| DIVISION A: 21ST CENTURY CURES | |
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| TITLE I: INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE | |
| Sec. 1001. National Institutes of Health Innovation Projects. | • Provides over $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.<br>• Ensures accountability by requiring a work plan and annual report. |
| Sec. 1002. Food and Drug Administration Innovation Projects. | • Provides $500 million to the Food and Drug Administration (FDA) over 10 years to implement provisions in Title III to move drugs and medical devices to patients more quickly, while maintaining the same standard for safety and effectiveness. |
| Sec. 1003. Account for the State Response to the Opioid Abuse Crisis. | • Provides $1 billion over 2 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.<br>• Ensures accountability without increase burden on states by requiring grantees to report on activities funded by the grant in the substance abuse block grant report. |
| Sec. 1004. Budgetary Treatment. | • Ensures savings in 21st Century Cures are not double-counted on the PAYGO scorecard. |
| TITLE II: DISCOVERY | |
| Subtitle A<br>National Institutes of Health Reauthorization | |
| Sec. 2001. National Institutes of Health Reauthorization. | • Reauthorizes the NIH for FY18-20. |
| Sec. 2002. EUREKA Prize Competitions | • Directs NIH to utilize its prize authority to support innovation prize competitions to advance biomedical science and improve health outcomes for diseases that are serious and represent a significant burden in the U.S.<br>• Requires tracking on the effect of innovations funded by prize competitions under this section and their effect on federal expenditures.<br>o Requires this information to be included in the Triennial Report. |
| Subtitle B<br>Advancing Precision Medicine | |
| Sec. 2011. Precision Medicine Initiative. | • Encourages the Secretary of Health and Human Services (HHS) to carry out a "Precision Medicine Initiative" to augment efforts to address disease prevention, diagnosis, and treatment.<br>• Among other activities, the initiative may include developing new approaches for:<br>o Addressing scientific, medical, public health, and regulatory science issues;<br>o Applying genomic technologies; and<br>o Gathering information from volunteers to better understand health and disease. |

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| | • Encourages the Secretary of HHS to coordinate with other federal departments, utilize public-private partnerships, and leverage existing data sources.<br>• Ensures that the Precision Medicine Initiative will comply with existing laws and regulations for the protection of human participants, protect the privacy of participants, and include a broad range of participants. |
| Sec. 2012. Privacy Protection for Human Research Subjects. | • Directs the Secretary of HHS to issue certificates of confidentiality to researchers that receive federal funding. Allows the Secretary of HHS to also issue certificates to privately funded researchers.<br>• Prohibits researchers to whom certificates are issued from disclosing the name of participants or any other identifiable data gathered during research, except when:<br>o Required by federal, state, or local law;<br>o Necessary to treat the individual in question;<br>o The individual gives consent; or<br>o Disclosure of information is for the purposes of other research in compliance with privacy laws.<br>• Prohibits researchers who are issued certificates from being compelled to disclose identifiable, sensitive information about participants that was gathered during research.<br>• Grants immunity from the legal process to all identifiable, sensitive information gathered during research. Such information can only be used in legal proceedings with the consent of the research participant.<br>• The protections of this section are afforded in perpetuity.<br>• Directs the Secretary of HHS to minimize the burden of compliance for researchers. The requirements of this section apply to all ongoing research authorized under section 301(d) of PHSA. |
| Sec. 2013. Protection of Identifiable and Sensitive Information. | • Allows the Secretary of HHS to exempt individual biomedical research data from being disclosed if the data is identifiable, or could be used for identification.<br>o Requires the Secretary of HHS to submit written basis for each disclosure exemption, made available to the public upon request to the Chief Freedom of Information Act Officer at HHS. |
| Sec. 2014. Data Sharing. | • Allows the Director of the NIH to require grant recipients to share the data that is generated from the NIH-funded research.<br>• Requires the data to be shared in a manner that is consistent with Federal laws and regulations, including laws and regulations for protection of human research participants, proprietary data, and national security interest. |
| Subtitle C<br>Supporting Young Emerging Scientists | |
| Sec. 2021. Investing in the Next Generation of Researchers | • Creates a "Next Generation of Researchers Initiative" in the Office of the Director at the NIH to coordinate, develop, modify, and prioritize policies and programs to improve opportunities for new researchers.<br>• Requires NIH to report to Congress on any actions taken in response to recommendations from the National Academy of Sciences as part of the study on policies affecting the next generation of researchers.<br>o Fiscal Year (FY) 2016 appropriations included direction for the National Academies to carry out such a study. |

