HR 34

21st Century Cures Act

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Chamber: House
Policy Area: Health
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Sponsor

Name: Rep. Bonamici, Suzanne [D-OR-1]
Party: Democratic • **State:** OR • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Del. Sablan, Gregorio Kilili Camacho [D-MP-At Large]	D · MP		Jan 6, 2015
Rep. DeFazio, Peter A. [D-OR-4]	D · OR		Jan 6, 2015
Rep. Johnson, Eddie Bernice [D-TX-30]	D · TX		Jan 6, 2015
Rep. Rohrabacher, Dana [R-CA-48]	R · CA		Jan 6, 2015
Rep. Schrader, Kurt [D-OR-5]	D · OR		Jan 6, 2015
Rep. Smith, Lamar [R-TX-21]	R · TX		Jan 6, 2015
Rep. Herrera Beutler, Jaime [R-WA-3]	R · WA		Jan 7, 2015

Committee Activity

Committee	Chamber	Activity	Date
Commerce, Science, and Transportation Committee	Senate	Reported By	Sep 22, 2015
Science, Space, and Technology Committee	House	Referred To	Jan 6, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HCONRES 174	Related bill	**Dec 6, 2016:** Motion to reconsider laid on the table Agreed to without objection.
114 HR 1561	Related bill	**Dec 2, 2016:** Message on Senate action sent to the House.
114 HRES 934	Related bill	**Nov 30, 2016:** Motion to reconsider laid on the table Agreed to without objection.
114 HR 1877	Related bill	**Sep 27, 2016:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 5659	Related bill	**Sep 22, 2016:** Received in the Senate and Read twice and referred to the Committee on Finance.
114 HR 5713	Related bill	**Sep 22, 2016:** Received in the Senate and Read twice and referred to the Committee on Finance.
114 HR 5447	Related bill	**Sep 19, 2016:** Referred to the Subcommittee on Health, Employment, Labor, and Pensions.
114 HR 5688	Related bill	**Jul 19, 2016:** Referred to the Subcommittee on Health.
114 HR 5210	Related bill	**Jul 6, 2016:** Received in the Senate and Read twice and referred to the Committee on Finance.
114 S 3115	Related bill	**Jun 29, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 5273	Related bill	**Jun 8, 2016:** Received in the Senate and Read twice and referred to the Committee on Finance.
114 HR 5414	Related bill	**Jun 8, 2016:** Referred to the House Committee on Energy and Commerce.
114 HR 5268	Related bill	**May 20, 2016:** Referred to the Subcommittee on Health.
114 HR 4966	Related bill	**Apr 22, 2016:** Referred to the Subcommittee on Health.
114 S 2713	Related bill	**Apr 18, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 428.
114 S 2745	Related bill	**Apr 18, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 430.
114 S 1077	Related bill	**Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 412.
114 S 1767	Related bill	**Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 414.
114 S 2030	Related bill	**Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 416.
114 S 2503	Related bill	**Apr 5, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 417.
114 S 2744	Related bill	**Apr 5, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 S 800	Related bill	**Apr 4, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 407.
114 S 849	Related bill	**Apr 4, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 408.
114 S 2055	Related bill	**Mar 14, 2016:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 388.
114 S 2669	Related bill	**Mar 10, 2016:** Read twice and referred to the Committee on Finance. (text of measure as introduced: CR S1441-1442)
114 HR 3716	Related bill	**Mar 3, 2016:** Received in the Senate and Read twice and referred to the Committee on Finance.
114 HR 3821	Related bill	**Feb 23, 2016:** Placed on the Union Calendar, Calendar No. 325.
114 S 607	Related bill	**Feb 5, 2016:** Referred to the Subcommittee on Health.
114 S 2261	Related bill	**Dec 18, 2015:** Referred to the Subcommittee on Health.
114 S 2188	Related bill	**Oct 21, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 S 2151	Related bill	**Oct 7, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 3291	Related bill	**Aug 12, 2015:** Referred to the Subcommittee on Health.
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 2299	Related bill	**Jun 1, 2015:** Referred to the Subcommittee on Health.
114 HR 2488	Related bill	**Jun 1, 2015:** Referred to the Subcommittee on Health.
114 HR 2416	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2426	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.

Bill	Relationship	Last Action
114 HR 2428	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2435	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2439	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2443	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2452	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 2548	Related bill	**May 22, 2015:** Referred to the Subcommittee on Health.
114 HR 1631	Related bill	**Mar 27, 2015:** Referred to the Subcommittee on Health.
114 HR 1469	Related bill	**Mar 20, 2015:** Referred to the Subcommittee on Health.
114 S 533	Related bill	**Feb 23, 2015:** Read twice and referred to the Committee on Commerce, Science, and Transportation.
114 S 202	Related bill	**Jan 21, 2015:** Read twice and referred to the Committee on Finance. (text of measure as introduced: CR S349)
114 HR 292	Related bill	**Jan 16, 2015:** Referred to the Subcommittee on Health.

Summary (as of Dec 13, 2016)

(This measure has not been amended since the House agreed to the Senate amendment with amendment on November 30, 2016. The summary of that version is repeated here.)

21st Century Cures Act

DIVISION A--21ST CENTURY CURES

21st Century Cures Act

TITLE I--INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

(Sec. 1001) This bill provides funding for National Institutes of Health (NIH) Innovation Projects, which include the Precision Medicine Initiative and the BRAIN Initiative. The NIH must submit a work plan to Congress that describes and justifies the projects.

