DIVISION A: 21ST CENTURY CURES	
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. • 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. • 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 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. • Requires tracking on the effect of innovations funded by prize competitions under this section and their effect on federal expenditures. o Requires this information to be included in the Triennial Report.
Subtitle B 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. • Among other activities, the initiative may include developing new approaches for: o Addressing scientific, medical, public health, and regulatory science issues; o Applying genomic technologies; and o Gathering information from volunteers to better understand health and disease. • Encourages the Secretary of HHS to coordinate with other federal

	departments, utilize public-private partnerships, and leverage existing data sources. • 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. • Prohibits researchers to whom certificates are issued from disclosing the name of participants or any other identifiable data gathered during research, except when: o Required by federal, state, or local law; o Necessary to treat the individual in question; o The individual gives consent; or o Disclosure of information is for the purposes of other research in compliance with privacy laws. • Prohibits researchers who are issued certificates from being compelled to disclose identifiable, sensitive information about participants that was gathered during research. • 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. • The protections of this section are afforded in perpetuity. • 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. 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. • 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 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. • 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. o Fiscal Year (FY) 2016 appropriations included direction for the National Academies to carry out such a study.
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. • Increases the maximum yearly loan repayment amount from $35,000 to $50,000. • 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 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. • Requires the coordinated strategy to identify strategic research priorities, including: o An assessment of biomedical and behavioral research, and opportunities for basic and translational research; o Priorities and objectives to advance prevention, treatment, and cures; o Emerging scientific opportunities, including public health challenges; and o Near-, mid-, and long-term scientific needs. • 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. • 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. • 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. 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. • Clarifies that directors of national research institutes or national centers must review and make final decisions on funding awards. • 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: o 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. o Make revisions to harmonize existing policies and reduce administrative burden.

	○ Consider: ▪ Modifying the timelines for reporting conflicts of interest; ▪ Ensuring that financial interest disclosure requirements are appropriate for awards that will directly fund research; and ▪ Updating any applicable training modules of the NIH related to federal financial interest disclosure. • 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. • 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. • 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: ○ Identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative; ○ Take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and ○ Take other actions to improve the coordination of regulations and policies with respect to research with laboratory animals. • Requires the Secretary of HHS to clarify the applicability of the requirements under the Office of Management and Budget (OMB) • 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. • Requires OMB to establish an advisory committee, called the "Research Policy Board". ○ 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: ▪ Providing thorough and informed analysis of regulations and policies; ▪ Identifying adverse consequences of existing policies and making actionable recommendations to improve such policies; ▪ 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 ▪ Conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes. ○ 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. 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. • 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. • 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. • 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). • Increases the clinical trial phase through which NCATS may support clinical trial activities for treatment of a rare disease of condition so long as– 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. • Improves transparency, including by requiring reporting on the methods and tools that had been developed since the last NCATS report and 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: o Information to better evaluate scientific opportunity, public health burdens, and progress reducing health disparities; 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. • 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. • Requires the Director of NIH to improve research related to minority populations. • Encourages the Director of the National Institute on Minority Health and Health Disparities to foster partnerships and encourage the funding of collaborative research projects. • Requires the Director of NIH to update guidelines for the inclusion of women in clinical research to reflect the most current science. • 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: o Pre-clinical experiment design, including analysis of sex as a biological variable; o Clinical experiment design; o Applicable levels of rigor in statistical methods, methodology, and analysis, and o Data and information sharing. • Requires the Director of NIH to consider the working group's recommendations and develop or update policies as appropriate within 18 months. • 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. o The report shall include recommendations for revising and updating the Rehabilitation Research Plan. o Specifies that the Rehabilitation Research Plan must also identify existing resources to support the purposes of the center. o 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. • Encourages coordination of medical rehabilitation research among agencies of NIH and other federal agencies, including through interagency agreements. • 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	• Establishes a Task Force on Research Specific to Pregnant Women and Lactating Women, to provide advice and guidance to the Secretary of

Women and Lactating Women.	HHS with the goal of addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women. • 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. • Requires the task force to prepare and submit a report to Congress that includes: o 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; o Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research; o Effective communication strategies with health care providers and the public on information relevant to pregnant and lactating women; o 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. o Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women. • 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. • 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. • Repeals the review and report on the Centers of Excellence.
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. 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 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. • 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. • 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 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. • 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. • 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 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	• Sets forth a sense of Congress that NIH and FDA should work with the

Clinical Study Network.	European Union, industry, and others to establish a global pediatric clinical study network.
TITLE III: DEVELOPMENT	
Subtitle A 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: o Appropriate ways to collect data for use by the FDA for use in regulatory decisions; o How patients wishing to propose draft guidance to FDA may submit such documents; o How FDA will respond to patient experience data submissions to FDA; o The format and content for patient experience data submissions to FDA; and 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 Advancing New Drug Therapies	
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. • 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. • 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 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. • 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 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. • Sponsors of the application still must submit all information to FDA.
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. • 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. • 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	• Requires the FDA to update guidance and regulations with regard to

Medicine Guidance and Regulations.	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. • 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. • Clarifies how dispute resolution works when the different centers of FDA do not agree. • Includes provisions for reporting on combination product regulation.
Subtitle E 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. • 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. • Requires CDC to provide a mechanism where health care facilities can report antimicrobial data that will be made available to the public.
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. • 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. • 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 Medical Device Innovations	
Sec. 3051. Breakthrough	• Establishes a breakthrough device pathway, which builds on the existing priority review device pathway.

Devices.	
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. • 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.
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. • Provides FDA with the authority to regulate software in these categories if there is found to be safety concerns.
Subtitle G 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. • 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. • Allows for the FDA commissioner to determine and fix the annual pay rate up to a limit to help attract and retain qualified employees. • 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. • 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 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. • 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. • 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. • 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. • 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. • This provision will sunset after September 30, 2022.
Sec.3085. Streamlining Project	• Updates current law to remove unnecessary steps that no longer reflect

BioShield Procurement.	the execution of the BioShield SRF today. • 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. • Requires the HHS Secretary to award a priority review voucher to the sponsor of a material threat MCM application upon approval. • 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. • 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 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 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. • 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: o Consider the optimal process to determine which vaccines would be beneficial and how to share that information to key stakeholders, o Examine and identify whether obstacles exist that inhibit the development of beneficial vaccines, o Make recommendations on how to remove any obstacles identified in order to promote and incentivize vaccine innovation and development. • 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. • Updates the vaccine injury compensation program related to maternal immunization
Subtitle J 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. • 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.
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: o Creating a digital health care provider directory to facilitate exchange; and o Requiring HHS to defer to HIT standards developed in the private sector. • 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. • 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. • 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. • Encourages the use of Health Information Exchanges to promote patient access by educating providers on allowable sharing of patient health information. • 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: o Barriers to access; o Complications health care providers experience when providing access; and 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 • 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.
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. • 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 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

Helping Families in Mental Health Crisis Reform Act of 2016

Title VI—Strengthening Leadership and Accountability

SUBTITLE A—Leadership

Sec. 6001. Assistant Secretary for Mental Health and Substance Use

Establishes an Assistant Secretary for Mental Health and Substance Use (Assistant Secretary) to head the Substance Abuse and Mental Health Services Administration (SAMHSA). The authorities of the existing SAMHSA Administrator are transferred to the Assistant Secretary.

Sec. 6002. Strengthening the Leadership of the Substance Abuse and Mental Health Services Administration

- Requires the Assistant Secretary to:
  - Maintain a system to disseminate research findings and evidence-based practices to service providers to improve treatment and prevention services and incorporate these findings into SAMHSA programs;
  - Ensure that grants are subject to performance and outcome evaluations and that center directors consistently document the grant process and conduct ongoing oversight of grantees;
  - Consult with stakeholders to improve community-based and other mental health services, including adults with a serious mental illness (SMI), and children with a serious emotional disturbance (SED);
  - Collaborate with other federal departments, including the Departments of Defense (DOD), Veterans Affairs (VA), Housing and Urban Development (HUD), and Labor (DOL) to improve care for veterans and service members, and support programs to address chronic homelessness; and
  - Work with stakeholders to improve the recruitment and retention of mental health and substance use disorder professionals.

Sec. 6003. Chief Medical Officer

- Establishes a Chief Medical Officer (CMO) within SAMHSA to assist the Assistant Secretary in evaluating and organizing programs within the agency and to promote evidence-based and promising best practices emphasizing clinical focus.
- Requires the CMO to have real-world experience providing mental health care or substance use disorder treatment services.
- Requires the CMO to coordinate with the Assistant Secretary for Planning and Evaluation (ASPE) to assess the use of performance metrics to evaluate SAMHSA programs, and to coordinate with the Assistant Secretary to ensure consistent utilization of appropriate performance metrics and evaluation designs.

