead be read as only requiring that (at least 45 days before the LCD takes effect) the MAC must post information on “where and when the proposed [LCD] was first made public” if the proposed LCD was previously made public (e.g. was proposed in another MAC jurisdiction), and as permitting a MAC to post “links to the proposed [LCD]” at a point when comments would be futile (after the final LCD has been adopted and will soon take effect). The bill does not explicitly state that MACs must post a proposed LCD and consider comments on the proposed LCD before adopting a final LCD, if that was intended. Moreover, while the Medicare Program Integrity Manual currently requires that MACs follow a basic notice-and-comment process in developing LCDs, this requirement could be eliminated via a Manual change unless established in statute or regulation. The provision does not appear to restrict the current Centers for Medicare &amp; Medicaid Services (CMS) practice of creating de facto national coverage policies by encouraging the adoption of the same LCD by most or all of the MACs, bypassing the National Coverage Determination (NCD) process.</p>
<p>Section 4010; <b>Medicare Pharmaceutical And Technology Ombudsman.</b></p>	<p>Identical to H.R. 6, as passed by the House in July 2015, this section requires the Secretary, within one year of enactment, to create a position for a pharmaceutical and technology ombudsman at CMS to address requests from pharmaceutical, biotechnology, medical device, or diagnostic product manufacturers with respect to Medicare coverage, coding, or payment.</p>



<p>Section 4011; Medicare Site-Of-Service Price Transparency.</p>	<p>Requires the Secretary to post information, starting in 2018<sup>31</sup>, on the estimated costs, to Medicare and to its beneficiaries, for items and services provided in hospital outpatient departments (HOPDs) compared to ambulatory surgical centers (ASCs). Because Medicare pays lower amounts in ASCs for some services that are also delivered in HOPDs, acquisition of ASCs by hospitals and conversion to HOPDs increases Medicare spending. This provision aims to drive volume to ASCs (paid at the lower rate) rather than to HOPDs by making beneficiaries aware of the differences in cost. Importantly, the legislation permits the Secretary to display the estimated out-of-pocket cost for a beneficiary with no supplemental insurance coverage for Part B cost-sharing — even though the vast majority of beneficiaries have supplemental insurance that pays some or all of that amount.</p>
<p>Section 4012; <b>Telehealth Services In Medicare.</b></p>	<p>As in the nearly-identical provision in H.R. 6<sup>32</sup>, § 4012 does not expand telehealth coverage.<sup>33</sup> The new provision simply provides for CMS and MedPAC to submit certain information on telehealth to Congress (which Congress presumably would use to evaluate the need for future legislation expanding Medicare coverage of telehealth), and expresses the sense of Congress on certain issues relevant to telehealth.</p> <p>CMS would be required to provide information to Congress on the beneficiary populations whose care could be improved the most by expanding telehealth, on initiatives by the Center for Medicare and Medicaid Innovation related to telehealth, on the high-volume procedures or diagnoses for which telehealth services might be suitable, and on barriers (under the current legal framework) that might prevent expanding telehealth coverage further. MedPAC would be required to provide information on telehealth services that could not currently be covered under fee-for-service Medicare for which MedPAC recommends coverage, and on barriers to telehealth under existing law and “solutions to address such barriers.”</p> <p>The sense of Congress language provides that: (1) States should cooperate to create common licensure requirements for providers furnishing telehealth services, to facilitate multi-state practices; (2) “eligible originating sites” under Medicare should be expanded; and (3) any expansion of Medicare telehealth coverage should recognize that telehealth services must be safe, effective, quality services that meet the ordinary standards for Medicare coverage and payment and are furnished by “clinically appropriate means.”</p>
<p><b>Title V — Savings</b></p>	
<p>Section 5001; Savings in the Medicare Improvement Fund</p>	<p>Increases the amount in the Medicare Improvement Fund from \$140 million to \$270 million for fiscal years 2021 and beyond.</p>
<p>Section 5002; Medicaid Reimbursement to States for Durable Medical Equipment</p>	<p>Requires that Medicaid reimbursement to states for durable medical equipment (DME) to be limited to Medicare rates effective January 1, 2018. Under prior law, the effective date was January 1, 2019. According to CBO, this provision will save an estimated \$2.5 billion over 10 years.</p>
<p>Section 5003; Penalties for Violations of Grants, Contracts, and Other Agreements</p>	<p>Clarifies and expands HHS OIG authority to use civil monetary penalties in cases of proven HHS grant or contract fraud.</p>
<p>Section 5004; Reducing Overpayments of Infusion Drugs</p>	<p>Effective January 1, 2017, changes the Medicare Part B payment for DME-infused drugs from 95 percent of the October 1, 2003 Average Wholesale Price to the 106 percent of the Average Sales Price, which is the rate paid for most Part B prescription drugs. This provision was influenced by a HHS-OIG report, which found that the Medicare payment rates for DME infusion drugs exceeded ASP by 54 to 122 percent annually over 2005 to 2011. According to the Congressional Budget Office (CBO), this provision is estimated to save \$660 million over 10 years.</p>
<p>Section 5005; Increasing Oversight of Termination of Medicaid Providers</p>	<p>Requires States to report to the Secretary information about a provider terminated from Medicaid and the Children’s Health Insurance Program (CHIP), including the reason for the termination, within 30 days of the effective date of the termination. The Secretary would be required to review such termination notifications, and if the Secretary determines that it is appropriate, then certain information about the termination would be made available on a Termination Notification Database. Terminated providers will also be excluded from Medicaid managed care organizations and CHIP, and Medicaid payment for services of such providers would be precluded.</p>



Section 5006; Requiring Publication of Fee-for-service Provider Directory	Requires States offering Medicaid on a fee-for-service basis or through a primary care case-management system, to publish and update annually on the State agency’s website a directory of physicians and providers who are enrolled with the State agency and who have received payment under the State plan in the prior 12 months.
Section 5008; Eliminating Federal Financial Participation with Respect to Expenditures under Medicaid for Agents Used for Cosmetic Purposes or Hair Growth	Prohibits Medicaid payment for drugs when used for cosmetic purposes or hair growth, except where “medically necessary.”
Section 5009; Amendment to the Prevention and Public Health Fund	Rescinds \$3.5 billion, spread over several years, from the Affordable Care Act’s Prevention and Public Health Fund.
Section 5011; Rescission of Portion of ACA Territory Funding	Rescinds \$464 million in unobligated funding for the territories under the Affordable Care Act.
Section 5012; Medicare Coverage of Home Infusion Therapy	This section is a modified version of the Medicare Home Infusion Site of Care Act (S. 275/H.R. 605). It provides a pathway for payment of “home infusion therapy” items and services (e.g., professional and nursing services, training and education, remote monitoring) that are furnished by a qualified home infusion therapy supplier in an individual’s home. The items and services would be payable under Part B as a single payment to the qualified home infusion therapy supplier, based on each infusion drug administration calendar day in an individual’s home. CBO estimates that this provision will save \$372 million over 10 years.
<b>Title VI — Strengthening Leadership and Accountability</b>	
<b>Subtitle A — Leadership</b>	
Section 6001; Assistant Secretary for Mental Health and Substance Use	Establishes an Assistant Secretary for Mental Health and Substance Use, referred to as the Assistant Secretary to head the Substance Abuse and Mental Health Services Administration (SAMHSA). The Assistant Secretary with the approval of the Secretary may also appoint a Deputy Assistant Secretary.
Section 6002; Strengthening the Leadership of the Substance Abuse and Mental Health Services Administration	<p>Requires the Assistant Secretary to develop a system with the Director of NIH to distribute relevant research findings to improve the delivery and effectiveness of prevention, treatment, and recovery support services.</p> <p>Directs the Assistant Secretary to work with relevant agencies of HHS on integrating mental health promotion and substance use disorder prevention, as well as mental and substance use disorders treatment services with general health promotion and treatment services. There should also be maintenance of a clearinghouse for substance use disorder information to ensure its dissemination to stakeholders, States, and the general public.</p> <p>Requires consultation and collaboration with stakeholders to improve community-based and other mental health services for members of the Armed Forces, veterans, family members of such members and veterans, homeless individuals, and those who have been arrested or incarcerated..</p> <p>Directs the Assistant Secretary to set standards for grant programs for mental and substance use disorders services and prevention programs after providing an opportunity for public input.</p>
Section 6003; Chief Medical Officer	Directs the Assistant Secretary to appoint a Chief Medical Officer (CMO) within SAMHSA to serve as a liaison between the Administration and providers of mental health and substance use disorders treatment and services. Directs the SMO to coordinate, organize, and evaluate programs to promote evidence-based best practices. The CMO must have academic qualifications and experience working in the related fields.