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| Sec. 2022. Improvement of Loan Repayment Program. | • Replaces NIH's existing loan repayment programs for researchers with one program for intramural researchers with up to four subcategories and one loan repayment program for extramural researchers with up to six subcategories.<br>• Increases the maximum yearly loan repayment amount from $35,000 to $50,000.<br>• Allows the Director of NIH to better target the loan repayment programs to meet workforce or scientific needs related to biomedical research by eliminating loan repayment subcategories or by adding a limited number of new subcategories. |
| Subtitle D<br>National Institutes of Health Planning and Administration | |
| Sec. 2031. National Institutes of Health Research Strategic Plan. | • Requires the Director of NIH, in consultation with the directors of the national research institutes and centers, to develop a six-year coordinated strategy to outline the direction of biomedical research investments made by the NIH, facilitate collaboration among the research institutes and centers, and advance biomedicine.<br>• Requires the coordinated strategy to identify strategic research priorities, including:<br>o An assessment of biomedical and behavioral research, and opportunities for basic and translational research;<br>o Priorities and objectives to advance prevention, treatment, and cures;<br>o Emerging scientific opportunities, including public health challenges; and<br>o Near-, mid-, and long-term scientific needs.<br>• Requires consideration of disease burden in the United States, rare diseases, and biological and social determinants of health. |
| Sec. 2032. Triennial Reports. | • Changes reports of the Director of the NIH from biennial to triennial.<br>• Requires a description of intra-NIH activities, including identification of the annual percentage of funds for conducting or supporting research that involves collaboration between two or more national research institutes or centers, and recommendations for promoting coordination.<br>• Specifies that "relevant age categories" must be identified in the demographic variables identified in the catalog of all research activities of the agency. |
| Sec. 2033. Increasing Accountability at the National Institutes of Health. | • Provides for the appointment of directors of national research institutes and national centers.<br>o Specifies that directors have five-year terms, may be reappointed at the end of a term, and clarifies that there is no limit to the number of terms that a director may serve.<br>• Clarifies that directors of national research institutes or national centers must review and make final decisions on funding awards.<br>• Requires the Secretary of HHS to submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes. |
| Sec. 2034. Reducing Administrative Burden for Researchers. | • Requires the Secretary of HHS, within two years of enactment, to: |

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| | ○ Lead a review of regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest.<br>○ Make revisions to harmonize existing policies and reduce administrative burden.<br>○ Consider:<br>▪ Modifying the timelines for reporting conflicts of interest;<br>▪ Ensuring that financial interest disclosure requirements are appropriate for awards that will directly fund research; and<br>▪ Updating any applicable training modules of the NIH related to federal financial interest disclosure.<br>• Requires NIH to implement measures to reduce administrative burdens related to monitoring of sub-recipients of grants by primary awardees of funding from the NIH.<br>• Requires the Secretary of HHS, in consultation with the NIH Director, to evaluate financial reporting procedures and requirements for NIH funding recipients and take action to avoid duplication to minimize burden to funding recipients.<br>• Requires the NIH Director, the Secretary of Agriculture, and the Commissioner of the FDA to review and revise as appropriate laboratory animal regulations and policies to reduce administration burden on investigators. The review shall:<br>○ Identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative;<br>○ Take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and<br>○ Take other actions to improve the coordination of regulations and policies with respect to research with laboratory animals.<br>• Requires the Secretary of HHS to clarify the applicability of the requirements under the Office of Management and Budget (OMB)<br>• Uniform Guidance for management and certification systems adopted by entities receiving federal research grants through HHS regarding documentation of personnel expenses, including clarification of the extent to which any flexibility applies to entities receiving grants.<br>• Requires OMB to establish an advisory committee, called the "Research Policy Board".<br>○ Requires the board to provide information on the effects of regulations related to federal research requirements and make recommendations on how to modify and harmonize regulations and policies to minimize administrative burden. Activities of the board may include:<br>▪ Providing thorough and informed analysis of regulations and policies;<br>▪ Identifying adverse consequences of existing policies and making actionable recommendations to improve such policies;<br>▪ Creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and |

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| | ▪ Conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.<br>o Requires the board, within two years of enactment, to submit a report containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policies, including the regulatory benefits and burdens.<br>o Requires GAO, within four years of enactment, to conduct an independent evaluation of the activities carried out by the board. This report is also required to review and access the Board's activities. |
| Sec. 2035. Exemption for the National Institutes of Health from the Paperwork Reduction Act Requirements. | • Exempts voluntary information collected during NIH research from current paperwork reduction initiatives (44 U.S.C. 3501). |
| Sec. 2036. High-Risk, High-Reward Research. | • Authorizes the national institutes and centers within NIH, with the approval of the Director of NIH, to use transactions other than a contract, grant, or cooperative agreement for the Precision Medicine Initiative, and for up to 50 percent of the funds available in the NIH Common Fund.<br>• In order to use this "other transactions authority," the institute or center must submit a proposal and receive approval for the use of other transactions.<br>• Requires the Secretary of HHS, acting through the Director of NIH, to evaluate activities within NIH associated with this high-risk, high-reward research and submit a report to Congress.<br>• Encourages NIH to conduct and support high-risk, high-reward research to address major current challenges. |
| Sec. 2037. National Center for Advancing Translational Sciences. | • Allows the National Center for Advancing Translational Sciences (NCATS) to support clinical trials through the end of phase IIB (previously IIA).<br>• Increases the clinical trial phase through which NCATS may support clinical trial activities for treatment of a rare disease of condition so long as–<br>o NCATS gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase II (previously IIB); No public or private organization provides credible written intent to NCATS that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB (previously IIA); and NCATS ensures that support of the clinical trial activities in phase III (previously IIB) will not increase the Federal Government's liability beyond the award value of the Center's support.<br>• Improves transparency, including by requiring reporting on the methods and tools that had been developed since the last NCATS report and |