Sec. 6004. Improving the Quality of Behavioral Health Programs

- Codifies the existing Center for Behavioral Health Statistics and Quality (CBHSQ) at SAMHSA.
- CBHSQ is required to coordinate with the Assistant Secretary, the ASPE, and the CMO to improve the quality of services provided by SAMHSA.

Sec. 6005. Strategic Plan

- Requires SAMHSA to develop a strategic plan every four years that identifies priorities, including a strategy for improving the recruitment, training, and retention of the mental health workforce.
- The plan must take into consideration recommendations of the ASPE and the Interdepartmental Serious Mental Illness Coordinating Committee established in Sec. 121.
- The plan will:
  - Identify strategic priorities, goals, and measurable objectives for mental and substance use disorder activities and programs;
  - Identify ways to improve program quality;

- Ensure programs are providing access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services;
- Identify ways to address workforce issues; and,
- Include a strategy to disseminate evidence-based best practices for prevention, diagnosis, early intervention, treatment, and recovery focusing on those with SMI, SED, and Substance Use Disorder (SUD).

Sec. 6006. Biennial Report Concerning Activities and Progress

- Requires SAMHSA to submit a biennial report to Congress containing a review of progress toward strategic priorities, goals, and objectives identified in the strategic plan as well as an assessment of programs, and a description of coordination activities.
- This report will also include program improvement recommendations made by the ASPE.
- The Assistant Secretary may also consolidate existing reporting requirements into the biennial report to ease the agency's administrative burden.

Sec. 6007. Authorities of the Centers for Mental Health Services (CMHS), Substance Abuse Prevention (CSAP), and Substance Abuse Treatment (CSAT)

- Updates statute to reflect changes in terminology as well as increases coordination and cooperation with other relevant federal agencies.
- Requires the Director of CMHS to collaborate with the National Institute of Mental Health (NIMH) to ensure mental health programs reflect the best available science and are evidence-based and to improve grants management.

Sec. 6008. Advisory Councils

- Amends current law regarding the advisory councils for SAMHSA, CSAT, CSAP, and CMHS to:
  - Add the Directors of the NIMH, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse as ex officio members of the applicable advisory councils;
  - Ensure that at least half of the appointed advisory council members for CMHS have a medical degree, doctoral degree in psychology, or an advanced degree in nursing or social work, and specialize in mental health; and
  - Ensure that at least half of the appointment advisory council members for CSAP and CSAT have a medical degree, doctoral degree, an advanced degree in nursing, public health, behavioral or social sciences, social work, or are a certified physician assistant, and have relevant experience.

Sec. 6009. Peer Review

- Ensures that at least half of the members of a peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work. The Secretary shall also ensure to the extent possible that peer review groups include broad geographic representation.

SUBTITLE B—Oversight and Accountability

Sec. 6021. Improving Oversight of Mental and Substance Use Disorders Programs Through the Assistant Secretary for Planning and Evaluation

- Outlines the role and responsibilities of the ASPE at the Department of Health and Human Services (HHS) in planning and evaluating activities related to mental health and substance use disorder programs.
- Requires the ASPE to provide recommendations to Secretary of HHS, the Assistant Secretary for Mental Health and Substance Use, and Congress on improving related mental and substance use disorder prevention and treatment programs.

- Requires the ASPE, within 180 days of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, to develop a strategy for conducting ongoing evaluations on key programs across the agency. The evaluation shall focus on:
    - Prevention, intervention, treatment, and recovery support services;
    - The reduction of homelessness and incarceration among those with mental illness or SUD; and
    - A plan for assessing the use of performance metrics to evaluate related activities by those receiving relevant grants, contracts, or cooperative agreements. The recommendations of the ASPE must be included in the biennial report required in Section 106.

Sec. 6022. Reporting for Protection and Advocacy Organizations

- Requires Protection and Advocacy Organizations to provide a detailed, disaggregated accounting of from where their funds were received. This does not represent a new reporting requirement.

Sec. 6023. GAO Study

- Requires the Government Accountability Office (GAO) to conduct a study on programs funded under Title I of the Protection and Advocacy for Individuals with Mental Illness Act.
- The report will review programs carried out by states and private, non-profit organizations, compliance with statutory and regulatory responsibilities including relating to the grievance procedure for clients, prospective clients or their family members, availability of adequate medical and behavioral health treatment, and denial of rights for individuals with mental illness.

SUBTITLE C—Interdepartmental Serious Mental Illness Coordinating Committee

Sec. 6031. Inter-Departmental Serious Mental Illness Coordinating Committee

- Creates a coordinating committee to evaluate federal programs related to SMI and provide recommendations to better coordinate mental health services for people with SMI.
- The committee is made up of HHS, the Centers for Medicare and Medicaid Services (CMS), the Department of Justice (DOJ), VA, DOD, HUD, the Department of Education, DOL, and the Social Security Administration (SSA), as well as patients, health care providers, researchers, a judge, and a law enforcement officer.
- The committee will make recommendations to Congress for better coordination of mental health services for people with SMI or SED and will convene working groups on relevant issues.
- The committee will sunset after six years.

Title VII—Ensuring Mental and Substance Use Disorder Prevention, Treatment, and Recovery Programs Keep Pace with Science and Technology

Sec. 7001. Encouraging Innovation and Evidence-Based Programs

- Establishes the National Mental Health and Substance Use Policy Laboratory (NMHSUPL) within SAMHSA and moves the existing functions of the Office of Policy, Planning, and Innovation (OPPI) underneath.
- The NMHSUPL will promote evidence-based practices and service delivery models through evaluating models that would benefit from further development and through expanding, replicating, or scaling evidence-based programs across a wider area.
- Authorizes the appropriation of $14 million for the period of fiscal years 2018-2020 for such grants.

Sec. 7002. Promoting Access to Information on Evidence-Based Programs and Practices

- Allows the Assistant Secretary to improve access to information on evidence-based programs and practices for states, local communities, nonprofit entities, and other stakeholders.

Sec. 7003. Priority Mental Health Needs of Regional and National Significance

- Updates and reauthorizes the Priority Mental Health Needs of Regional and National Significance Program to support prevention, treatment, and rehabilitation of mental health services and other programs to target responses based on mental health needs.
- Reauthorizes the appropriation at the last appropriated level of $394,550,000 for fiscal years 2018-2022.

Sec. 7004. Substance Use Disorder Treatment Needs of Regional and National Significance

- Updates and reauthorizes the Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program to improve the quality and availability of treatment and rehabilitation services for substance use disorder services in targeted areas.
- Reauthorizes the appropriation at the last appropriated level of $333,806,000 for fiscal years 2018-2022.

Sec. 7005. Priority Substance Use Disorder Prevention Needs of Regional and National Significance

- Updates and reauthorizes the Priority Mental Health Needs of Regional and National Significance Program to support projects and programs for prevention of substance use and other programs to target responses based on health needs.
- Reauthorizes the appropriation at the last appropriated level of $211,148,000 for fiscal years 2018-2022.

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

Sec. 8001. Community Mental Health Services Block Grant

- Gives states additional flexibility to use Community Mental Health Services (CMHS) block grant funding to provide community mental health services for adults with SMI and children with SED.
- Updates state plan requirements to:
    - Identify a single state agency to administer the grant and establish goals and objectives.
    - Describe how the state promotes evidence-based practices, including programs for SMI.
    - Ensure states will:
        - Coordinate services to maximize efficiency, effectiveness, quality, and cost-effectiveness to improve outcomes.
        - Provide for an organized community-based system of care for individuals with mental illness and co-occurring disorders.
- Reauthorizes the CMHS Block Grant at the last appropriated level of $532,571,000 for fiscal years 2018-2022.

Sec. 8002. Substance Abuse Prevention and Treatment Block Grant

- Clarifies the state will ensure ongoing training for substance use disorder prevention and treatment professionals on recent trends in drug abuse in the state, evidence-based practices for substance use disorder services, performance-based accountability, and data collection and reporting requirements.
- Modifies the state plan requirements to:
    - Include a description of the state's system of care;
    - Identify a single state agency to administer the grant and establish goals and objectives;
    - Provide information on the need for substance use disorder prevention and treatment services;
    - Describe state and local coordination of prevention and treatment services with other agencies;
    - Describe how the state promotes evidence-based practices;
    - Describe how the state integrates substance use disorder services with primary health care and mental health care;
- Reauthorizes the block grant at the last appropriated level of $1,858,079,000 billion for fiscal years 2018-2022.