<p>Section 6004; Improving the Quality of Behavioral Health Programs</p>	<p>Directs the Assistant Secretary to maintain the Center for Behavioral Health Statistics and Quality (CBHSQ) at SAMHSA. The Center is to be headed by a Director appointed by the Secretary with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields. The Director is required to coordinate the Administration’s integrated data strategy; provide statistical and analytical support for activities of the Administration; recommend performance metrics to evaluate activities; and coordinate with Federal officials to improve the quality of services provided by the Administration.</p> <p>Includes slight technical changes to the collection of data on substance abuse.</p>
<p>Section 6005; Strategic Plan</p>	<p>Requires the Assistant Secretary to develop a strategic plan no later than September 20, 2018 and every four years after, that would identify strategic goals, priorities, and measurable objectives for mental and substance use disorder activities and programs carried out by SAMHSA, including evidence-based programs. The plan should also identify ways to improve the quality of relevant services for individuals; collaborate with HRSA to improve the mental health workforce; and disseminate evidence-based best practices surrounding delivery of mental health services. The Assistant Secretary is required to submit the strategic plan to Congress and post the plan on SAMHSA’s website.</p>
<p>Section 6006; Biennial Report Concerning Activities and Progress</p>	<p>Requires the Assistant Secretary to submit a biennial report to Congress which contains a description of progress towards strategic priorities, goals, and objectives in the strategic plan; the extent to which programs and activities meet goals and performance measures; and how gaps in mental and substance use disorders services and are being addressed to improve outcomes. The report should also contain a description of how the Administration coordinates with other federal departments and stakeholders for mental and substance use disorder activities and the implementation of research findings in improved programs.</p> <p>Provides that the report should include recommendations to improve programs within the Administration.</p>
<p>Section 6007; Authorities of the Centers for Mental Health Services (CMHS), Substance Abuse Prevention (CSAP), and Substance Abuse Treatment (CSAT)</p>	<p>Requires the Director of CMHS to collaborate with the Director and Chief Medical Officer of the National Institute for Mental Health (NIMH) to ensure programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices.</p> <p>Makes other slight technical changes to the duties of the Director of the Center.</p> <p>Makes additions to the duties of the Director of CSAP, some of which include: sponsorship of regional workshops on the prevention of drug and alcohol abuse through the reduction of risk and the promotion of resiliency; collaboration with Directors of other relevant Federal institutes to promote the study of substance abuse prevention and implementation of research findings; and the development and dissemination of educational materials to prevent the transmission of communicable diseases by individuals at high risk for substance abuse.</p> <p>Makes technical changes to the duties performed by the Director of CSAT including among others: ensuring consistent documentation of application criteria when awarding and overseeing grants, and working with relevant entities to promote the expansion of support services and systems of care aimed at recovery.</p>
<p>Section 6008; Advisory Councils</p>	<p>Adds the Directors of NIMH, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse to the list of <i>ex officio</i> members of the SAMSHA, Centers for Substance Abuse Treatment, Substance Abuse Prevention, and Mental Health Services advisory councils that advise, consult with, and make recommendations to Administration officials. At least half of the members of the advisory council must have relevant advanced academic degrees and experience in providing substance use disorder services or the development and implementation of programs to prevent substance misuse.</p>

Section 6009; Peer Review	This section includes an additional requirement that more than half of members of any peer review group that are reviewing a grant, cooperative agreement, or contract related to mental illness treatment must be licensed and experienced professionals in the prevention, diagnosis, treatment, or recovery of mental illness and have a relevant advanced academic degree. In addition, the peer review groups should include broad geographic representation, as stated under this section.
<b>Subtitle B — Oversight and Accountability</b>	
Section 6021; Improving Oversight of Mental and Substance Use Disorders Programs Through the Assistant Secretary for Planning and Evaluation	Requires the Assistant Secretary for Planning and Evaluation (ASPE) to ensure efficient and effective planning and evaluations of mental health and substance use disorder prevention and treatment programs. Within 180 days of enactment, the ASPE is required to develop a strategy for conducting ongoing evaluations that identify priority programs to be evaluated. This section states the strategy should include a plan for evaluating programs related to prevention, intervention, treatment, and recovery support services; the reduction of homelessness; and public health and health services. The ASPE should consult with other appropriate Administration officials and provide recommendations on improving the quality of prevention and treatment programs, which should be included in the biennial report described in section 6003.
Section 6022; Reporting for Protection and Advocacy Organizations	Makes publicly available the annual report describing the activities, accomplishments, and expenditures of systems to protect and advocate for the rights of individuals with mental illness. This section also requires as part of the report, a detailed account for each system stating how funds are spent and arranged by whether funds were received from the Federal Government, State government, local government, or a private entity.
Section 6023; GAO Study	Requires GAO, the , Secretary, and the Assistant Secretary for Mental Health and Substance Abuse to conduct an independent evaluation and submit a report to Congress on programs funded by allotments under Title I of the Protection and Advocacy for Individuals with Mental Illness Act within 18 months of enactment. The report should include a review of the relevant programs and their compliance with statutory and regulatory responsibilities including relating to family engagement; the grievance procedure for clients or prospective clients of the system; investigation of alleged abuse and neglect; availability of adequate medical and behavioral health treatment; denial of rights; and grantees' compliance with the Federal prohibition on lobbying.
<b>Subtitle C — Interdepartmental Serious Mental Illness Coordinating Committee</b>	
Section 6031; Inter-Departmental Serious Mental Illness Coordinating Committee	<p>Requires the establishment of a committee known as the Interdepartmental Serious Mental Illness Coordinating Committee, within three months of enactment. The Committee must meet at least two times per year, and should submit to Congress and other relevant agencies a report which summarizes advances in serious mental illness (SMI) and serious emotional disturbance research related to the prevention, diagnosis, intervention, treatment, and recovery of such conditions. In addition, the report should include an evaluation of the effect Federal programs have on public health and public health outcomes such as rates of suicide, overdoses, hospitalizations; quality of services; and other criteria determined by the Secretary. The report should make recommendations for actions agencies can take to better coordinate the administration of mental health services.</p> <p>Directs that the Committee be composed of Federal representatives and no less than fourteen non-Federal public members, with the Secretary serving as the Chair of the Committee. The non-Federal members of the Committee are required to have relevant experience in the research or advocacy, or be in a relevant health profession or service. The Committee sunsets six years after establishment.</p>