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| | those that are being used, if any, by FDA to support medical product reviews. |
| Sec. 2038. Collaboration and Coordination to Enhance Research. | • Requires the Director of NIH to assemble accurate data to be used to assess research priorities, including:<br>  o Information to better evaluate scientific opportunity, public health burdens, and progress reducing health disparities;<br>  o Data on study populations of clinical research funded by and conducted at each national research institute and national center that specify the inclusion of women, members of minority groups, relevant age categories, and other demographic variables determined necessary.<br>• Requires the Director of NIH to foster and encourage collaboration between NIH-funded clinical research projects. Such collaboration would allow for an increase in the number of subjects studied and the utilization of diverse study populations, with special consideration given to biological, social, and other determinants of health that contribute to health disparities.<br>• Requires the Director of NIH to improve research related to minority populations.<br>• Encourages the Director of the National Institute on Minority Health and Health Disparities to foster partnerships and encourage the funding of collaborative research projects.<br>• Requires the Director of NIH to update guidelines for the inclusion of women in clinical research to reflect the most current science.<br>• Requires that the Director of NIH hold a workshop to get input on appropriate age groups in research and update policies, as appropriate. |
| Sec. 2039. Enhancing the Rigor and Reproducibility of Scientific Research. | • Requires the Secretary of HHS, acting through the Director of NIH, to convene a working group to develop recommendations for a formal policy to enhance the rigor and reproducibility of NIH-funded scientific research. The working group shall consider, as appropriate:<br>  o Pre-clinical experiment design, including analysis of sex as a biological variable;<br>  o Clinical experiment design;<br>  o Applicable levels of rigor in statistical methods, methodology, and analysis, and<br>  o Data and information sharing.<br>• Requires the Director of NIH to consider the working group's recommendations and develop or update policies as appropriate within 18 months.<br>• Requires the working group to report to Congress on recommendations and any subsequent policy changes within two years. |
| Sec. 2040. Improving Medical Rehabilitation Research at the National Institutes of Health. | • Specifies that NIH must update their Rehabilitation Research Plan periodically, or at least every five years, and requires the agency to develop objectives and benchmarks that will allow NCMRR to measure success and report to Congress on annual progress.<br>  o The report shall include recommendations for revising and updating the Rehabilitation Research Plan.<br>  o Specifies that the Rehabilitation Research Plan must also identify existing resources to support the purposes of the center. |

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| | ○ Ensures coordination and periodic review of the state of medical rehabilitation science and outreach to the research community in connection with revisions to the research plan.<br>• Encourages coordination of medical rehabilitation research among agencies of NIH and other federal agencies, including through interagency agreements.<br>• Defines the term "medical rehabilitation research" to mean the science of mechanisms and interventions that prevent, improve, restore, or replace lost underdeveloped, or deteriorating function. |
| Sec. 2041. Task Force on Research Specific to Pregnant Women and Lactating Women. | • Establishes a Task Force on Research Specific to Pregnant Women and Lactating Women, to provide advice and guidance to the Secretary of HHS with the goal of addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women.<br>• The task force shall be composed of federal and non-federal members, and will meet at least two times each year. The task force sunsets in two years unless the Secretary of HHS extends it for two more years.<br>• Requires the task force to prepare and submit a report to Congress that includes:<br>○ A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies;<br>○ Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research;<br>○ Effective communication strategies with health care providers and the public on information relevant to pregnant and lactating women;<br>○ Identification of federal activities, including the state of research on pregnancy and lactation; recommendations for coordination and collaboration; dissemination of research findings and information; and existing efforts to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes.<br>○ Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.<br>• Requires the Secretary of HHS, after considering the task force's recommendations and consulting with relevant HHS agencies, to update regulations and guidance regarding the inclusion of pregnant women and lactating women in clinical research.<br>• Requires the Secretary of HHS to also consider criteria to require additional protections or exclude pregnant or lactating women from participating in research. |
| Sec. 2042. Streamlining National Institutes of Health Reporting Requirements. | • Trans-NIH Research Reporting – requires the head of each national research institute or center to submit a report, to be included in the triennial report, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and one or more other national research institutes or national centers.<br>• Repeals the review and report on the Centers of Excellence. |