Sec. 8003. Additional Provisions Related to the Block Grants

- Allows states to submit a joint application for the mental health and substance abuse block grants. This is a codification of existing practice.
- Allows the Assistant Secretary to waive application deadlines and compliance requirements for states in the case of a public health emergency declared by the HHS Secretary.

Sec. 8004. Study of Distribution of Funds under the Substance Abuse Prevention and Treatment Block Grant and the Community Mental Health Services Block Grant

- Requires the Secretary of HHS to study whether funding for the mental health and substance abuse block grants are being distributed to states and territories according to need, and recommend changes if necessary.
- Requires the report to be submitted to Congress within two years of enactment of the bill.

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

SUBTITLE A—Helping Individuals and Families

Sec. 9001. Grants for Treatment and Recovery for Homeless Individuals

- Reauthorizes and makes technical updates to grants for treatment and recovery for homeless individuals to support mental health and substance use disorder services.
- Reauthorizes appropriations at the last appropriated level of $41,304,000 for each of fiscal years 2018-2022.

Sec. 9002. Grants for Jail Diversion Programs

- Reauthorizes and makes technical updates to develop and implement programs to divert individuals with a mental illness from the criminal justice system to community-based services.
- Reauthorizes appropriations at the last appropriated level of $4,269,000 for each of fiscal years 2018-2022.

Sec. 9003. Promoting Integration of Primary and Behavioral Health Care

- Reauthorizes grants to support integrated care models for primary care and behavioral health care services.
- Requires grant applicants to submit a plan to provide integrated services to special populations.
- Reauthorizes appropriations at the last appropriated level of $51,878,000 for each of fiscal years 2018-2022.

Sec. 9004. Projects for Assistance in Transition from Homelessness

- Reauthorizes and makes updates to 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.
- Directs the Administrator to evaluate the formula used to determine funding allotments and report to Congress within two years.
- Reauthorizes appropriations at the last appropriated level of $64,635,000 for each of fiscal years 2018-2022.

Sec. 9005. National Suicide Prevention Lifeline Program

- Requires the Secretary to continue the National Suicide Prevention Lifeline program, including:
    - Coordinating a network of crisis centers to provide suicide prevention and crisis intervention services;
    - Maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources;
    - Consulting with the Secretary of Veterans Affairs to ensure veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline.
- Authorizes appropriations at the last appropriated level of $7,198,000 for each of fiscal years 2018-2022.

Sec. 9006. Connecting Individuals and Families with Care

- Requires the Secretary to maintain the National Treatment Referral Routing Service to help individuals and families locate mental health and substance use disorder treatment providers through a nationwide phone system and internet website.

Sec. 9007. Strengthening Community Crisis Response Systems

- Authorizes the Secretary to award grants to state and local governments, Indian tribes, and tribal organizations to strengthen community-based crisis response systems or to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities.
- An entity receiving a grant must submit a report at the Secretary's request, including an evaluation of the effect of such grants on local crisis response activities for individuals receiving crisis planning and early intervention support, individuals reporting improved outcomes, and individuals receiving regular follow-up care following a crisis.
- Authorizes the appropriation of $12.5 million for the period of fiscal years 2018-2022.

Sec. 9008. Garrett Lee Smith Memorial Act Reauthorization

- Codifies the suicide prevention technical assistance center to provide information and training for suicide prevention, surveillance, and intervention strategies for all ages, particularly among groups at high risk.
    - Reauthorizes the appropriation at the last appropriated level of $5,988,000 for each of fiscal years 2018-2022.
- Reauthorizes the Youth Suicide Early Intervention and Prevention Strategies grants to states and tribes, and clarifies that states may receive continuation grants after the first grant is awarded.
    - Reauthorizes the appropriation of $30 million for each of fiscal years 2018-2022.

Sec. 9009. Adult Suicide Prevention

- Establishes suicide prevention and intervention programs grants for individuals aged 25 years or older. The grants are to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.
- Authorizes the appropriation of $30 million for the period of fiscal years 2018-2022.

Sec. 9010. Mental Health Awareness Training Grants

- Reauthorizes grants to states, political subdivisions of states, Indian tribes, tribal organizations, and nonprofit private entities to train teachers, appropriate school personnel, emergency services personnel, and others, as appropriate, to recognize the signs and symptoms of mental illness, to become familiar with resources in the community for individuals with mental illnesses, and for the purpose of the safe de-escalation of crisis situations involving individuals with mental illness.
- Reauthorizes the appropriation at the last appropriated level of $14,963,000 for each of fiscal years 2018-2022.

Sec. 9011. Sense of Congress on prioritizing American Indians and Alaska Native youth within suicide prevention program

- States it is the Sense of Congress that the Secretary of HHS should prioritize programs and activities for populations with disproportionately high rates of suicide, such as American Indians and Alaska Natives.

Sec. 9012. Evidence-Based Practices for Older Adults

- Requires the Secretary to disseminate information and provide technical assistance on evidence-based practices for mental health and substance use disorders in older adults.

Sec. 9013. National Violent Death Reporting System

- Encourages the Director of the Centers for Disease Control and Prevention (CDC) to improve, particularly through the inclusion of other states, the existing National Violent Death Reporting System.

- The reporting system was created in 2002 and currently collects surveillance data from 32 states.

Sec. 9014. Assisted Outpatient Treatment

- Increases and extends an existing authorization for a grant program for Assisted Outpatient Treatment at SAMHSA.
- Reauthorizes appropriations of $15 million in fiscal year 2017, $20 million for fiscal year 2018, $19 million for each of fiscal years 2019 and 2020, and $18 million for each of fiscal years 2021 and 2022.

Sec. 9015. Assertive Community Treatment

- Establishes a grant program establish, maintain, or expand assertive community treatment programs for adults with SMI.
- The Secretary is required to report no later than 2021 an evaluation of;
    - Any cost savings and public health outcomes;
    - Rate of involvement with the criminal justice system of patients; and,
    - Rates of homelessness among patients.
- Authorizes appropriations of $5 million for the period of fiscal years 2018-2022.

Sec. 9016 Sober Truth on Preventing Underage Drinking Reauthorization

- Reauthorizes the Interagency Coordinating Committee for $1 million for each of fiscal years 2018-2022, the National Media Campaign to Prevent Underage Drinking for $1 million for each of fiscal years 2018-2022, the Community- Based Coalition Enhancement grants for $5 million for each of fiscal years 2018-2022, and funding for additional research on underage drinking for $3 million for each of fiscal years 2018-2022.
- The Secretary may also make grants under this section for practices to reduce alcohol use among individuals under the age of 21 through screening and brief intervention.

Sec. 9017. Center and Program Repeals

- Repeals section 514 of the Public Health Service Act relating to methamphetamine and amphetamine initiatives, section 506B of the Public Health Service Act relating to ecstasy and other club drugs, and eight other outdated programs.

SUBTITLE B—Strengthening the Health Care Workforce

Sec. 9021. Mental and Behavioral Health Education Training Grants

- Reauthorizes grants to institutions of higher education or accredited professional training programs to support the recruitment and education of mental health care providers.
- Creates a priority for programs that train psychology, psychiatry, and social work professionals to work in integrated care settings, and programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships.
- Requires the Administrator to include in the biennial report an assessment on the effectiveness of grants.
- Reauthorizes the appropriation of such sums as may be necessary for fiscal years 2017-2021.
- Reauthorizes appropriations at the last appropriated level of $50 million for each of fiscal years 2018-2022.

Sec. 9022. Strengthening the Mental and Substance Use Disorders Workforce

- Authorizes the Secretary to establish a training demonstration program within the Health Resources and Services Administration (HRSA) to award five-year minimum grants for:
    - Medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings;
    - Nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorder services in underserved community-based settings; and

    - Establishing, maintaining, or improving academic programs that provide training to improve the ability to recognize, diagnose, and treat mental and substance use disorders.
- Requires a study on the results of the demonstration project.
- Authorizes appropriations of $10 million for fiscal years 2018-2022.

Sec. 9023. Clarification on Current Eligibility for Loan Repayment Programs.

- Directs the Administrator of HRSA to clarify the existing eligibility of child and adolescent psychiatrists for the National Health Service Corps (NHSC) Loan Repayment Program.
- This section does not expand participation in the NHSC.