<p><b>Title VII — Ensuring Mental and Substance Use Disorders Prevention, Treatment, and Recovery Programs Keep Pace with Science and Technology</b></p>	
<p>Section 7001; Encouraging Innovation and Evidence-Based Programs</p>	<p>Establishes a National Mental Health and Substance Use Policy Laboratory (NMHSUPL) within SAMHSA to continue to operate authorities and activities that were in effect for the Office of Policy, Planning, and Innovation.</p> <p>Directs the Laboratory to identify, coordinate, and facilitate the implementation of policy changes with likely effects on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services; and to work with the Center for Behavioral Health Statistics and Quality to collect appropriate information from grantees to evaluate and disseminate information on evidence-based practices and identify and coordinate policies and programs related to mental and substance use disorders.</p> <p>The Laboratory must periodically review programs and activities operated by the Administration and formulate recommendations for improving programs. The Assistant Secretary in coordination with the Laboratory may award grants to stakeholders in order to develop evidence-based interventions.</p> <p>\$7 million is authorized to be appropriated for the program.</p>
<p>Section 7002; Promoting Access to Information on Evidence-Based Programs and Practices</p>	<p>Directs the Assistant Secretary to improve access to reliable and valid information on evidence-based programs and practices for states, local communities, nonprofit entities, and other stakeholders by posting the information online.</p> <p>Provides that the Assistant Secretary may establish a period for submission of applications for evidence-based programs and practices and publish a notice of such application in the Federal Register. The metrics used to evaluate applications must be made publicly available.</p>
<p>Section 7003; Priority Mental Health Needs of Regional and National Significance</p>	<p>Updates the Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program by adding the Secretary should address the priority mental health needs of regional and national significance through the provision or assistance for systems change grants including statewide family network grants and client-oriented and consumer run self-help activities. Authorizes \$394.5 million to be appropriated for fiscal years 2018 through 2022 to carry out this program, an increased amount over current law.</p>
<p>Section 7004; Substance Use Disorder Treatment Needs of Regional and National Significance</p>	<p>Codifies the Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program and makes slight changes, directing the Secretary to address the priority substance abuse treatment needs of regional and national significance through targeted capacity response programs that permit stakeholders to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions.</p> <p>Authorizes \$333.8 million to be appropriated for fiscal years 2018 through 2022 (an increase over current law).</p>
<p>Section 7005; Priority Substance Use Disorder Prevention Needs of Regional and National Significance</p>	<p>Makes slight changes to the Priority Mental Health Needs of Regional and National Significance Program by directing the Secretary to address priority substance abuse treatment needs of regional and national significance through targeted capacity response programs including such programs that focus on emerging drug abuse issues.</p> <p>Authorizes appropriations of \$211.1 million for fiscal years 2018 through 2022 (a decrease from current law).</p>

**Title VIII — Supporting State Prevention Activities and Responses to Mental Health and Substance Use Disorder Needs**

<p>Section 8001; Community Mental Health Services Block Grant</p>	<p>Allows states to spend Community Mental Health Services (CMHS) block grant funds for the added purpose of providing community mental health services for adults with SMI and children with a serious emotional disturbance. Requires the Secretary to submit a plan every two years at the minimum with a description of the State’s system of care. The plan should identify the single State agency that will be responsible for the administration of the program under the grant; provide for an organized community-based system of care for individuals with mental illness; and include a description of the ways in which the State and local entities will coordinate services to maximize services and programs to produce the best outcomes. In addition, the plan must include a description of how the State promotes evidence-based practices, case mismanagement services; activities that engage adults with serious mental illness; and the purpose the State uses the block grant funds. In addition, States are directed to spend no less than 10 percent of the total amount of funds received each fiscal year to support evidence-based programs that address the needs of these individuals, this section states.</p> <p>Authorizes \$532.5 million to be appropriated for each FY 2018 through 2022 to carry out the program, an increased amount than allotted under current law.</p>
<p>Section 8002; Substance Abuse Prevention and Treatment Block Grant</p>	<p>Makes technical changes to State grants for treatment services for persons who inject drugs.</p> <p>Modifies a funding agreement for grants to States, requiring the State to ensure the prevention, treatment, and recovery personnel operating in the State’s substance abuse systems have an opportunity to receive additional training.</p> <p>Repeals the requirement that a State submit an assessment of needs. In addition, noncompliance by a State is modified in order to allow the State to negotiate an agreement with the Secretary to prevent a reduction in funding allotments.</p> <p>When applying for a grant, a State must submit a plan that includes a description of the State’s system of care to promote evidence-based practices; train substance abuse and mental disorder workforce; integrate services with primary health care; statewide prevention efforts; and number of individuals in treatment across the state.</p> <p>Decreases funding for the grant programs , authorizing appropriations of \$1.8 billion for fiscal years 2018 through 2022.</p>
<p>Section 8003; Additional Provisions Related to the Block Grants</p>	<p>Allows the Secretary to grant an extension or waive application deadlines or compliance with other requirements on a State by State basis for mental health and substance abuse block grants in the case of a public health emergency. In addition, the Secretary may permit states to submit a joint application.</p>
<p>Section 8004; Study of Distribution of Funds under the Block Grants</p>	<p>Requires the Secretary to conduct a study on the formulas used for the distribution of funds for mental health and substance abuse block grants and to determine if the allotments are being distributed to states and territories according to need. The Secretary must recommend changes to grant allotments and submit a report to Congress with findings and recommendations from the study within two years of enactment.</p>

**Title IX — Promoting Access to Mental Health and Substance Use Disorder Care**

**Subtitle A — Helping Individuals and Families**

<p>Section 9001; Grants for Treatment and Recovery for Homeless Individuals</p>	<p>Makes slight technical changes to terminology in provisions of the law related to grants for the treatment and recovery for homeless individuals.</p> <p>Authorizes appropriations of \$41.3 million for each FY 2018 through 2022, a decrease from current law.</p>
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<p>Section 9002; Grants for Jail Diversion Programs</p>	<p>Changes application requirements for grants for jail diversion programs, as applicants must ensure that community-based mental health services will be available for the individuals who are diverted from the criminal justice system, and that such services are evidence-based not based on best known practices.</p> <p>The Secretary must give special consideration to entities that propose to use grant funding to support jail diversion services for veterans.</p> <p>Authorizes appropriations of \$4.3 million for fiscal years 2018 through 2022, a decrease from current law.</p>
<p>Section 9003; Promoting Integration of Primary and Behavioral Health Care</p>	<p>Changes the definitions of eligible entity, integrated care, and special population for integration incentive grants and cooperative agreements.</p> <p>Allows the Secretary to award grants and cooperative agreements to eligible entities to support the improvement of integrated care for primary and behavioral health care to promote full integration and coordination in clinical practices between primary and behavioral health care; support the improvement of integrated care models; and promote integrated care services related to screening, diagnosis, prevention, and treatment of disorders. An eligible entity may receive \$2 million for a year through a grant or cooperative agreement, however, this amount may be adjusted depending on the number of applications and eligible entities that receive funding prior to the enactment.</p> <p>Funding sunsets after five years.</p> <p>An entity that receives a grant must submit an annual report to the Secretary.</p> <p>Authorizes \$51.878 million to be appropriated for fiscal years 2018 through 2022 for the program.</p>
<p>Section 9004; Projects for Assistance in Transition from Homelessness</p>	<p>Makes slight technical changes and reauthorizes grants for states to provide services to homeless individuals who are suffering from serious mental illness, or co-occurring serious mental illness and substance use disorders.</p> <p>Authorizes \$64.6 million to be appropriated for fiscal years 2018 through 2022 ( less than current law).</p> <p>Within two years of enactment, the Assistant Secretary must conduct a study evaluating the formula used to make allotments to States and submit the results of the findings in a report to Congress.</p>
<p>Section 9005; National Suicide Prevention Lifeline Program</p>	<p>Requires the Secretary to continue the National Suicide Prevention Lifeline program. In maintaining the program, the Secretary should coordinate a network of crisis centers; maintain a suicide prevention hotline to link callers to resources; and consult with the Secretary of VA to ensure veterans have access to special services.</p> <p>Authorizes \$7.196 million to be appropriated for fiscal years 2018 through 2022.</p>
<p>Section 9006; Connecting Individuals and Families with Care</p>	<p>Requires the Assistant Secretary to maintain the National Treatment Referral Routing Service to assist individuals and families in locating mental health and substance use disorder treatment providers. This program would include a nationwide phone number that provides information on local health care providers to individuals and an internet website to search for providers and organizations.</p>