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| Sec.2043. Reimbursement for Research Substances and Living Organisms. | • Where research products are made available through contractors, allows the Secretary of HHS to direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such research products.<br>  o The amounts collected are to be credited to the appropriations accounts that incurred the cost to make the research product involved available. |
| Sec. 2044. Sense of Congress on Increased Inclusion of Underrepresented Populations in Clinical Trials. | • Encourages the National Institute on Minority Health and Health Disparities to include within its strategic plan ways to increase representation of underrepresented populations in clinical trials. |
| Subtitle E<br>Advancement of the National Institutes of Health Research and Data Access | |
| Sec. 2051. Technical Updates to Clinical Trials Database. | • Makes technical updates to the clinical trials data base requirements to allow information from device clinical trials to be posted prior to clearance or approval if the manufacturer requests that the information be posted earlier.<br>• Makes technical updates to the clinical trials database to clarify whether combination products are considered drug clinical trials or device clinical trials for purposes of the database. |
| Sec. 2052. Compliance Activities Report. | • Requires a report on actions taken to encourage compliance with the clinical trials database, including education and outreach.<br>• Requires a report on the status of clinical trials registered in the clinical trials database, as well as activities taken to encourage education and outreach on data bank registration. |
| Sec. 2053. Updates to Policies to Improve Data. | • Updates policies to ensure reporting of data from valid analyses for certain clinical trials. |
| Sec. 2054. Consultation. | • Requires the Secretary of HHS to consult with agencies and other stakeholders to receive recommendations related to enhancements to the clinical trial registry. |
| Subtitle F<br>Facilitating Collaborative Research | |
| Sec. 2061. National Neurological Conditions Surveillance System. | • Provides that the Secretary of HHS shall, as appropriate, improve the collection of information on the incidence and prevalence of neurological diseases and conditions, which may be through the establishment of a registry, in order to facilitate research and improve public health. This is intended to be carried out by the Centers for Disease Control and Prevention (CDC). |
| Sec. 2062. Tick-borne Diseases. | • This section would help to accelerate improved methods for prevention, diagnosis, and treatment of tick-borne diseases, including Lyme disease. It would establish a working group to prepare a report summarizing federal research efforts related to Lyme disease and other tick-borne diseases. The working group terminates 6 years after the date of enactment of this Act. |
| Sec. 2063. Accessing, Sharing, and Using Health Data for Research Purposes. | • Requires the Secretary of HHS to issue guidance clarifying that certain researchers may remotely access protected health information if specific security and privacy safeguards are maintained. |

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| | • Requires the Secretary of HHS to issue guidance clarifying circumstances under which an authorization to use and disclose protected health information for future research purposes contains sufficient information.<br>• Establishes a working group to study and report on whether the uses and disclosures of protected health information for research purposes should be modified. |
| Subtitle G<br>Promoting Pediatric Research | |
| Sec. 2071. National Pediatric Research Network. | • Requires NIH to continue to support the National Pediatric Research Network. It would be composed of research institutions that would operate as a consortium in order to pool resources and coordinate activities related to pediatric rare diseases or birth defects. |
| Sec. 2072. Global Pediatric Clinical Study Network. | • Sets forth a sense of Congress that NIH and FDA should work with the European Union, industry, and others to establish a global pediatric clinical study network. |
| TITLE III: DEVELOPMENT | |
| Subtitle A<br>Patient-Focused Drug Development | |
| Sec. 3001. Patient Experience Data. | • Requires the FDA to include a statement regarding any patient experience data that was used at the time a drug is approved. Patient experience data includes data collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers). |
| Sec. 3002. Patient-focused Drug Development Guidance. | • Requires the FDA to issue guidance regarding how to collect patient experience data. Such guidance documents shall address:<br>o Appropriate ways to collect data for use by the FDA for use in regulatory decisions;<br>o How patients wishing to propose draft guidance to FDA may submit such documents;<br>o How FDA will respond to patient experience data submissions to FDA;<br>o The format and content for patient experience data submissions to FDA; and<br>o How the FDA plans to use relevant patient experience data and related information when evaluating the risks and benefits of a drug. |
| Sec. 3003. Streamlining Patient Input. | • Exempts FDA from going through the Paperwork Reduction Act clearance process when requesting information from patients regarding their disease or treatments, allowing FDA to get more timely feedback from patients. |
| Sec. 3004. Report on Patient Experience Drug Development. | • Requires FDA to report on FDA's 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, 2028, and 2031. |
| Subtitle B<br>Advancing New Drug Therapies | |