Sec. 9024. Minority Fellowship Program

- Codifies the Minority Fellowship Program for the Secretary to increase the number of professionals who provide mental or substance use disorder services to underserved, minority populations, and to improve the quality of mental and substance use disorder prevention and treatment for ethnic minorities.
- Authorizes appropriations of $12,669,000 for each of fiscal years 2018-2022.

Sec. 9025. Liability Protections for Health Professional Volunteers at Community Health Centers

- Provides medical liability protections for volunteers at deemed Community Health Centers through the Federal Tort Claims Act to remove barriers for volunteering.
- Requires the Attorney General to report to Congress annually on an estimate of claims to be paid during the year.
- Sunsets the coverage after five years.

Sec. 9026. Reports

- Requires SAMHSA and HRSA to issue a report on national- and state-level projections for the supply and demand of mental health and substance use disorder health workers and trends within the mental health and substance use disorder provider workforce.
- Requires Comptroller General to study peer-support specialist programs in states receiving grants from SAMHSA and report to Congress on:
    - Hours of formal work or volunteer experience related to mental and substance use disorders conducted;
    - Types of peer support specialist exams and codes of ethics required for such programs; and
    - Recommended skill sets and requirements for continuing education.

SUBTITLE C—Mental Health on Campus Improvement

Sec. 9031. Mental Health and Substance Use Disorder Services on Campus

- Reauthorizes the Mental Health and Substance Use Disorder Services on Campuses grant program and allows for the education of students, families, faculty, and staff to increase awareness and training to respond effectively to students with mental health and substance use disorders, to provide outreach to administer voluntary screenings and assessments to students, to enhance networks with health care providers who treat mental health and substance use disorders, and to provide direct mental health services. Incorporates consideration of the needs of veterans enrolled as students on campus
- Reauthorizes appropriations of $7 million for each of fiscal years 2018-2022.

Sec. 9032. Interagency Working Group on College Mental Health

- Provides federal leadership by establishing an interagency working group to discuss mental and behavioral health on college campuses and to promote federal agency collaboration to support innovations in mental health services and supports for students on college and university campuses.
- Authorizes appropriations of $1 million for the period of fiscal years 2018-2022 to carry out these activities.

Sec. 9033. Mental and Behavioral Health Outreach and Education on College Campuses

- Directs the Secretary of HHS in collaboration with the CDC to convene an interagency, public-private sector work group to plan, establish, and begin coordinating and evaluating a targeted, public-education campaign to focus on mental and behavioral health on the campuses of institutions of higher education.
- Authorizes appropriations of $1 million for the period of fiscal years 2018-2022 to carry out these activities.

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

Sec. 10001. Programs for Children with Serious Emotional Disturbances

- Reauthorizes and updates programs to provide comprehensive community mental health services to children with SED.
- Reauthorizes appropriations at the last appropriated level of $119,026,000 for fiscal years 2018-2022.

Sec. 10002. Increasing Access to Pediatric Mental Health Care

- Authorizes HRSA to award grants to promote behavioral health integration in pediatric primary care.
- Establishes eligibility requirements for statewide or regional pediatric mental health care telehealth programs in order to receive grant funding.
- Requires grantees to submit a comprehensive evaluation of activities carried out and a performance and outcome evaluation.
- Requires the state receiving the grant to match at least 20 percent of the federal funds.
- Authorizes appropriations of $9 million for the period of fiscal years 2018-2022.

Sec. 10003. Substance Use Disorder Treatment and Early Intervention Services for Children and Adolescents

- Reauthorizes and makes technical updates to grants for substance use disorder treatment and early intervention for children and adolescents to provide early identification and services.
- Reauthorizes appropriations at the last appropriated level of $29.6 million for each of 2018-2022.

Sec. 10004. Children's Recovery from Trauma

- Reauthorizes the National Child Traumatic Stress Initiative (NCTSI), which supports a national network of child trauma centers, including university, hospital, and community-based centers and affiliate members.
- Supports the coordinating center's collection, analysis, and reporting of child outcome and other data to inform evidence-based treatments and services. Also supports the continuum of training initiatives related to such evidence-based treatments, interventions, and practices offered to providers.
- Encourages the collaboration between NCTSI and HHS to disseminate evidence-based and trauma-informed interventions, treatments, and other resources to appropriate stakeholders.
- Reauthorizes appropriations at the last appropriated level of $46.9 million for each of fiscal years 2018-2022.

Sec. 10005. Screening and Treatment for Maternal Depression

- Establishes a grant program for states to establish, improve, or maintain programs for screening assessment and treatment services for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.
- Allows the Secretary to prioritize grants to states proposing to improve or enhance access to screening services for maternal depression in primary care settings.

- Activities supported by the grant should include providing appropriate training to health care providers, information to health care providers on maternal depression screening, treatment, and follow-up support services, and linkages to community-based resources.
- Authorizes the appropriation of $5 million for each of fiscal years 2017-2021.

Sec. 10006. Infant and Early Childhood Mental Health Promotion, Intervention, and Treatment
- Establishes a grant program to develop, maintain, or enhance mental health prevention, intervention, and treatment programs for infants and children at significant risk of developing or showing early signs of mental disorders, including SED, or social or emotional disability.
- The Secretary will ensure that programs receiving grants are replicable and utilize evidence-informed or evidence-based models, practices, and methods.
- Requires the state receiving the grant to match at least 10 percent of the federal funds.
- Authorizes $20 million for the period of fiscal years 2018-2022.

Title XI—Compassionate Communication on HIPAA

Sec. 11001. Sense of Congress
- The Sense of Congress finds that clarification is needed regarding existing permitted uses and disclosures of health information under the Health Information Portability and Accountability Act (HIPAA) by health care professionals to communicate with caregivers of adults with SMI to facilitate treatment.

Sec. 11002. Confidentiality of Records
- Requires the Secretary to, within a year of finalizing updated rules related to the confidentiality of health records related to alcohol and drug abuse, convene relevant stakeholders to determine the effect of the regulation on patient care, health outcomes, and patient privacy.

Sec. 11003. Clarification on Permitted Uses and Disclosures of Protected Health Information
- Directs the Secretary through the Director of the Office for Civil rights to clarify circumstances when a health care provider or covered entity may use or disclosure protected health information related to the treatment of an adult with a mental or substance use disorder.

Sec. 11004. Development and Dissemination of Model Training Programs
- Requires the Secretary to identify or recognize private or public entities to develop model training and educational programs to educate health care providers, regulatory compliance staff, and others regarding the permitted use and disclosure of health information under HIPAA.
- Authorizes appropriations of $10 million for the period of fiscal years 2018-2022.

Title XII—Medicaid Mental Health Coverage

Sec. 12001. Rule of Construction Related to Medicaid Coverage of Mental Health Services and Primary Care Services Furnished on the Same Day
- Clarifies that nothing in the Medicaid statute should be construed as prohibiting separate payment for the provision of mental health and primary care services provided to an individual on the same day.

Sec. 12002. Study and Report Related to Medicaid Managed Care Regulation
- Directs the Secretary acting through the Administrator of CMS to conduct a study and report on the provision of care to adults aged 21 to 65 enrolled in Medicaid managed care plans receiving treatment for a mental health disorder in an Institution for Mental Diseases (IMD). The report is due within three years and must include information on the number of individuals receiving treatment in IMDs, their lengths of stay, and how Medicaid managed care plans determine when to provide services in an IMD in lieu of other benefits, such as community-based mental health services.

Sec. 12003 Guidance on Opportunities for Innovation

- Directs the Administrator of CMS to issue a State Medicaid Director letter, within one year of enactment, on opportunities to design innovative service delivery systems to improve care for individuals with serious mental illness or serious emotional disturbance.

Sec. 12004. Study and Report on Medicaid Emergency Psychiatric Demonstration Project

- Directs the Secretary, acting through the Administrator of CMS to collect, analyze, and report on data from states that participated in the Medicaid Emergency Psychiatric Demonstration Project establish under Section 2707 of the Affordable Care Act. The report is due no later than two years after enactment.

Sec. 12005. Providing EPSDT Services to Children in IMDS

- This section specifies that, effective January 1, 2019, children receiving Medicaid-covered inpatient psychiatric hospital services are also eligible for the full range of early and periodic screening, diagnostic, and treatment services.