<p>Section 9007; Strengthening Community Crisis Response Systems</p>	<p>Authorizes the Secretary to award competitive grants to state and local governments and Indian tribes and tribal organizations to enhance community-based crisis response systems; or to develop, maintain, or enhance a database of beds at facilities with mental illness or substance abuse disorders. The application must include a plan for promoting integration between public and private entities engaged in crisis response; develop memoranda of understanding with the entities and models for minimizing hospital readmissions; and address gaps in community resources for crisis intervention and prevention. In addition, the application should include a plan for developing, maintaining, or enhancing a real-time internet-based database with information about beds in inpatient facilities. Grantees must submit to the Secretary a report evaluating the effects of such grant on local crisis response services; improved functional outcomes; and follow up care.</p> <p>Authorizes appropriations for the program amounting to \$12.5 million for FY 2018 through 2022.</p>
<p>Section 9008; Garrett Lee Smith Memorial Act Reauthorization</p>	<p>Requires the Assistant Secretary to establish a center to provide appropriate information, training, and technical assistance to key stakeholders regarding the prevention of suicide among all ages, particularly those at high risk of suicide.</p> <p>Outlines the responsibilities of the center and broadens the suicide intervention and prevention strategies for all ages rather than simply being targeted at youth.</p> <p>Authorizes \$5.9 million in appropriations for the program for fiscal years 2018 through 2022.</p>
<p>Section 9009; Adult Suicide Prevention</p>	<p>Establishes suicide prevention and intervention programs grants for individuals the age of 25 or older. The purpose of the grants are to raise awareness of suicide, establish referral processes, and improve care and outcomes for individuals who are at risk of suicide. Eligible entities are defined under this section and the funds must be used to implement programs that screen for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide; implement evidence-based practices; and raise awareness and reduce the stigma of suicide. The Secretary is charged with evaluating the activities funded by the grants and provide training and assistance to grant recipients. Adult suicide prevention grants sunset in five years.</p> <p>Authorizes \$30 million to be appropriated for fiscal years 2018 through 2022.</p>
<p>Section 9010; Mental Health Awareness Training Grants</p>	<p>Adds to the list of entities that may be awarded mental health awareness training grants to include veterans, law enforcement, and other categories of individuals determined by the Secretary. In addition, this section changes the use of these grants to be for evidence-based programs that provide training and education on recognizing the signs and symptoms of mental illness, resources available in the community, and how to safely de-escalate a crisis situation.</p> <p>Authorizes \$14.7 million to be appropriated for each of fiscal years 2018 through 2022.</p>
<p>Section 9011; Sense of Congress on American Indians and Alaska Native youth within suicide prevention program</p>	<p>Directs the Secretary to prioritize suicide prevention programs and activities for populations with disproportionately high rates of suicide such as American Indians and Alaska Natives.</p>
<p>Section 9012; Evidence-Based Practices for Older Adults</p>	<p>Requires the Secretary to disseminate information and provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance abuse disorders among geriatric populations.</p>
<p>Section 9013; National Violent Death Reporting System</p>	<p>Encourages the Director of CDC to improve the existing National Violent Death Reporting System through the inclusion of additional states.</p>
<p>Section 9014; Assisted Outpatient Treatment</p>	<p>This section extends the grant program for Assisted Outpatient Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA) through fiscal year 2022 as opposed to fiscal year 2018, as provided under current law.</p> <p>Increases the amount of funding authorized to be appropriated for the program through fiscal year 2022.</p>

<p>Section 9015; Assertive Community Treatment</p>	<p>Establishes a grant program for eligible entities that establish, maintain, or expand assertive community treatment programs for adults with SMI. Special consideration may be given to the potential of the applicant’s program to reduce hospitalizations, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.</p> <p>Directs the Assistant Secretary to submit a report on the grant program to Congress by fiscal year 2021 which would include an evaluation of cost savings, rates of involvement with the criminal justice system and homelessness of patients; and patient and family satisfaction. The report must also provide appropriate information, training, and technical assistance to grant recipients to assist programs.</p> <p>Authorizes \$5 million to be appropriated for fiscal years 2018 through 2022.</p>
<p>Section 9016; Sober Truth on Preventing Underage Drinking Reauthorization</p>	<p>Reauthorizes appropriations for each of fiscal years 20018 through 2022 for the interagency coordinating committee on the prevention of underage drinking; a national media campaign to prevent underage drinking; community-based coalition enhancement grants to prevent underage drinking; and additional research on underage drinking.</p> <p>Also establishes grants for pediatric health care providers to reduce underage drinking through means such as offering interventions to discourage alcohol use; education for parents about the dangers, diagnosis, and treatment of alcohol disorders; and patient referrals to appropriate care.</p>
<p>Section 9017; Center and Program Repeals</p>	<p>Repeals the methamphetamine and amphetamine treatment initiative; grants to eligible entities to provide early intervention substance abuse services for children and adolescents; and grants for prevention, treatment, and rehabilitation model projects for high risk youth.</p> <p>Makes technical changes to grants for services for children of substance abusers and repeals grants for services for affected families and removes restrictions on grants for services for children of substance abusersd.</p> <p>Eliminates grants for establishment of national centers of excellence for depression; for the provision of aftercare services for youth offenders who have been discharged from facilities in the juvenile or criminal justice system and have serious emotional disturbances or are at risk of developing such disturbances; and for the provision of integrated child welfare and mental health services for children and adolescents under 19 years of age in the child welfare system or at risk for becoming part of the system.</p>
<p><b>Subtitle B — Strengthening the Health Care Workforce</b></p>	
<p>Section 9021; Mental and Behavioral Health Education Training Grants</p>	<p>Permits the Secretary to award grants to eligible institutions of higher education to support the education of students in behavioral health-related fields, and encourages recruiting and placement of such students in areas with high need and high demand populations. Directs the Secretary to prioritize programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings in relevant fields.</p> <p>Requires the Secretary to submit a biennial report to Congress on the assessment of the effectiveness of the grants.</p> <p>Authorizes \$50 million to be appropriated for the grants for each of fiscal years 2018 through 2022.</p>

<p>Section 9022; Strengthening the Mental and Substance Use Disorders Workforce</p>	<p>Authorizes the Secretary to establish a demonstration program within the Health Resources and Service Administration (HRSA) to award grants to support training for healthcare workers to practice psychiatry and addiction medicine in underserved community-based settings that integrate mental and substance abuse disorders treatment and services with primary care. Grants will also be awarded to entities that establish, maintain, or improve academic units or programs that provide training on the diagnosis and treatment of mental and substance use disorders, or develop evidence-based practices for the design of units or programs including curriculum content standards. Grant money must be used for the training of residents and fellows, and other providers, and recipients must enter into a partnership with organizations to carry out activities. A list of eligibility criteria and guidelines for priority review are also included in this provision.</p> <p>Grants are awarded for a minimum of five years.</p> <p>Each grant recipient must submit data within 90 days after completion of the first year of the training program and each subsequent year the program is in effect, and the Secretary must submit an analytical report to Congress within one year of receipt of this data.</p> <p>Authorizes \$10 million for fiscal years 2018 through 2022 to be appropriated for the program.</p>
<p>Section 9023; Clarification on Current Eligibility for Loan Repayment Programs</p>	<p>Directs the Administrator of HRSA to clarify the current eligibility of child and adolescent psychiatrists for the National Health Service Corps (NHSC) Loan Repayment Program.</p>
<p>Section 9024; Minority Fellowship Program</p>	<p>Directs the Secretary to maintain a program titled the Minority Fellowship Program, under which the Secretary will award fellowships to increase the knowledge of practitioners on the prevention, treatment, and recovery of individuals who are from racial and ethnic minority populations with mental and substance use disorders. In addition, this program aims to improve the quality of services delivered to racial and ethnic minority populations and increase the number of culturally competent professionals who deliver these services.</p> <p>Authorizes \$12.7 million to be appropriated for fiscal years 2018 through 2022 for the program.</p>
<p>Section 9025; Liability Protections for Health Professional Volunteers at Community Health Centers</p>	<p>Provides medical liability protections for volunteers at Community Health Centers by deeming a health professional volunteer an employee of the Public Health Service for a year beginning when a transfer was made, and considers a health care practitioner a health professional volunteer.</p> <p>Before May 1 of each fiscal year, the Attorney General in consultation with the Secretary must submit to Congress a report on the estimated number of claims by professional volunteers to be paid in the next year and include the number of claims filed and paid the previous year.</p> <p>The provision takes effect October 1, 2017 and sunsets after five years.</p>
<p>Section 9026; Reports</p>	<p>Requires SAMHSA and HRSA to conduct a study and post on the HHS website a report on the adult and pediatric mental and substance use disorder workforce to inform Federal, State, and local efforts to enhance the workforce. The report must contain national and state-level projections of supply and demand of workforce by profession; an assessment of workforce capacity and strengths and weaknesses; and information on trends within the workforce over the next five years.</p> <p>Requires GAO to conduct a study and submit a report to Congress within two years on peer-support specialist programs in up to ten states that receive funding from SAMHSA to examine and identify best practices related to training and credential requirements for peer-support specialist programs.</p>