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| Sec. 3011. Qualification of Drug Development Tools. | • Establishes a review pathway at FDA for biomarkers and other drug development tools that can be used to help shorten drug development time and reduce the failure rate in drug development. |
| Sec. 3012. Targeted Drugs for Rare Diseases. | • Clarifies the authority of the FDA with regard to genetically targeted drugs for rare diseases.<br>• Allows sponsors of genetically targeted or variant protein targeted drugs to rely on data for the same or similar technology from previously approved applications by the same sponsor.<br>• Does not alter the existing approval standards for drugs. |
| Sec. 3013. Reauthorization of Program to Encourage Treatments for Rare Pediatric Diseases. | • 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. |
| Sec. 3014. GAO Study of Priority Review Voucher Programs. | • Requires GAO to study all the priority review voucher programs to see the impact on drug development and any unintended consequences. |
| Sec. 3015. Amendments to the Orphan Drug Grants. | • Updates the orphan drug grant program to clarify that grants may be used for observational studies that help understand the natural history of a rare disease or condition and in the development of a therapy for a rare disease or condition. |
| Sec. 3016. Grants for Studying Continuous Drug Manufacturing. | • Allows the FDA to issue grants to further the studying of continuous manufacturing for drugs. |
| Subtitle C<br>Modern Trial Design and Evidence Development | |
| Sec. 3021. Novel Clinical Trial Designs. | • Requires FDA to hold a public meeting and issue guidance documents that would assist sponsors in incorporating adaptive designs and novel statistical modeling into new drug applications. |
| Sec. 3022. Real World Evidence. | • Requires FDA to evaluate the use of real world evidence to help support the approval of a new indication for a previously approved drug and to help support or satisfy post-approval study requirements. |
| Sec. 3023. Protection of Human Research Subjects. | • Requires the Secretary of HHS to harmonize differences between the human subject regulations under the Common Rule and the Federal Food Drug and Cosmetic Act.<br>• Streamlines the institutional review board process for trials that are being conducted at multiple sites. |
| Sec. 3024. Informed Consent Waiver or Alteration for Clinical Investigations. | • 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. |
| Subtitle D<br>Patient Access to Therapies and Information | |
| Sec. 3031. Summary Level Review. | • Allows FDA to rely upon qualified data summaries to support the approval of an application for a new indication of an already approved drug.<br>• Sponsors of the application still must submit all information to FDA. |

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| Sec. 3032. Expanded Access Policy. | • Requires that pharmaceutical companies have publicly accessible compassionate use policies for drugs treating serious or life-threatening conditions. |
| Sec. 3033. Accelerated Approval for Regenerative Advanced Therapies. | • Allows FDA to grant accelerated approval for regenerative therapeutic products.<br>• Directs FDA to consider the unique characteristics of regenerative therapeutic products and provide a rationale with a determination of whether or not to grant accelerated approval.<br>• Does not change the standards of evidence or limit any other of the authorities of the FDA. |
| Sec. 3034. Classification of Devices Used with Regenerative Advanced Therapies. | • Establishes that devices used with a regenerative therapeutic product will be considered moderate risk devices, unless the Secretary determines that the device or intended use requires a higher risk classification. |
| Sec. 3035. Updated Regenerative Medicine Guidance and Regulations. | • Requires the FDA to update guidance and regulations with regard to regenerative therapeutic products, and hold a public meeting to encourage innovation. |
| Sec. 3036. Standards for Regenerative Medicine and Advanced Therapies. | • Requires FDA to consult with stakeholders and the National Institute of Standards and Technology in order to establish standards, to support the development, evaluation, and review of regenerative medicine and advanced therapies products.<br>• Defines "regenerative medicine and advanced therapies" – includes cell therapy gene therapy, gene-modified cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. |
| Sec. 3037. Health Care Economic Information. | • Clarifies the scope of permissible manufacturer communications regarding health care economic information to certain entities. |
| Sec. 3038. Combination Product Innovation. | • Improves the regulation of combination products – products that contain both a drug and device, for example – by requiring that FDA meet with sponsors and agree early in development how to best study the combination product to meet the standard for approval.<br>• Clarifies how dispute resolution works when the different centers of FDA do not agree.<br>• Includes provisions for reporting on combination product regulation. |
| Subtitle E<br>Antimicrobial Innovation and Stewardship | |
| Sec. 3041. Antimicrobial Resistance Monitoring. | • Requires reporting from CDC and FDA on information and data regarding human resistance to antimicrobial drugs.<br>• Requires CDC to distribute educational materials related to antimicrobial stewardship programs or practices to health care facilities, such as long-term care facilities and community and rural hospitals.<br>• Requires CDC to provide a mechanism where health care facilities can report antimicrobial data that will be made available to the public. |