Sec. 12006. Electronic Visit Verification System Required for Personal Care Services and Home Health Care Services Under Medicaid

- Directs States to require the use of an electronic visit verification system for Medicaid-provided personal care services and home health services (but this policy does not require States to adopt a single system for providers within their State). States that do not require a system for personal care services by January 1, 2019, and home health services by January 1, 2023, will face a modest, incremental reduction in percentage. This policy offsets the cost of Sec. 705.

Title VIII—Mental Health Parity

Sec. 13001. Enhanced Compliance with Mental Health and Substance Use Disorder Coverage Requirements

- Requires the Departments of HHS, Labor, and Treasury to release a compliance program guidance providing illustrative examples of past findings of compliance and noncompliance with existing mental health parity requirements, including disclosure requirements and non-quantitative treatment limitations.
- Requires HHS to seek public comment on ways to improve consumer access to documents about mental health and substance use disorder benefits which are required by law to be disclosed.
- Requires HHS to issue new guidance documents to assist health plans comply with existing mental health parity requirements.
- Guidance documents will be subject to a comment period of no less than 60 days before being finalized.
- Clarifies the Secretaries' of HHS, Labor, and Treasury authority to audit a health plan in the case that such plan has been found to have violated existing mental health parity laws 5 times.

Sec. 13002. Action Plan for Enhanced Enforcement of Mental Health and Substance Use Disorder Coverage

- Requires HHS to convene a public meeting within six months of enactment to produce an action plan for improved federal and state coordination related to the enforcement of mental health parity and addiction equity requirements.
- The action plan must take into consideration the recommendations of the President's Mental Health and Substance Use Disorder Parity Task Force Final Report released in October of 2016.
- The action plan must identify specific, strategic objectives regarding how the various federal and state agencies charged with enforcement of mental health parity and addiction equity requirements will collaborate to improve enforcement; provide a timeline for when such objectives shall be met; and provide specific examples of how such objectives may be met.

Sec. 13003. Report on Investigations Regarding Parity in Mental Health and Substance Use Disorder Benefits

- Requires the Administrator of the Centers for Medicare & Medicaid Services to conduct an annual report for five years summarizing the results of all closed federal investigations completed during the preceding year with findings of any serious violation regarding compliance with exiting mental health parity requirements.

Sec. 13004. GAO study on Parity in Mental Health and Substance Use Disorders Benefits

- Requires GAO, within three years of enactment, to conduct a study on the enforcement of existing mental health parity requirements; including compliance with non-quantitative treatment limitations, an assessment of how the Secretary has used its authority to conduct audits, a review of how the various federal and state agencies responsible for enforcing mental health parity requirements have improved enforcement in line with the stated objectives outlined in the action plan under Sec. 605, and recommendations for additional enforcement, education, and coordination activities and legal authorities could better ensure compliance with existing mental health parity requirements.

Sec. 13005. Information and Awareness on Eating Disorders

- Allows HHS to update resource lists and fact sheets related to eating disorders and increase public awareness, through existing programs and activities, on the signs and symptoms of eating disorders and treating individuals with eating disorders.

Sec. 13006. Education and Training on Eating Disorders

- Allows HHS to facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to identify individuals with eating disorders, provide early intervention services, and refer patients to appropriate treatment.

Sec. 13007. Clarification of Existing Parity Rules

- Clarifies the coverage of eating disorder benefits, including residential treatment, under existing mental health parity requirements.

TITLE XIV – MENTAL HEALTH AND SAFE COMMUNITIES

SUBTITLE A–Mental Health and Safe Communities

Sec. 14001. Law Enforcement Grants for Crisis Intervention Teams, Mental Health Purposes

- Amends the Byrne Justice Assistance Grant (JAG) Program to allow law enforcement to use funds for the creation of mental health response and corrections programs, including police crisis intervention teams. Also allows state and local governments to use Byrne JAG funds in order to comply with current laws requiring the upload of certain mental health records to the National Instant Criminal Background Check System (NICS).
- Amends the Community Oriented Policing Services Grant Program (COPS) to allow law enforcement to use funds for specialized mental health response training, including crisis de-escalation.
- Amends the Fire Prevention and Control Act to allow existing grant funds to be used for training first responders and paramedics on best practices for responding to mental health emergencies, including crisis de-escalation.

Sec. 14002. Assisted Outpatient Treatment Programs

- Allows federal mental health court grant funds to be used for the creation of court-ordered outpatient treatment programs to prevent the escalation of mental health crises.

Sec. 14003. Federal Drug and Mental Health Courts

- Requires the Attorney General and the Director of the Administrative Office of United States Courts to create a Drug and Mental Health Court pilot program in at least one Federal Judicial District. As part of this program, low-level offenders who are mentally ill or addicted to narcotics would be eligible for diversion from prison so long as they comply with an intensive court-mandated treatment program. A large number of state and local governments operate similar problem-solving court programs.

Sec. 14004. Mental Health in the Judicial System

- Amends the America's Law Enforcement and Mental Health Project Act to allow state and local governments to use funds for the creation and deployment of behavioral health risk and needs assessments for mentally ill individuals in the criminal justice system.

Sec. 14005. Forensic Assertive Community Treatment Initiatives

- Amends the Mentally Ill Offender Treatment and Crime Reduction (MIOTCRA) to allow state and local governments to use existing authorized grant funds for the operation of Forensic Assertive Community Treatment (FACT) Initiatives. FACT Initiatives provide high-intensity community-based services for individuals with mental illness who are involved in the criminal justice system.

Sec. 14006. Assistance for Individuals Transitioning Out of Systems

- Amends the Second Chance Act to allow state and local governments to use reentry demonstration project grant funds for the provision of mental health treatment and transitional services (including housing) for mentally ill offenders who are re-entering the community.

Sec. 14007. Co-occurring Substance Abuse and Mental Health Challenges in Drug Courts

- Amends the federal Drug Court Grant Program to allow state and local governments to use their existing grant funds to include targeted interventions for individuals who have both a mental health and substance abuse disorder. Also allows funds to be used for the training of drug court professionals to identify and respond to these co-occurring disorders.

Sec. 14008. Mental Health Training for Federal Uniformed Services

- Requires the appropriate cabinet-level Secretary to provide mental health crisis and response training programs for members of each of the Federal Uniformed Services.

Sec. 14009. Advancing Mental Health as Part of Offender Reentry

- Amends the Second Chance Act to allow state and local governments to use reentry demonstration project grant funds under this program for the purpose of providing mental health services and to coordinate transitional services for individuals re-entering society with mental illness, substance abuse problems, or a chronic homelessness.

Sec. 14010. School Mental Health Crisis Intervention Teams

- Amends the Department of Justice Secure Our Schools program to allow state and local governments to use existing grant funds to develop and operate school-based mental health crisis intervention teams that include coordination with law enforcement agencies and specialized training for school officials.

Sec. 14011. Active-shooter Training for Law Enforcement

- Permanently authorizes the existing Department of Justice VALOR Initiative, which provides crisis response training and active-shooter training for federal, state, and local law enforcement officials.

Sec. 14012. Co-occurring Substance Abuse and Mental Health Challenges in Residential Substance Abuse Treatment Programs

- Amends the Residential Substance Abuse Treatment grant program to allow state and local governments to use funds for the purpose of developing and implementing specialized residential substance abuse treatment programs that provide treatment to individuals with co-occurring mental health and substance abuse disorders.

Sec. 14013. Mental Health and Drug Treatment Alternatives to Incarceration Programs

- Updates the existing Prosecution Drug Treatment Alternatives to Incarceration Program statute to allow state and local governments to use grant funds under this program for creating and operating programs that divert individuals with mental illness and co-occurring disorders from prisons and jails pursuant to a court-supervised intensive treatment program. Current law only allows funds under this program to be used for addressing substance abuse issues.

Sec. 14014. National Criminal Justice and Mental Health Training and Technical Assistance

- Amends MIOTCRA to allow the Attorney General to use existing authorized funds to award grants to non-profit organizations for the creation of a National Criminal Justice and Mental Health Training Center. This entity would coordinate best practices on responding to mental illness in the criminal justice system, and would provide technical assistance to governmental agencies who wish to implement these best practices.

Sec. 14015. Improving Department of Justice Data Collection on Mental Illness Involved in Crime

- Requires the Attorney General to collect and disseminate data regarding the involvement of mental illness in all homicides, as well as deaths or serious bodily injuries involving law enforcement officers.

Sec. 14016. Reports on the Number of Mentally Ill Offenders in Prison

- Requires the Comptroller General of the United States to submit a report to Congress detailing the federal, state, and local costs of imprisonment for individuals with serious mental illness, including the number and types of crimes committed by mentally ill individuals.