**Subtitle C — Mental Health on Campus Involvement**

<p>Section 9031; Mental Health and Substance Use Disorder Services on Campus</p>	<p>Broadens the criteria for which an institute of higher education may receive a grant for mental and behavioral health services on campuses to include: the prevention of mental and substance use disorders, reduction of associated stigma, and improvement of the identification and treatment for students at risk. An institute of higher education eligible for this grant could provide educational means to increase awareness of mental and substance use disorders; operation of hotlines; preparation of informational materials; notification to students about services; administration of voluntary screenings and assessments; training of students, faculty, and staff to respond to students in need; and the creation of a network to link such institutions with providers. In addition, the institution may provide prevention and treatment services to students through telehealth; conduct research through counseling or the health center; support student groups; employ trained staff; and develop and support evidence-based best practices. Grantees must provide an outline of the objectives of the program to be carried out under the grant and a description of the policies and procedures of the institution related to applicable laws.</p> <p>Authorizes \$7 million to be appropriated for fiscal years 2018 through 2022, an increase of the amount allotted under current law.</p>
<p>Section 9032; Interagency Working Group on College Mental Health</p>	<p>Requires the Secretary to establish a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education. Under this section, the Task Force is to be comprised of a representative from each Federal agency that has jurisdiction over or is affected by mental health and education policies and projects. The Task Force is charged with coordinating a national effort to discuss and evaluate evidence and knowledge on mental and behavioral health services available to institutions of higher education; determine the range of actions to improve such services on college campuses; examine and address the needs of students; survey Federal agencies to determine which policies are most effective; establish goals across agencies, develop a strategy; and make recommendations. The Task Force is directed to consult national organizations with expertise in mental and behavioral health and mental health professionals on campuses of higher education.</p> <p>Authorizes \$1 million to be appropriated for fiscal years 2018 through 2022.</p>
<p>Section 9033; Mental and Behavioral Health Outreach and Education on College Campuses</p>	<p>Requires the Secretary, in through CDC, to convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign to increase access to and reduce the stigma associated with mental health services on college campuses. The campaign must be designed to improve the understanding of mental health; encourage help-seeking behaviors; make the connection between mental and behavioral health and academic success; and assist the general public in identifying early warning signs and reduce the stigma of mental illness. The working group is charged with developing a plan that targets promotional and educational efforts at students; implementation of research-based public health messages and activities; supports local efforts to reduce stigma; and develops and proposes the implementation of social marketing campaigns targeted at students.</p> <p>Authorizes t \$1 million to be appropriated for the program for fiscal years 2018 through 2022.</p>

**Title X — Strengthening Mental and Substance Use Disorder Care for Children and Adolescents**

<p>Section 10001; Programs for Children with Serious Emotional Disturbances</p>	<p>Directs the Secretary to make grants to public entities to provide comprehensive community mental health services to children with a serious emotional disturbance which may also include efforts to identify and serve children at risk.</p> <p>Changes current law to provide an individual with access to systems of comprehensive care through the age of 21, as opposed to limiting access to only those people <i>under</i> the age of 21 under current law. A participating public entity must annually submit a report to the Secretary and the State involved on the activities carried out using the grant.</p> <p>Directs the Secretary to provide technical assistance to a public entity if requested, regardless of whether such entity is receiving a grant.</p> <p>Authorizes \$119 million to be appropriated for fiscal years 2018 through 2022 (an increase over current law).</p>
<p>Section 10002; Increasing Access to Pediatric Mental Health Care</p>	<p>Authorizes HRSA, in coordination with other relevant Federal agencies, to award grants to promote behavioral health integration in pediatric primary care by supporting the development or improvement of statewide or regional pediatric mental health care telehealth access programs. A pediatric mental healthcare telehealth access program must be a statewide or regional network of pediatric mental health teams and support. A pediatric mental health team consists of at least one case coordinator, child and adolescent psychiatrist, and licensed clinical mental health professional. The program must also assess critical behavioral consultation needs among pediatric providers; develop a database to support practices; provide telephone or telehealth consultations when requested; conduct training and provide information to pediatric providers; assist with referrals; and establish ways to monitor increased access to services for children. Entities must submit an application to the Secretary and an evaluation of activities carried out with the funds received under the grant.</p> <p>Authorizes \$9 million to be appropriated for fiscal years 2018 through 2022 for the program, but requires grantees to match at least 20 percent of the Federal funds provided in the grant.</p>
<p>Section 10003; Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents</p>	<p>Directs the Secretary to award grants, contracts, or cooperative agreements to public and private nonprofit entities to provide early identification services for children and adolescents at risk of substance abuse disorders, and children with co-occurring mental illness and substance use disorders. Grants would fund programs that provide assistance to pregnant women and parenting women with substance use disorders and connect them to community resources.</p> <p>Applicants for the grants will be given priority if they apply evidence-based and cost-effective methods and coordinate treatment services with educational, juvenile justice, child welfare, substance abuse, and mental health agencies. Priority will no longer be given to applicants who propose to address the relationship between substance abuse and violence, as provided under current law.</p> <p>Authorizes \$29 million to be appropriated for each fiscal years 2018 through 2022 for the program (a decrease from the \$40 million appropriated for fiscal years 2001 through 2003 under current law).</p>

<p>Section 10004; Children’s Recovery from Trauma</p>	<p>Directs the Secretary to award grants to develop and maintain programs that allow for the continued operation of the National Child Traumatic Stress Initiative (NCTSI) and evidence-based practices for identifying and treating mental, behavioral, and biological disorders of youth who have experienced or witnessed a traumatic event.</p> <p>Changes the criteria an applicant must meet in order to be given priority for grant review.</p> <p>Directs the NCTSI coordinating center to collect, analyze, report, and make publicly available treatment process and outcome data; coordinate training initiatives in evidence-based and trauma-informed treatments, interventions, and practices; and collaborate with the Secretary and appropriate agencies.</p> <p>An award to a recipient may not be for less than four years and not exceed five years, as provided under current law.</p> <p>Authorizes \$46.887 million to be appropriated for the program for fiscal years 2018 through 2022 (an annual decrease from the \$50 million per year currently allotted).</p>
<p>Section 10005; Screening and Treatment for Maternal Depression</p>	<p>Directs the Secretary to provide grants to States to develop, improve, or maintain programs for the screening, assessment, and treatment of maternal depression for women who are pregnant or were recently pregnant. In order to apply, a State must submit an application that includes explanations of how its program will increase the percentage of women screened and treated for maternal depression, and how if a current program is expanded it would increase access to these services. Requires the Secretary to give priority to States proposing to improve or enhance access to screening services in the primary care setting.</p> <p>Activities eligible for funding through a grant would include those that provide relevant information and training to health care providers.</p> <p>Authorizes \$5 million to be appropriated for the program.</p>
<p>Section 10006. Infant and Early Childhood Mental Health Promotion, Intervention, and Treatment</p>	<p>Establishes grants for the development, maintenance, or enhancement of infant and early childhood mental health promotion, intervention, and treatment programs. Eligible children are under the age of 12 who are at risk, show early signs, or have been diagnosed with a mental illness and may benefit from early intervention , treatment programs, or specialized school programs.</p> <p>An eligible entity may use the awarded funds to provide mental health promotion and early intervention services or mental illness treatment services; training for healthcare professionals; health consultation to personnel of early care and education programs; training for mental health clinicians; and assessment, diagnostic, and intervention services for eligible children. The eligible entity must match at least 10 percent of the total amount of Federal funds provided through the grant.</p> <p>Authorizes \$20 million to be appropriated for fiscal years 2018 through 2022 for the program.</p>
<p><b>Title XI — Compassionate Communications on HIPAA</b></p>	
<p>Section 11001; Sense of Congress Regarding Compassionate Communication on HIPAA</p>	<p>Expresses Congress’ findings that clarification is needed regarding the privacy required under the HIPAA Privacy Rule for adult patients with SMI, in particular the extent to which health care professionals should be able, in the best interest of the patient, to disclose PHI to the caregivers of such patients.</p>
<p>Section 11002; Confidentiality of Records</p>	<p>Requires HHS, within one year after the agency updates its regulations governing the confidentiality of alcohol and drug abuse patient records, to convene relevant stakeholders to determine the effect of those regulations on patient care, health outcomes, and patient privacy.</p>