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| Sec. 3042. Limited Population Pathway. | • Provides FDA with the flexibility to approve antimicrobial drugs based on a limited population if the drug treats a life-threatening infection.<br>• If FDA approves a drug based on a limited population, the labeling and advertising of an antimicrobial drug shall contain "Limited Population" along with a proprietary name of the drug.<br>• Gives FDA the authority to review and approve promotional materials of a drug approved based on a limited population at least 30 days prior to drug dissemination. |
| Sec. 3043. Prescribing Authority. | • Clarifies and reiterates that nothing in this section will restrict the prescribing authority of antimicrobial drugs or limit the practice of health care providers. |
| Sec. 3044. Susceptibility Test Interpretive Criteria for Microorganisms. | • Provides FDA with the authority to rely on third party experts when updating guidelines for how much of a drug to use and which infections the drug is useful in treating. |
| Subtitle F<br>Medical Device Innovations | |
| Sec. 3051. Breakthrough Devices. | • Establishes a breakthrough device pathway, which builds on the existing priority review device pathway. |
| Sec. 3052. Humanitarian Device Exemption. | • 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. |
| Sec. 3053. Recognition of Standards. | • 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. |
| Sec. 3054. Certain Class I and Class II Devices. | • Requires FDA to update lists regarding the appropriate regulation of Class I and Class II devices. |
| Sec. 3055. Classification Panels. | • Improves the medical device classification panel review process at FDA to ensure adequate expertise among panel members to assess the device and allow for presentation by the device sponsor to the panel, among other things. |
| Sec. 3056. Institutional Review Board Flexibility. | • Strikes 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. |
| Sec. 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. |
| Sec. 3058. Least Burdensome Device Review. | • Requires an audit by the FDA ombudsman and an assessment of the measurements used to track the implementation of the least burdensome requirements.<br>• 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. |

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| Sec. 3059. Cleaning Instructions and Validation Data Requirement. | • Encourages and clarifies that the FDA requires cleaning and validation data for reusable medical devices. |
| Sec. 3060. Clarifying Medical Software Regulation. | • Identifies five specific categories of medical software that, given certain conditions, will not be regulated as a medical device by the FDA based on their low level of risk to patients.<br>• Provides FDA with the authority to regulate software in these categories if there is found to be safety concerns. |
| Subtitle G<br>Improving Scientific Expertise and Outreach at FDA | |
| Sec. 3071. Silvio O. Conte Senior Biomedical Research Service. | • Increases the number of positions in the research service, allows increased salary, and changes the qualifications to include engineers so the service can serve FDA in addition to other HHS agencies.<br>• Requires GAO to conduct a study of the program, including the impact of the changes made in this section. |
| Sec. 3072. Hiring Authority for Scientific, Technical, and Professional Personnel. | • Provides FDA with the authority to appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products.<br>• Allows for the FDA commissioner to determine and fix the annual pay rate up to a limit to help attract and retain qualified employees.<br>• Requires FDA to publish a report on workforce planning that includes an analysis of the workforce needs at the FDA and a recruitment and retention plan for hiring qualified scientific, technical and professional candidates.<br>• Requires GAO to also report on this provision, including on the progress the FDA has made in recruiting and retaining qualified staff. |
| Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes. | • Requires FDA to pilot one or more intercenter institute(s) to help develop and implement processes for coordination of activities in major disease areas between the drug, biologics, and device centers. |
| Sec. 3074. Scientific Engagement. | • 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, and requires . |
| Sec. 3075. Drug Surveillance. | • Makes targeted edits to FDA's drug surveillance program to allow FDA to focus on risk. |
| Sec. 3076. Reagan-Udall Foundation for the Food and Drug Administration. | • Modernizes Reagan-Udall, an independent, non-profit organization established by Congress to help FDA keep up with the fast pace of science. |
| Subtitle H<br>Medical Countermeasures Innovation | |
| Sec. 3081. Medical Countermeasure Guidelines. | • Requires timely and accurate recommended utilization guidelines for qualified Medical Countermeasures (MCMs), including for products in the Strategic National Stockpile.<br>• 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. |