Sec. 14017. Department of Veterans Affairs Patients' Rights

- Ensures that veterans enjoy due process protections before being adjudicated as mentally ill by the Veterans Administration

Sec. 14018. Reauthorization of Appropriations

- Reauthorizes MIOTCRA at the previously authorized (but expired) level of $50 million/yr.

SUBTITLE B–Comprehensive Justice and Mental Health

Sec. 14021. Sequential Intercept Model

- Authorizes the Sequential Intercept Model which outlines sequential points at which a person with mental illness can be "intercepted" and kept from going further into the criminal justice system.

Sec. 14022. Prison and Jails

- Authorizes funding for prison and jail-based programs, including transitional and re-entry programs that reduce the likelihood of recidivism when a mentally-ill offender is released.

Sec. 14023. Allowable Uses

- Expands the allowable use of grant resources to enhance the capabilities of law enforcement, corrections, and mental health personnel to better identify and respond to individuals with mental illnesses who consume a disproportionate quantity of crisis services.

Sec. 14024. Law Enforcement Training

- Authorizes resources for expanded training activities, providing more officers with a basic understanding of the issues involved when responding situations with individuals with mental health crises.

Sec. 14025. Federal Law Enforcement Training

- Requires the Attorney General to create programs that offer federal first responders and tactical units comprehensive training in procedures to identify and respond appropriately to incidents involving mentally ill individuals.

Sec. 14026. GAO Report

- Requires a GAO report detailing the practices that federal first responders, tactical units, and corrections officers are trained to use in responding to individuals with mental illness, procedures to appropriately respond to incidents, the application of evidence-based practices in criminal justice settings, and recommendations on how the Department of Justice can improve information sharing and dissemination of best practices.

Sec. 14027. Evidence Based Practices

- Requires DOJ to prioritize grant applications to those who use evidence-based interventions and risk assessment tools to reduce recidivism.

Sec. 14028. Transparency, Program Accountability and Enhancing Local Authority

- Clarifies that an offender may participate in a MIOTCRA program only if the offender is selected unanimously for participation in the program by the prosecuting attorney, the defense attorney, the judge, the mental health agency representative, and the probation officer.

Sec. 14029. Grant Accountability

- Requires the Inspector General of the Department of Justice to conduct annual audits of all grant recipients under the bill’s provisions to prevent waste, fraud, and abuse of funds by grantees.

Division C: Increasing Choice, Access, and Quality in Health Care for Americans	
TITLE XV: Provisions Relating to Medicare Part A	
Sec. 15001. Development of Medicare study for HCPCS versions of MS-DRG codes for similar hospital services.	• Requires the Secretary to translate inpatient hospital codes (International Classification of Disease) to outpatient hospital (Healthcare Common Procedure Classification System) codes for 10 surgical procedures. This "crosswalk" is required to be completed no later than January 1, 2018.
Sec.15002. Establishing beneficiary equity in the Medicare hospital readmissions program.	• Requires the Secretary to implement a transitional risk adjustment methodology to serve as a proxy of socio-economic status for the Hospital Readmissions Reduction Program, including the clarification that the proxy should only apply to a hospital's Medicare population. • In addition to the transitional adjustment, the section clarifies that the Secretary is able to permanently use a more refined methodology following the analysis required by the *Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014*. • The section also requires a study by the Medicare Payment Advisory Commission (MedPAC), and allows for an analysis of "V-codes" and an exploration of potential exclusions.
Sec. 15003. Five-year extension of the rural community hospital demonstration program.	• Requires the Secretary to extend the current-law Rural Community Hospital Demonstration for an additional 5 years.
Sec. 15004. Regulatory relief for LTCHs.	• Provides regulatory relief for Long-Term Care Hospitals (LTCHs) by allowing LTCHs to qualify for a "mid-build" exception to the current law moratorium on bed expansion. • The section is offset by a reduction to LTCHs outlier payments, requiring a higher threshold for LTCHs discharges to qualify for outlier payments.
Sec. 15005. Savings from IPPS MACRA pay-for through not applying documentation and coding adjustments.	• Reduces the payment update that was included in the bipartisan *Medicare and CHIP Reauthorization Act (MACRA) of 2015.* Specifically, the update of 0.5 percent for fiscal year 2018, is changed to an update of 0.4588.
Sec. 15006. Extension of certain LTCH Medicare payment rules	• Makes a modification to the *Bipartisan Budget Act of 2013 (BBA '13). BBA '13* prohibited the Secretary from enforcing the LTCH 25-percent rule (no more than 25-percent of a LTCH's admissions can come from the same inpatient acute hospital) through June 30, 2016. This section extends the prohibition for an additional 12-months from October 1, 2016 through October 1, 2017.

Sec 15007. Application of rules on the calculation of hospital length of stay to all LTCHs.	• Makes a modification to the *Bipartisan Budget Act of 2013 (BBA '13).* *BBA '13* carved-out Medicare Advantage (MA) and site neutral discharges from the calculation of the 25-day average length of stay requirement for all LTCHs operating under the Medicare program prior to December 26, 2013. This section affords the same relief to any LTCH that takes advantage of the current law moratorium exception.
Sec. 15008. Change in Medicare classification for certain hospitals.	• Codifies changes, in statute, that the Centers for Medicare and Medicaid Services (CMS) has already made to its regulations for certain applicable LTCHs who were exempted from the inpatient prospective payment system established in the *Tax Equity and Fiscal Responsibility Act of 1982*.
Sec. 15009. Temporary extension to the application of the Medicare LTCH site neutral provisions for certain spinal cord specialty hospitals.	• Provides for a temporary exception of the LTCH site neutral criteria for certain hospitals that treat patients nationwide with brain and spinal cord injuries for fiscal years 2018 and 2019.
Sec. 15010. Temporary extension to the application of the Medicare LTCH site neutral provision for certain discharges with severe wounds.	• Provides for a temporary exception of the LTCH site neutral criteria for payments for hospitalizations for severe wounds for all grandfathered LTCHs for fiscal year 2018.
Subtitle B Provisions to Medicare Part B	
Sec. 16001. Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.	• Provides for an exception to section 603 of the *Bipartisan Budget Act of 2015 (BBA '15)* for those hospital outpatient departments (HOPDs) that were defined as "mid-build" prior to November 2, 2015. • "Mid-build" is defined as a provider that had a binding written agreement with an outside, unrelated, party for the actual construction of the HOPD. To qualify as "mid-build," each HOPD will be required to submit a certification from the provider's Chief Executive Officer/Chief Operating Officer that the HOPD meets the definition of mid-build prior to 60 days after the date of enactment (per the amendment in the nature of a substitute). • Further, each mid-build HOPD will be required to submit an attestation that it meets the requirements of being provider- based (42 Code of Federal Regulations 413.65) by December 31, 2016 or if later, 60 days after the date of enactment (per the amendment in the nature of a substitute). • In addition, the section also requires the Secretary to audit the accuracy of these attestations. HOPDs that meet all of above requirements will receive the full HOPD payment rate beginning January 1, 2018 instead of the lower physician fee schedule or

	ambulatory surgical center payments required under the *BBA '15*. • Finally, those off- campus HOPDs that submitted a voluntary attestation prior to December 2, 2015 will receive the full HOPD payment rate beginning January 1, 2017.
Sec. 16002. Treatment of cancer hospitals in off-campus outpatient departments of providers.	• Provides that Prospective Payment System (PPS)-exempt cancer hospitals are not included in the payment changes made under section 603 of the *BBA '15*. This ensures that these facilities' payments continue under their existing separate system, as opposed to the inpatient and outpatient PPS systems. • The section also requires cancer HOPDs to attest (described above) and requires the Secretary to audit the accuracy of the attestation. Section 202 also includes a payment reduction to the target payment-to-cost ratio that is used to calculate the additional payments that PPS-exempt cancer hospitals receive.
Sec.16003. Treatment of eligible professionals in ambulatory surgical centers for meaningful use and MIPS.	• Excludes physicians who furnish substantially all of their Medicare services at ambulatory surgical centers (ASC) from the penalties under the Electronic Health Records (EHR) Incentives Program and subsequent program under the Merit-Based Incentive Payment System (MIPS). This exclusion ends three years after the Secretary of the Department of Health and Human Services, in consultation with stakeholders, determines that EHRs are available at the ASC setting.
Sec. 16004. Continuing Access to Hospitals Act of 2016.	• Prohibits the Secretary from enforcing the "direct supervision" regulations under 42 Code of Federal Regulations (CFR) 410.27 for calendar year 2016. 42 CFR 410.27 requires that services and supplies, furnished in Critical Access Hospitals (CAHs), that assist clinicians in the treatment of patients must be provided with "direct supervision." Direct supervision, as defined by 42 CFR 410.32, means that a physician or non-physician practitioner must be immediately available to furnish assistance and direction throughout the performance of a procedure.
Sec. 16005. Delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation	• Delays the application of competitive bid pricing used with CRT accessories used with Group 3 power wheelchairs for six months to be compliant with Congressional understanding of the *Medicare Improvements for Patients and Providers Act (MIPPA) of 2008* provision prohibiting such application of competitive bidding through a simple date change.