Section 11003; Clarification on Permitted Uses and Disclosures of Protected Health Information	Expresses Congress’ findings that clarification is needed regarding the extent to which the HIPAA Privacy Rule prevents disclosure of PHI of an adult patient with SMI; in particular, the extent to which health care professionals should be able, in the best interest of the patient, to disclose PHI to the caregivers of such a patient.
Section 11004; Development and Dissemination of Model Training Programs	Requires HHS, within one year of enactment and in coordination with other relevant agencies and the input of experts, to identify or direct the creation of model programs and materials for training persons who may be involved in the care of patients seeking or undergoing treatment for a mental illness or substance abuse on the permissible disclosures of PHI of such patients.
<b>Title XII — Medicaid Mental Health Coverage</b>	
Section 12001; Rule of Construction Related to Medicaid Coverage of Mental Health Services and Primary Care Services Furnished on the Same Day	Establishes a rule of construction clarifying that nothing in the Medicaid statute prohibits a state Medicaid plan or waiver program from making separate payment for provision of mental health and primary care services provided to the same individual on the same day.
Section 12002; Study and Report Related to Medicaid Managed Care Regulation	Requires the Secretary to conduct a study of the extent to which states are providing capitated payments to Medicaid managed care plans or prepaid inpatient health plan for enrollees who are receiving services in institutions for mental diseases (IMDs). The study must include information on the number of individuals receiving services in IMDs, the range of and average length of stay at IMDs, criteria used to place patients in IMDs in lieu of other benefits (including the full range of community-based services), and the impact of providing IMD services based on capitated payments.
Section 12003; Guidance on Opportunities for Innovation	Requires that, not later than one year after enactment, CMS must issue a State Medicaid Director letter on opportunities to design innovative service delivery systems, including community-based services, for adults with SMI or children with a serious emotional disturbance.
Section 12004; Study and Report on Medicaid Emergency Psychiatric Demonstration Project	Requires that the Secretary, within two years of enactment, collect and analyze data from states and report to Congress on the Medicaid Emergency Psychiatric Demonstration Project established under Section 2707 of the Affordable Care Act. The report must include information on the number of IMDs receiving payment, reductions in Medicaid spending, disproportionate share hospital payments to IMDs, and changes in the utilization of emergency room services by individuals with severe mental illness who were enrolled in the program.
Section 12005; Providing EPSDT Services to Children in IMDS	Effective January 2019, children receiving Medicaid-covered inpatient psychiatric hospital services may receive the full range of early and periodic screening, diagnostic, and treatment (EPSDT) services, regardless whether those services are provided by IMDs.
Section 12006; Electronic Visit Verification System Required for Personal Care Services and Home Health Care Services Under Medicaid	Authorizes a reduction of one percentage point, when fully phased in, from the federal medical assistance percentage (FMAP) that states receive for Medicaid payment of in-home provider visits if the State does not establish an electronic visit verification system, by 2019 (for personal care services visits) and by 2023 (for home health visits).
<b>Title XIII — Mental Health Parity</b>	
Section 13001. Enhanced Compliance with Mental Health and Substance Use Disorder Coverage Requirements	Requires the Secretaries of HHS, Labor, and Treasury, and their respective Inspectors General, to publish a compliance program guidance document describing examples of non-quantitative treatment limitations (NQTLs) derived from investigations of noncompliance with mental health parity requirements.
Section 13002; Action Plan for Enhanced Enforcement of Mental Health and Substance Use Disorder Coverage	Requires HHS to convene a public meeting to produce an action plan for improved federal and state coordination to enforce mental health parity and addiction equity requirements.
Section 13003; Report on Investigations Regarding Parity in Mental Health and Substance Use Disorder Benefits	Requires the Administrator of CMS to publish an annual report for five years summarizing results of all closed federal investigations completed in the preceding year with serious violation of compliance with existing mental health and substance abuse parity requirements.

Section 13004; GAO study on Parity in Mental Health and Substance Use Disorders Benefits	Requires GAO to conduct a study of the enforcement of existing mental health parity requirements. The study will examine the extent to which NQTLs, including medical necessity criteria, are used in violation of federal and state laws and the effectiveness of HHS, the Labor Department, and state agencies in such enforcement.
Section 13005; Information and Awareness on Eating Disorders	Allows HHS to update resource lists and fact sheets related to eating disorders and increase public awareness
Section 13006. Education and Training on Eating Disorders	Allows HHS to facilitate identification programs and materials for educating and training health professionals in strategies to identify individuals with eating disorders, provide early intervention services, and refer patients to appropriate treatment.
Section 13007. Clarification of Existing Parity Rules	Requires that if a group health plan or health insurance issuer offers benefits for the treatment of eating disorders, including residential treatment, such benefits are covered under existing requirements for parity of mental health and medical benefits. The provision does not require plans to cover residential treatment for eating disorders.
<b>Title XV — Provisions Relating to Medicare Part A</b>	
Section 15001; Development of Medicare HCPCS Version of MS-DRG Codes for Similar Hospital Services	Requires CMS to develop Healthcare Common Procedure Coding System (HCPCS) versions of Medicare Severity-Diagnosis Related Groups (MS-DRGs) to translate outpatient surgical codes into inpatient surgical MS-DRGs. This section mirrors provisions in Ways and Means Committee Chair Kevin Brady’s (R-TX) October 2014 discussion draft, which included a HCPCS/MS-DRG crosswalk requirement as one of the steps to help develop a unified hospital payment system.
Section 15002; Establishing Beneficiary Equity in the Medicare Hospital Readmission Program	Requires the Secretary to implement, for purposes of the Hospital Readmissions Reduction Program, a transitional adjustment factor which allows for separate comparisons of hospitals within groups defined by the Secretary. The Secretary is required to define the groups of hospitals based on their overall proportion of inpatients who are entitled to or enrolled for benefits under part A and who are full-benefit dual eligible individuals. Implementation must be budget neutral. This section also requires MedPAC to conduct a study on overall hospital readmissions and whether such readmissions are related to any changes in outpatient and emergency services furnished.
Section 15003; Five-Year Extension of the Rural Community Hospital Demonstration Program	<p>Extends the Rural Community Hospital Demonstration, established under section 410 of the Medicare Modernization Act and extended by the Affordable Care Act, for an additional five years.</p> <p>Allows more hospitals to participate in the demonstration, including by soliciting applications from rural community hospitals in all states.</p>
Section 15004; Regulatory Relief for LTCHs	Provides relief from the moratoria on new beds in LTCHs and LTCH satellites, for bed expansion in certain “mid-build” LTCHs. To offset the cost, this section reduces the Medicare high cost outlier payment for LTCHs effective October 1, 2017.
Section 15005; Savings from IPPS MACRA Pay-For Through Not Applying Documentation and Coding Adjustments	Reduces the adjustment to inpatient hospital payment rates under the Medicare Access and CHIP Reauthorization Act (MACRA) from “an increase of 0.5 percentage points” to “an increase of 0.4588 percentage points” in 2018.
Section 15006; Extension of Certain LTCH Medicare Payment Rules	Extends the prohibition under the Bipartisan Budget Act of 2013, which capped the number of LTCH admissions that can come from a single inpatient acute hospital at 25 percent, “through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017.”
Section 15007; Application of Rules on the Calculation of Hospital Length of Stay to All LTCHs	Under prior law, only hospitals that were designated LTCHs as of December 10, 2013 could exclude patients for whom payment was made under the site neutral payment rate or Medicare Advantage from the length of stay calculation required for LTCHs and satellites. This section removes the limitation and entitles LTCHs that were not designated as of December 10, 2013 to the same exclusions for purposes of the length of stay calculation.
Section 15008; Change in Medicare Classification for Certain Hospitals	Changes the designation for certain sub-clause (II) LTCHs, which under prior law only needed a 20-day average inpatient length stay (versus 25 days for other LTCHs), and switches them to a reasonable cost payment scheme by statute.