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| | • Clarifies the reporting requirement's annual deadline and that such report shall be submitted to the congressional committees of jurisdiction. |
| Sec. 3082. Clarifying BARDA Contracting Authority. | • 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) shall carry out the programs funded by the Special Reserve Fund, as well as the procurement contracts, grants, and cooperative agreements under BARDA. |
| Sec. 3083. Countermeasure Budget Plan. | • Requires HHS to annually develop a five-year budget plan based on identified MCM priorities.<br>• 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.<br>• Clarifies when this plan is required to be submitted to Congress and that it will be made publicly available. |
| Sec. 3084. Medical Countermeasures Innovation. | • 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 multiuse platform technologies.<br>• This provision will sunset after September 30, 2022. |
| Sec.3085. Streamlining Project BioShield Procurement. | • Updates current law to remove unnecessary steps that no longer reflect the execution of the BioShield SRF today.<br>• Ensures that there are no unnecessary delays in the development, procurement, and stockpiling of medical countermeasures to protect the American people. |
| Sec. 3086. Encouraging Treatments for Agents that Present a National Security Threat. | • Establishes a priority review voucher to encourage the development of drugs and vaccines for agents that present national security threats.<br>• Requires the HHS Secretary to award a priority review voucher to the sponsor of a material threat MCM application upon approval.<br>• Consistent with the targeted priority review vouchers under current law, this priority review voucher can be transferred and used to receive priority review of another drug application at a later date.<br>• This provision will sunset after October 1, 2023. |
| Sec. 3087. Paperwork Reduction Act Waiver During a Public Health Emergency. | • Waives the Paperwork Reduction Act requirements during the investigation of, response to, and post-response review of an event when it is determined by the HHS Secretary to be a public health emergency and the circumstances necessitate a waiver. |
| Sec. 3088. Clarifying Food and Drug Administration Emergency Use Authorization. | • Clarifies that FDA's authorities with respect to emergency use authorizations applies to animal drugs. |
| Subtitle I<br>Vaccine Access, Certainty, and Innovation | |
| Sec. 3091. Predictable Review Timelines of Vaccines by the Advisory Committee on Immunization Practices. | The Advisory Committee on Immunization Practices (ACIP) convenes meetings to consider the use of a new vaccine or a new indication for a vaccine following FDA licensure. In the event the vaccine is not considered |

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| | at the first scheduled meeting, the ACIP will provide an update on the committees review. |
| Sec. 3092. Review of Processes and Consistency of Advisory Committee on Immunization Practices Recommendations. | This section would require 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 shall publish a report on the results of the review, including recommendations on improving the consistency of the process. |
| Sec. 3093. Encouraging Vaccine Innovation. | • Vaccine Meetings – 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.<br>• Report on Vaccine Innovation – Requires the Secretary, within one year of enactment, to issue a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease. The report shall review the current status of vaccine development and:<br>o Consider the optimal process to determine which vaccines would be beneficial and how to share that information to key stakeholders,<br>o Examine and identify whether obstacles exist that inhibit the development of beneficial vaccines,<br>o Make recommendations on how to remove any obstacles identified in order to promote and incentivize vaccine innovation and development.<br>• Consultation – 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.<br>• Updates the vaccine injury compensation program related to maternal immunization |
| Subtitle J<br>Technical Corrections | |
| Sec. 3101. Technical Corrections. | • Makes technical corrections to the Food, Drug, and Cosmetic Act. |
| Sec. 3102. Completed Studies. | • Strikes studies from the law that have been completed. |
| TITLE IV: DELIVERY | |
| Sec. 4001. Assisting Doctors and Hospitals in Improving Quality of Care for Patients. | • Reduces documentation burden on health care providers while maintaining quality.<br>• Encourages certification of health information technology (HIT) for specialty providers and sites of service. |
| Sec. 4002. Transparent Reporting on Usability, Security, and Functionality. | • Establishes a grant program to create an unbiased reporting system to engage stakeholders and gather information about electronic health record (EHR) usability, interoperability, and security to help providers better choose EHR products. |

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| Sec. 4003. Interoperability. | • Expedites interoperability among EHRs by developing or supporting a voluntary model framework and common agreement for the secure exchange of health information to help foster bridging between networks by:<br>  o Creating a digital health care provider directory to facilitate exchange; and<br>  o Requiring HHS to defer to HIT standards developed in the private sector.<br>• Combines and reforms existing HIT Policy and Standards Advisory Committees to create a more streamlined HIT Advisory Committee to specifically address issues related to interoperability, privacy, and security.<br>• The new HIT Advisory Committee will engage stakeholders to identify priorities for standards adoption. |
| Sec. 4004. Information Blocking. | • Establishes authority for the HHS Office of the Inspector General to investigate claims of information blocking and assign penalties for practices found to be interfering with the lawful sharing of EHRs. |
| Sec. 4005. Leveraging Electronic Health Records to Improve Patient Care. | • Encourages the exchange of health information between registries and electronic health record systems.<br>• Adds developers of health information technology to Patient Safety Organizations to help improve the safety of HIT products for patients. |
| Sec. 4006. Empowering Patients and Improving Patient Access to their Electronic Health Information. | • Supports the certification and development of patient-centered EHRs so that patients have better access to their secure and up-to-date health information.<br>• Encourages the use of Health Information Exchanges to promote patient access by educating providers on allowable sharing of patient health information.<br>• Requires HHS to educate health care providers on allowable uses and sharing of patient health information and clarify misunderstandings that may be currently impeding lawful sharing. |
| Sec. 4007. GAO Study on Patient Matching. | • Requires the Government Accountability Office (GAO) to conduct a study on methods for securely matching patient records to the correct patient. |
| Sec. 4008. GAO Study on Patient Access to Health Information. | • Requires the GAO to carry out a review of patient access to health information, including:<br>  o Barriers to access;<br>  o Complications health care providers experience when providing access; and<br>  o Methods patients may use for requesting their personal health information. |
| Sec. 4009. Streamlining Transfers Used for Educational Purposes. | • Exempts certain transfers of value from reporting requirements that health care providers have noted have a chilling effect on their engagement in important continuing medical education activities. |
| Sec. 4010. Improving Medicare Local Coverage Determinations. | • Increases transparency around the Local Coverage Determination (LCD) process<br>• Begins the process of bringing greater accountability to the actions of those contracting with the Centers for Medicare and Medicaid Services (CMS) to manage the operation of the Medicare program. |