technology (CRT) wheelchairs.	
Sec. 16006. Allowing physical therapists to utilize locum tenens arrangements under Medicare.	• Allows physical therapists furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area, or a rural area to use specified locum tenens arrangements for payment purposes in the same manner as such arrangements are used to apply to physicians furnishing substitute physicians services for other physicians.
Sec. 16007. Extension of the transition to new payment rates for durable medical equipment (DME) under the Medicare program.	• Delays the application of competitively bid prices for durable medical equipment (DME) suppliers in non-competitively bid areas (CBAs) retroactively from July 1, 2016 through December 31, 2016.
Sec. 16008. Requirements in determining adjustments using information from competitive bidding programs.	• Requires that the Secretary take into account, when determining adjustments in the use of competitively bid prices in DME the average travel time and cost associated with furnishing items as well as the resulting number of suppliers in the area.
Subtitle C Other Medicare Provisions	
Sec. 17001. Delay in authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality.	• Delays for three years, the authority to terminate MA contracts based solely on plans failing to achieve minimum quality ratings under the MA STARS rating system. The delay would not prevent CMS from terminating plans for the other ten performance categories considered in the Past Cycle Performance Review at anytime.
Sec. 17002. Requirement for enrollment data reporting for Medicare.	• Requires the Secretary to publish Medicare enrollment data by Congressional District, zip code, and state on an annual basis. This data includes MA, Part D, and fee-for-service enrollment data. • This section also requires the Secretary to release this comprehensive enrollment report for the Medicare program by May 1, but no later than June 1, of each calendar year for the prior year.
Sec. 17003. Updating the Welcome to Medicare package.	• Requires the Secretary to revise the pre-Medicare eligibility enrollment notification to include, in a simplified manner, the available options for receiving benefits under the Medicare program, including through the original Medicare fee-for- service program, MA, and Part D.

	• The section also requires the Secretary to reach out to stakeholders on their recommendations on what such notice would include.
Sec. 17004. No payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area.	• Provides the Secretary with the authority to deny reimbursement for services by providers/suppliers within an area the Secretary has designated as a moratoria area. The authority would apply across the Medicare, Medicaid, and CHIP programs.
Sec. 17005. Preservation of Medicare beneficiary choice under Medicare Advantage.	• Allows, starting in 2019, an MA eligible individual, during the first three months of any year, to change a previous election to receive benefits through the original Medicare fee-for-service program or an MA plan, and to elect coverage under part D. • This continuous open enrollment and disenrollment period during the first three months of any year starting in 2019 shall apply with respect to a prescription drug plan only in the case of an individual who, previous to such change in enrollment, is enrolled in an MA plan. • Prohibits unsolicited marketing or marketing materials from being sent to such an eligible individual during the continuous open enrollment and disenrollment period.
Sec. 17006. Allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan.	• Allows individuals suffering from end-stage renal disease to enroll in any MA plan for plan years beginning in 2021. • Removes the standard acquisition costs (SACs) for kidneys from the benchmark and bid. SACs would be compensated for by traditional Medicare. Requires CMS to provide a report to Congress by 2023 regarding the impact of the provisions of this section related to spending, enrollment and sufficiency of data under the traditional Medicare and Medicare Advantage programs for ESRD beneficiaries. • Adjusts the CMS-HCC Risk Adjustment Model to improve accuracy by directing the Secretary to take into account the total number of diseases, multiple years of data, and Medicare-Medicaid dual eligibility status. • Directs the Secretary to evaluate the impact of including additional diagnosis codes related to mental health and substance use disorders, chronic kidney disease, and other factors in the ESRD-Risk Adjustment Model. • Requires MedPAC to conduct an evaluation on the impact of these changes to the overall accuracy of the risk scores under the MA program, and the Secretary to submit a report to Congress every three years beginning by December 31, 2018 on revisions to the risk adjustment and ESRD risk adjustment models.

Sec. 17007. Improvements to the assignment of beneficiaries under the Medicare Shared Savings Program.	• Establishes additional requirements for assigning Medicare fee-for-service beneficiaries to accountable care organizations (ACOs) under the Medicare shared savings program. (The program enables ACOs to receive payments for savings stemming from care coordination and management.) • Specifically, the bill requires the basis for assignment to reflect beneficiaries' utilization of not only primary care services provided by ACO physicians, but also those furnished in federally qualified health centers or rural health clinics.
Subtitle D Other Provisions	
Sec. 18001. Exception from group health plan requirements for qualified small employer health reimbursement arrangements.	• Exempts small employers who operate qualified Health Reimbursement Accounts (HRAs) from the penalties imposed by Obamacare through rules relating to “group health plans.” • To qualify, an HRA would need to supplement existing health coverage of an employee, and reimbursement payments to any given employee would be capped at $4,950 ($10,000, if an HRA also provides for reimbursements for an employee’s family members), indexed for inflation.

Division D- Child and Family Services and Support
Section by Section Summary
Prepared by the Human Resources Subcommittee, Committee on Ways and Means

Sec. 19000. Short title.
This Act may be cited as the ‘‘Family First Prevention Services Act of 2016’’.

TITLE XIX—INVESTING IN PREVENTION AND FAMILY SERVICES
Sec. 19001. Purpose.
Contains the purpose of this title, which is to enable states to use federal funds available under title IV-B and title IV-E of the Social Security Act to enhance their support to children and families and prevent foster care placements.

Subtitle A—Prevention Activities Under Title IV–E
Sec. 19011. Foster care prevention services and programs.
This section would amend the title IV–E foster care and permanency program to give states and tribes the option of receiving partial federal reimbursement for state expenditures to provide services that enable children to remain safely at home, or with a kin care provider. These prevention activities would include mental health and substance abuse prevention and treatment services, and in-home parent skill-based programs (including parenting skills training, parent education, and individual and family counseling). This section would also allow small states (with less than 200,000 children) to select from three possible base years when determining their maintenance of effort requirement, clarifies that the receipt of prevention services does not disqualify a child from being eligible for IV-E foster care at a later date, and that territories are eligible for prevention funding.

Sec. 19012. Foster care maintenance payments for children with parents in a licensed residential family-based treatment facility for substance abuse.
This section would permit title IV–E foster care maintenance payment support, for up to 12 months, for a child in foster care who is placed with a parent in a licensed residential family-based treatment facility.

Sec. 19013. Title IV–E payments for evidence-based kinship navigator programs.
States would be permitted to claim 50% federal reimbursement of the cost of providing kinship navigator programs provided the HHS Secretary determines the programs are operated in accordance with promising, supported, or well-supported practices.

Subtitle B—Enhanced Support Under Title IV–B

Sec. 19021. Elimination of time limit for family reunification services while in foster care and permitting time-limited family reunification services when a child returns home from foster care.
This section permits the use of Promoting Safe and Stable Families funding for family reunification services to be provided to a child in foster care (and to his or her parent(s)/ primary caregiver), regardless of the amount of time the child has been in foster care.

Sec. 19022. Reducing bureaucracy and unnecessary delays when placing children in homes across State lines.
No later than October 1, 2026, this provision would require a state, territory, or tribe operating a title IV–E program, to include use of an electronic interstate case processing system as part of its procedures for timely placement of children across state lines. Additionally, this section would require HHS to reserve a total of $5 million in any FY2017 discretionary funding provided for the PSSF program for states to use for this purpose.

Sec. 19023. Enhancements to grants to improve well-being of families affected by substance abuse.
This section would require HHS to continue to award existing competitive "regional partnership grant" funds for five years (FY2017–FY2021), would stipulate that partnerships may be established on a statewide basis, and it would remove the prohibition on state-agency only partnerships. It would also require that in addition to the state child welfare agency, every funded partnership must include the state agency that administers the federal substance abuse prevention and treatment block grant.