<p>Section 15009; Temporary Exception to the Applicable of the Medicare LTCH Site Neutral Provisions for Certain Spinal Cord Specialty Hospitals</p>	<p>Provides a temporary exception from the Medicare LTCH site neutral payment rate for hospitals: (1) that were designated as a not-for-profit LTCH on June 1, 2014; and (2) where, of the discharges in 2013 for which payment was made under this section, at least 50 percent were for catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions (classified in specified MS-LTCH-DRGs). This exception applies to discharges in cost reporting periods beginning during 2018 and 2019.</p>
<p>Section 15010; Temporary Extension to the Application of the Medicare LTCH Site Neutral Provisions for Certain Discharges with Severe Wounds</p>	<p>Provides a temporary exception to the Medicare LTCH site-neutral payment for discharges that: (1) are from a grandfathered LTCH; (2) are classified in specified MS-LTCH-DRGs; and (3) are with respect to an individual treated by a LTCH for a severe wound. Defines a “severe wound” as a “stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.” This exception applies to discharges occurring in a cost report period beginning during FY 2018.</p>
<p><b>Title XVI — Provisions Relating to Medicare Part B</b></p>	
<p>Section 16001; Continuing Medicare Payment Under HOPD Prospective Payment System for Services Furnished by Mid-Build Off-Campus Outpatient Departments of Providers</p>	<p>Provide exceptions to the site-neutral payment provision under the Bipartisan Budget Act of 2015, which requires certain off-campus hospital outpatient departments to bill under another applicable payment system (e.g., Medicare Physician Fee Schedule) instead of the outpatient prospective payment system.</p> <p>Under section 16001, so-called “mid-build” HOPDs can continue to bill under OPSPs: (1) during 2017, if the hospital submitted an attestation to CMS before December 2, 2015 that the HOPD was a department of the hospital; or (2) beginning in 2018, if the HOPD was “mid-build” (i.e., the hospital had a “binding written agreement with an outside unrelated party for the actual construction of such department”) when the Bipartisan Budget Act of 2015 was enacted.</p>
<p>Section 16002; Treatment of Cancer Hospitals in Off-Campus Outpatient Department of a Provider Policy</p>	<p>Exempts outpatient departments of prospective payment system-exempt cancer hospitals from the site-neutral payment, provided that the hospital submits to CMS an attestation that the outpatient department meets the provider-based requirements under 42 C.F.R. § 413.65 within 60 days of enactment.</p>
<p>Section 16003; Treatment of Eligible Professionals in Ambulatory Surgical Centers for Meaningful Use and MIPS</p>	<p>Excludes eligible professionals who furnish substantially all covered professional services in an ambulatory surgical center from the penalties under the EHR Incentive Program and the MIPS Program. This section sunsets no later than three years after the Secretary determines that certified EHR technology applicable to the ambulatory surgical center setting is available.</p>
<p>Section 16004; Continuing Access to Hospitals Act of 2016</p>	<p>Requires the Secretary to continue to apply through CY 2016 the CMS enforcement instruction, titled “Enforcement Instruction on Supervision Requirements for Outpatient Therapeutic Services in Critical Access and Small Rural Hospitals for CY 2013.” This enforcement instruction prohibits the Secretary from enforcing the “direct supervision” requirement by physicians for therapeutic hospital outpatient services.</p> <p>Requires MedPAC to submit to Congress a report analyzing the effect of extending this enforcement instruction on access to healthcare by beneficiaries, economic impact, the impact on hospital staffing needs, and on quality of healthcare to beneficiaries.</p>
<p>Section 16005; Delay of Implementation of Medicare Fee Schedule Adjustments for Wheelchair Accessories and Seating Systems When Used in Conjunction with Complex Rehabilitation Technology (CRT) Wheelchairs</p>	<p>Extends the prohibition that bars the Secretary from using information on payment determined under the competitive acquisition programs to adjust payment for wheelchair accessories when furnished in connection with Group 3 complex rehabilitative power wheelchairs, from January 1, 2017 to July 1, 2017.</p>
<p>Section 16006; Allowing Physical Therapists to Utilize Locum Tenens Arrangements under Medicare</p>	<p>Permits <i>locum tenens</i> arrangements under the Medicare program for outpatient physician therapists in a health professional shortage area, a medically underserved area, or a rural area.</p>

Section 16007; Extension of the Transition to New Payment Rates for Durable Medical Equipment Under the Medicare Program	Extends the transition for applying DME competitive bidding rates to non-competitive bidding areas. For items and services furnished from January 1, 2016 to December 31, 2016, the payment adjustment is based on 50 percent of the adjustment payment amount established under the regulations and 50 percent of the unadjusted fee schedule amount. Additionally, for items and services furnished on or after January 1, 2017, the payment adjustment is equal to 100 percent of the adjustment payment amount.
Section 16008; Requirements in Determining Adjustments Using Information from Competitive Bidding Programs	For items and services furnished on or after January 1, 2019, this section requires the Secretary to consider the following when making adjustments to DME payment rates using information from competitive bidding programs: (1) stakeholder input; and (2) the highest amount bid by a winning supplier in the competitive acquisition area and a comparison with the non-competitive acquisition area of the average travel distance and cost associated with furnishing the items and services in the area, the average volume of items and services furnished by suppliers in the area, and the number of suppliers in the area.
<b>Title XVII — Other Medicare Provisions</b>	
Section 17001; Delay in Authority to Terminate Contracts for Medicare Advantage Plans Failing to Achieve Minimum Quality Ratings	Prohibits the Secretary, from the date of enactment through the end of plan year 2018, from terminating a Medicare Advantage contract solely because the plan has failed to achieve a minimum quality rating under the five-star rating system.
Section 17002; Requirements for Enrollment Data Reporting for Medicare	Requires the Secretary to submit a report to Congress on Medicare enrollment data, including data on individuals receiving benefits under Medicare Part A, fee-for-service enrollment, and enrollment under Parts C and D.
Section 17003; Updating the Welcome to Medicare Package	Requires the Secretary to solicit information from stakeholders on information included in the “Welcome to Medicare” package within 6 months after enactment. Additionally, within 12 months after the request for information, the Secretary must revise the Welcome to Medicare Package to include information about options for receiving benefits under Medicare, including through the Parts A/B fee-for-service program, Medicare Advantage plans under Part C, and prescription drug plans under Part D.
Section 17004; No Payment for Items and Services Furnished by Newly Enrolled Providers or Suppliers Within a Temporary Moratorium Area	In areas in which the Secretary has imposed a temporary moratorium on the enrollment of new providers in Medicare, Medicaid, or CHIP, this section denies payment to new providers for items and services furnished on or after October 1, 2017. However, a State will not be required to comply with the temporary moratorium if the State determines that the moratorium would adversely impact beneficiary access to medical assistance under Medicaid or CHIP.
Section 17005; Preservation of Medicare Beneficiary Choice under Medicare Advantage	Provides that, through 2018, during the first 45 days of the year, an individual enrolled in a MA plan may dis-enroll from a MA plan to enroll in Medicare Parts A/B and, optionally, a Part D qualified prescription drug plan. Additionally, this section provides that starting in 2019, MA eligible individuals may change their election during the first three months of a year.
Section 17006; Allowing End-Stage Renal Disease Beneficiaries to Choose a Medicare Advantage Plan	<p>Effective for plan years beginning on or after January 1, 2021, removes the prohibition that barred individuals with end-stage renal disease from enrolling in a MA plan.</p> <p>For plan years beginning with 2021, the Secretary must exclude the estimated standard acquisition costs for kidney transplants from the benchmark and bid amounts.</p> <p>Directs the Secretary to evaluate whether the five-star rating system should include quality measures specific to beneficiaries with end-stage renal disease who enroll in a MA plan.</p> <p>Requires the Secretary to take into account the total number of diseases or conditions of an individual enrolled in a MA plan for purposes of MA risk adjustment.</p> <p>Requires the Secretary to take into account in the risk adjustment model the dual eligibility status, the impact of including additional diagnosis codes related to mental health and substance use disorders, and as the severity of chronic kidney disease.</p> <p>These changes to the risk adjustment model must be phased in over a three-year period, starting in 2019.</p>

Section 17007; Improvements to the Assignment of Beneficiaries under the Medicare Shared Savings Program	Requires the Secretary to determine the method for assigning beneficiaries to a Medicare Shared Savings Program Accountable Care Organization (ACO) based on the following: (1) for performance years beginning on after 2012, primary care services provided by an ACO professional; and (2) for performance years beginning on or after January 1, 2019, services provided by a federally qualified health center or rural health center.
<b>Title XVIII — Other Provisions</b>	
Section 18001; Exception from the Group Health Plan Requirements for Qualified Small Employer Health Reimbursement Arrangements	Exempts small employers who operate qualified health reimbursement arrangements (HRAs) from penalties imposed under the Affordable Care Act's market reforms for group health plans. To qualify, a HRA must supplement existing health coverage of an employee and reimbursement payments would be capped at \$4,950 (or \$10,000 for a family).