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| Sec. 4011. Medicare Pharmaceutical and Technology Ombudsman. | • Creates a new Medicare Pharmaceutical and Technology ombudsman to address problems relating to coverage of new and life-saving technologies. |
| Sec. 4012. Medicare Site-of-Service Price Transparency. | • Gives seniors the ability to shop among certain sites of service for certain services so that they can identify the most cost-effective treatments and better control their out-of-pocket costs. |
| Sec. 4013. Telehealth Services in Medicare. | • Supports the efforts of the Energy and Commerce Bipartisan Telemedicine Member Working Group.<br>• Requires specific actions of government bodies identified as critical to developing a long-term solution to telehealth services under the Medicare program. |
| TITLE V: SAVINGS | |
| Sec. 5001. Savings in the Medicare Improvement Fund. | • Amends the dollar figure in the Medicare Improvement Fund available to the HHS Secretary. |
| Sec. 5002. Medicaid Reimbursement to States for Durable Medical Equipment. | • Modifies the implementation date of the current law limitation federal Medicaid reimbursement to states for durable medical equipment, prosthetics, orthotics, and supplies to Medicare reimbursement rates. This limitation would be effective starting January 1, 2018. |
| Sec. 5003. Penalties for Violations of Grants, Contracts, and Other Agreements. | • Clarifies and expands the HHS Office of the Inspector General's authority to use civil monetary penalties in cases of proven HHS grant or contract fraud. |
| Sec. 5004. Reducing Overpayments of Infusion Drugs. | • Sets payment amounts for Part B drugs infused through durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items using the methodology used for most physician-administered drugs: Average Sales Price (ASP) plus 6 percent. Applying the ASP+6 percent methodology to DMEPOS infused drugs would result in payment amounts that reflect actual transaction prices. This change is based on findings from the HHS OIG which found that the current payment methodology –based on manufacturer sticker prices that were in effect in 2003 – currently over pays some drugs while underpaying for others. |
| Sec. 5005. Increasing Oversight of Termination of Medicaid Providers. | • Improves the ability of States to identify health care providers who have been terminated from participating in Medicare or in another State's Medicaid or CHIP program, by requiring providers participating in Medicaid and CHIP managed care to enroll with the State, and increasing required reporting, sharing of information, and standardization of documentation of reasons for termination. |
| Sec. 5006. Requiring Publication of Fee-for-Service Provider Directory. | • Requires State Medicaid programs provide beneficiaries served under fee-for-service or primary care case management programs an electronic directory of physicians participating in the program. The directory would include the physician's name, specialty, address and telephone number. Additionally, for physicians serving as case managers through PCCM programs, information on whether the physician is accepting new patients, and the physician's cultural and linguistic capabilities. |
| Sec. 5007. Fairness in Medicaid Supplemental Needs Trusts. | • Under current law, a special needs trust can only be established by parents, grandparents, legal guardians, or a court. Individuals wanting to set up special needs trusts for themselves have to file a petition with a court, which can take many months. This provision permits non-elderly |

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| | individuals with disabilities to establish their own special needs trust without having to file a petition with a court. A special needs trust is a specific type of trust defined in Medicaid statute that can only be established on behalf of non-elderly individuals with disabilities. |
| Sec. 5008. Eliminating Federal Financial Participation With Respect to Expenditures Under Medicaid for Agents Used for Cosmetic Purposes or Hair Growth. | • Eliminates federal Medicaid matching funds for prescription drugs used for cosmetic purposes or hair growth unless they are determined to be medically necessary. Currently, states are not required to cover these types of prescription drugs. |
| Sec. 5009. Amendment to the Prevention and Public Health Fund. | • Rescinds $3.5 billion from the Prevention and Public Health Fund. |
| Sec. 5010. Strategic Petroleum Reserve Drawdown. | • Directs the DOE to sell a portion of he SPR, subject to certain conditions. Under this bill, the proceeds from such sales would be deposited in the general fund of the Treasury by the end of each fiscal year and could not be spent to purchase oil for the reserve. |
| Sec. 5011. Rescission of Portion of ACA Territory Funding | • Rescinds $464 million available to territories under the 1323(c)(1) of the Affordable Care Act. |
| Sec. 5012. Medicare Coverage of Home Infusion Drug Therapy | • Updates infusion payment policy to better reflect the totality of servicing beneficiaries |