Subtitle C—Miscellaneous

Sec. 19031. Reviewing and improving licensing standards for placement in a relative foster family home.
This section would require HHS to identify reputable model standards for licensing foster family homes not later than October 1, 2017. No later than April 1, 2018 each state would be required to submit information to HHS on whether its own licensing standards are fully consistent with the model standards identified by HHS, and if not, why this inconsistency is appropriate for the state.

Sec. 19032. Development of a statewide plan to prevent child abuse and neglect fatalities.
This section would rewrite the existing state plan requirement to require the state child welfare agency to more fully document the steps it takes to track and prevent child maltreatment deaths, as well as explain how they are implementing a comprehensive plan to deal with this problem.

Sec. 19033. Modernizing the title and purpose of title IV–E.
This section would change the formal heading of title IV–E to "Federal Payments for Foster Care, Prevention, and Permanency," to reflect the authorization of title IV–E prevention services and programs included in this bill, as well as make other changes to conform underlying law with the new language added by this title.

Sec. 19034. Effective dates.
Contains the effective dates for this title.

TITLE XX—ENSURING THE NECESSITY OF A PLACEMENT THAT IS NOT IN A FOSTER FAMILY HOME

Sec. 20001. Limitation on Federal financial participation for placements that are not in foster family homes.

Under this section, title IV–E foster care maintenance payment support would not be available for more than two weeks for an otherwise eligible child who is placed in a setting that is not a foster family home, unless the placement setting is a—

- "Qualified residential treatment program" (provided additional requirements are met);
- Setting specializing in providing prenatal, postpartum, or parenting supports for youth;
- Supervised independent living setting (provided the child was at least 18 years of age);
- Licensed residential family-based treatment center (pro- vided the child was placed with the parent and had not been in this setting for more than 12 months);
- A setting providing high-quality residential care and supportive services to children and youth who have been found to be, or who are at risk of becoming, sex trafficking victims; or;
- If the state has a small percentage of children in congregate care or has substantially reduced group home placements, specifies an optional alternate staffing model if the state demonstrates they can adequately meet the needs of children in these settings.

This section also clarifies that a state can continue to receive federal reimbursement for administrative expenses associated with overseeing a child placed in foster care, even if the child is placed in a congregate care setting for which the state will no longer receive federal reimbursement.

Sec. 20002. Assessment and documentation of the need for placement in a qualified residential treatment program.

For any child placed in a "qualified residential treatment program," this provision would require states to have additional case review procedures as follows:

- Assessment and determination by qualified individual within 30 days of placement;
- Assemble a "Family and Permanency Team" to work with the qualified individual on placement assessment;
- Court approval or disapproval of placement determination within 60 days of placement;
- Ongoing review of placement setting decision by state agency; and
- Additional oversight for stays beyond specified time periods.

Sec. 20003. Protocols to prevent inappropriate diagnoses.

This section would require states to include in this plan the state's established procedures to ensure children are not inappropriately placed in a non-family setting, due to an inappropriate diagnosis of mental illness, behavioral disorders, medically fragile conditions, or developmental disabilities.

Sec. 20004. Additional data and reports regarding children placed in a setting that is not a foster family home.

This section would rewrite this reporting requirement to list more types of non-foster family home settings for which specific information must be included in the report and would additionally request information on the gender and race/ethnicity of children placed in these settings, and whether the non-foster family home is the first placement setting for the child or, if not, the number and type of previous placement settings.

Sec. 20005. Effective dates; application to waivers.

Specifies the effective dates of sections in this title. This section also would allow states to delay, for up to two years, changes to federal reimbursement for group home placements, giving states more time to adapt to this change. States electing to delay these changes would also delay their receipt of federal funds for prevention services by the same length of time.

TITLE XXI—CONTINUING SUPPORT FOR CHILD AND FAMILY SERVICES

Sec. 21001. Supporting and retaining foster families for children.

This section would further provide family support services including services designed to support and retain foster families so they can provide quality family-based settings for children in foster care. It would provide a separate appropriation of $8 million in FY2018 for HHS to make competitive grants to states or tribes to support recruitment and retention of high-quality foster families.

Sec. 21002. Extension of child and family services programs.

This section would extend this same annual level of discretionary and mandatory funding authority for the Child Welfare Services program and the Promoting Safe and Stable Families program in each of FY2017–FY2021. This section would extend the entitlement of eligible state highest courts to Court Improvement Program grant funding through each of FY2017–FY2021.

Sec. 21003. Improvements to the John H. Chafee Foster Care Independence Program and related provisions.

This section would permit states to certify that they use CFCIP funds to serve youth who have aged out of foster care and are not yet 23 years of age but only if the HHS Secretary determines that the state has elected to extend federal title IV–E foster care to children up to age 21; or that the state provides comparable assistance with state or other non-title IV–E funds. It would permit HHS to redistribute any CFCIP or Education and Training funds that are not spent within the two-year time frame to one or more states (including tribes) that apply for these funds.

TITLE XXII—CONTINUING INCENTIVES TO STATES TO PROMOTE ADOPTION AND LEGAL GUARDIANSHIP

Sec. 22001. Reauthorizing adoption and legal guardianship incentive programs.

This section would continue for five fiscal years (FY2016– FY2020) state's eligibility to earn these incentive payments and would extend annual discretionary funding authority, at the current law annual level of $43 million, for each of five fiscal years (FY2017–FY2021).

TITLE XXIII—TECHNICAL CORRECTIONS

Sec. 23001. Technical corrections to data exchange standards to improve program coordination.

This section would rewrite these provisions to require HHS to develop regulations concerning the categories of information that state child welfare agencies must be able to exchange with another state agency as well as federal reporting and data exchange required under applicable federal law.

Sec. 23002. Technical corrections to State requirement to address the developmental needs of young children.
This section would clarify that a state must describe in its title IV–B Child Welfare Services plan what it is doing to address the developmental needs of all vulnerable children under five years of age who receive benefits or services under the title IV–B programs or the title IV–E foster care and permanency program (not just children in foster care).

TITLE XXIV—ENSURING STATES REINVEST SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE

Sec. 24001. Delay of adoption assistance phase-in.
This section would delay the age-related expansion of eligibility for title IV–E adoption assistance that was enacted as part of the *Fostering Connections to Success and Increasing Adoptions Act of 2008* (P.L. 110-351). The delay would affect children with special needs who are under four years of age when their adoption assistance agreement is finalized. Specifically children with special needs who are two but not yet four years of age would be eligible for title IV–E adoption assistance without meeting an income test as of FY 2020 (instead of current law October 1, 2016) and any child with special needs (regardless of age) would be eligible for title IV–E adoption assistance, without an income test, as of FY 2021 (instead of current law October 1, 2017). This section allows children between the ages of two but not yet four who were eligible from October 1, 2016 through December 31, 2016 to maintain their eligibility for this increased federal adoption assistance funding.

Sec. 24002. GAO study and report on State reinvestment of savings resulting from increase in adoption assistance.
This section would require the Government Accountability Office (GAO) to study whether states are complying with the requirement that they spend, for child welfare purposes, an amount equal to the amount of savings (if any) resulting from phasing out the income eligibility requirements for federal adoption assistance and the requirement that not less than 30% of any such savings be used for post-adoption or post-guardianship services and services to support and sustain positive outcomes, and permanency, for children who might otherwise enter foster care.

TITLE XXV—SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS

Sec. 25001. Short Title.
This Act may be cited as the ‘‘Social Impact Partnerships to Pay for Results Act’’.

Sec. 25002. Social Impact Partnerships to Pay for Results.
Would reserve $100 million from funds already appropriated for the TANF Contingency Fund in FY2017 for the federal government to pay for outcomes through Social Impact Partnership projects. Under these projects, state and local governments would raise their own money and pay for a social service, then be repaid by the federal government only if a rigorous, independent evaluation showed the service achieved the intended result.

Sec. 25003. Extension of Temporary Assistance for Needy Families (TANF) Program

Would extend TANF and related programs through September 30, 2017.

Sec. 25004. Strengthening Welfare Research and Evaluation and Development of a What Works Clearinghouse

The Department of Health and Human Services (in coordination with the Department of Labor) would establish a "What Works Clearinghouse" to catalogue approaches helping welfare recipients move into work. The overall measurement of poverty would also be improved by taking advantage of data already held by other federal agencies. These activities are funded by reserving one-third of one percent of the TANF block grant for these activities, rather than the current piecemeal approach.

Sec. 25005. Technical Corrections to Data Exchange Standards to Improve Program Coordination

Would correct existing law to comport language with similar language now incorporated into other programs.