Below are the sections not included in the table:

- Section 1004; Budgetary treatment
- Section 2032; Triennial Reports
- Section 2035; Exemption for the National Institutes of Health from the Paperwork Reduction Act Requirements
- Section 2052; Compliance Activities Reports
- Section 3071; Silvio O. Conte Senior Biomedical Research Service
- Section 3072; Hiring Authority for Scientific, Technical, and Professional Personnel
- Section 3076; Reagan-Udall Foundation for the Food and Drug Administration
- Section 3087; Paperwork Reduction Act Waiver During a Public Health Emergency
- Section 3101; Technical Corrections
- Section 3102; Completed Studies
- Section 5007; Fairness in Medicaid Supplemental Needs Trusts
- Section 5010; Strategic Petroleum Reserve Drawdown

Title XIV of the Cures Act incorporates the Mental Health and Safe Communities Act sponsored by Rep. Martha McSally (R-AZ-2) and Sen. John Cornyn (R-TX), as well as the Comprehensive Justice and Mental Health Reform Act sponsored by Rep. Doug Collins (R-GA-9) and Sen. Al Franken (D-MN). It includes the following provisions:

Subtitle A—Mental Health And Safe Communities

- Section 14001; Law Enforcement Grants For Crisis Intervention Teams, Mental Health Purposes.
- Section 14002; Assisted Outpatient Treatment Programs.
- Section 14003; Federal Drug And Mental Health Courts.
- Section 14004; Mental Health In The Judicial System.
- Section 14005; Forensic Assertive Community Treatment Initiatives.
- Section 14006; Assistance For Individuals Transitioning Out Of Systems.
- Section 14007; Co-Occurring Substance Abuse And Mental Health Challenges In Drug Courts.
- Section 14008; Mental Health Training For Federal Uniformed Services.
- Section 14009; Advancing Mental Health As Part Of Offender Reentry.
- Section 14010; School Mental Health Crisis Intervention Teams.
- Section 14011; Active-Shooter Training For Law Enforcement.
- Section 14012; Co-Occurring Substance Abuse And Mental Health Challenges In Residential Substance Abuse Treatment Programs.



- Section 14013; Mental Health And Drug Treatment Alternatives To Incarceration Programs.
- Section 14014; National Criminal Justice And Mental Health Training And Technical Assistance.
- Section 14015; Improving Department Of Justice Data Collection On Mental Illness Involved In Crime.
- Section 14016; Reports On The Number Of Mentally Ill Offenders In Prison.
- Section 14017; Codification Of Due Process For Determinations By Secretary Of Veterans Affairs Of Mental Capacity Of Beneficiaries.
- Section 14018; Reauthorization Of Appropriations.

#### Subtitle B—Comprehensive Justice And Mental Health

- Section 14021; Sequential Intercept Model.
- Section 14022; Prison And Jails.
- Section 14023; Allowable Uses.
- Section 14024; Law Enforcement Training.
- Section 14025; Federal Law Enforcement Training.
- Section 14026; GAO Report.
- Section 14027; Evidence Based Practices.
- Section 14028; Transparency, Program Accountability, And Enhancement Of Local Authority.
- Section 14029; Grant Accountability.

## Footnotes

- 1 “Qualification” and “qualified” are defined to mean “a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.”
- 2 Defined to mean “(A) a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and (B) includes a surrogate endpoint. This section defines “surrogate endpoint” to mean “a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and: (A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or (B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product.”
- 3 Defined to mean “(A) a measurement of a patient’s symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and (B) includes a patient-reported outcome.” This section defines “patient-reported outcome” to mean “a measurement based on a report from a patient regarding the status of the patient’s health condition without amendment or interpretation of the patient’s report by a clinician or any other person.”
- 4 Defined to mean “an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.”
- 5 A determination not to accept a submission must not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.
- 6 Defined to mean “collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.”
- 7 Defined to mean “... with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.”
- 8 Requestors may request a meeting with the Secretary to discuss the basis of the Secretary’s decision to rescind or modify the determination before the effective date of the rescission or modification.
- 9 For purposes of this section, defined to mean (A) a drug that is the subject of an FDA application “for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening; (B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and (C) incorporates or utilizes a genetically targeted technology.” The term “genetically targeted technology” means a “technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene.”



- 10 Defined to mean (A) a drug that is the subject of an FDA application “for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening; (B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and (C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.”
- 11 Has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).
- 12 The provision also clarifies that it “shall not be construed to alter the substantial evidence standard or the Secretary’s authority to require post-approval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.”
- 13 The provision defines “qualified data summary” to mean “a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.”
- 14 Section 3031 defines “qualified indication” to mean “an indication for a drug that the Secretary determines to be appropriate for summary level review.”
- 15 “Regenerative medicine therapy” includes “cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.”
- 16 The term “antimicrobial” includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth or other microorganisms as appropriate. Proposed as 42 U.S.C. § 247d-5(k).
- 17 This section would also require the Secretary to “provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.”
- 18 Data collected under Section 3041 must be made public by the Secretary.
- 19 This would include the following activities: (1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs; (2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and (3) promoting antimicrobial stewardship. Proposed as 42 U.S.C. § 247d-5(i).
- 20 Proposed as 42 U.S.C. § 247d-5(j). The Secretary would also be required to use available systems, including the National Healthcare Safety Network or other identified systems to fulfill the requirements or conduct activities under this section.
- 21 Proposed as 21 U.S.C. § 356(h).
- 22 Such drug “may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.” The legislation would clarify that nothing in this subsection could be construed to alter the substantial evidence standards or any applicable standards with respect to marketing authorization.
- 23 The report must assess “the extent to which the use of the pathway ... has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.”
- 24 Defined to mean: (1) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and (2) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.
- 25 Defines “interpretive criteria standard” to mean “a compilation of susceptibility test interpretive criteria developed by a standard development organization” that meets the criteria of this subsection.
- 26 If provided by the Secretary through regulations, “antimicrobial drugs” may include: (i) drugs other than systemic antibacterial and antifungal drugs; and (ii) biological products (as defined in section 351 of the PHSA) to the extent such products exhibit antimicrobial activity.
- 27 Defined as “a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).”
- 28 FDA must post notice in the Federal Register no later than the date on which the Interpretive Criteria Website is established.
- 29 The organization must: (1) establish and maintain procedures to address potential conflicts of interest and ensure transparent decision-making; (2) hold open meetings to ensure that there is an opportunity for public input by interested parties and establishes and processes are in place to ensure that such input is considered in decision-making; and (3) permit its standards to be made publicly available through an acceptable source (e.g., National Library of Medicine).
- 30 The term “adequate expertise” means that the membership of the classification panel includes: (i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and (ii) at least one voting member who is knowledgeable about the technology of the device. The Secretary must provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.
- 31 The House-passed version of H.R. 6 was identical to this provision except for a 2017 effective date.
- 32 Insignificant technical changes were made in the more recent version.

- 33 Medicare coverage of telehealth services is limited in several ways. Most importantly, telehealth services can only be furnished to beneficiaries in certain rural or underserved areas. In addition, the beneficiary must be at an eligible “originating site” (various specified medical facilities) when receiving the services, the services must be on a list of telehealth services maintained and annually updated by CMS, and to qualify as “telehealth” the services must be furnished via real-time audio and video conferencing.

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