(Sec. 1002) This bill provides funding for the Food and Drug Administration (FDA) activities required by this bill. The FDA must submit a work plan to Congress that describes and justifies the activities.

(Sec. 1003) This bill provides funding for Department of Health and Human Services (HHS) grants to states to address the opioid abuse crisis.

(Sec. 1004) The budgetary effects of this division of this bill are excluded from PAYGO scorecards.

TITLE II--DISCOVERY

Subtitle A--National Institutes of Health Reauthorization

(Sec. 2001) This bill amends the Public Health Service Act to reauthorize the NIH through FY2020.

(Sec. 2002) The NIH must support prize competitions to fund areas of biomedical science that could realize significant advancements or improve health outcomes.

Subtitle B--Advancing Precision Medicine

(Sec. 2011) HHS is encouraged to carry out a Precision Medicine Initiative to address disease prevention, diagnosis, and treatment. In implementing the initiative, HHS must implement secure data sharing and ensure inclusion of a broad range of participants.

(Sec. 2012) The bill revises provisions regarding disclosure by researchers of the identifiable, sensitive information of research subjects. HHS must prohibit researchers from disclosing such information from federally funded research to persons not connected to the research, with exceptions. Researchers may apply to have other research covered by this prohibition.

(Sec. 2013) HHS may exempt identifiable information collected for biomedical research from disclosure under the Freedom of Information Act.

(Sec. 2014) The NIH may require recipients of grants or cooperative agreements to share scientific data.

Subtitle C--Supporting Young Emerging Scientists

(Sec. 2021) The bill establishes the Next Generation of Researchers Initiative in the NIH to promote, provide, and improve opportunities for new researchers and earlier research independence.

(Sec. 2022) The bill revises loan repayment programs for health professionals conducting research to increase the maximum repayment amount and to give the NIH the authority to expand eligibility for the programs based on workforce and scientific priorities.

Subtitle D--National Institutes of Health Planning and Administration

(Sec. 2031) NIH must publish a strategic plan that addresses research, training, the biomedical workforce, and collaboration with other agencies. The strategic plans of the national research institutes must ensure that future activities take into account women and minorities and are focused on reducing health disparities.

(Sec. 2032) The bill revises reporting requirements for the NIH and certain national research institutes.

(Sec. 2033) The Director of the NIH is given the authority to appoint the directors of the national research institutes. The term of office of these directors is set to five years, with no limit on the number of reappointments.

Before a national research institute awards a grant for a research project (R-series grant) the director of the institute must review and approve the award.

HHS must report on efforts to eliminate duplicative research that is scientifically unnecessary.

(Sec. 2034) HHS and the NIH must review and revise policies, including policies on conflicts of interest and laboratory animals, to reduce the administrative burden on researchers while maintaining the integrity and credibility of research findings.

The Office of Management and Budget must establish a Research Policy Board to make recommendations to minimize the administrative burden of federal research policies while maintaining responsible oversight.

(Sec. 2035) The Paperwork Reduction Act does not apply to voluntary information collection during NIH research.

(Sec. 2036) The NIH may approve requests by national research institutes to fund research through transactions other than contracts, grants, or cooperative agreements. National research institutes must conduct and support high-risk, high-reward research.

(Sec. 2037) The National Center for Advancing Translational Sciences may support additional phases of clinical trials.

(Sec. 2038) In assessing research priorities, the NIH must publish data on certain clinical research study populations. The NIH must foster collaboration among clinical research projects that use human subjects and that collect similar data to increase the number and diversity of subjects.

Advisory council reports must include certain demographic data for clinical research subjects.

The NIH must: (1) encourage efforts to improve research related to the health of sexual and gender minority populations; (2) develop policies for NIH-funded basic research projects to assess how differences between male and female cells, tissues, or animals may be examined and analyzed; (3) convene a workshop on age groupings and age exclusions in

human research; (4) publish guidelines addressing consideration of age in human research; and (5) publish the number of children included in NIH research.

The National Institute on Minority Health and Health Disparities may foster partnerships among the national research institutes and encourage the funding of collaborative research projects to achieve NIH goals related to minority health and health disparities.

(Sec. 2039) The NIH must convene a working group to make recommendations to enhance the rigor and reproducibility of NIH-funded research.

(Sec. 2040) The bill revises requirements for medical rehabilitation research, including to revise the purpose of the National Center for Medical Rehabilitation Research (NCMRR) and to transfer responsibility for development of a comprehensive research plan for medical rehabilitation research to NCMRR from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(Sec. 2041) HHS must establish the Task Force on Research Specific to Pregnant Women and Lactating Women to report on issues including development of safe and effective therapies for such women.

(Sec. 2043) Contractors making substances and living organisms available for research on behalf of HHS may collect payments on behalf of HHS for incurred costs.

Subtitle E--Advancement of the National Institutes of Health Research and Data Access

(Sec. 2051) The bill revises provisions regarding the clinical trial registry data bank to permit earlier publication of certain data and to categorize clinical trials for combination products.

(Sec. 2052) The NIH and the FDA must report on information in the clinical trial registry data bank, activities undertaken to encourage compliance with data bank requirements, and actions to enforce compliance.

(Sec. 2053) The results of NIH-funded clinical trials that include women and minorities must be submitted to NIH's clinical trial data bank.

Subtitle F--Facilitating Collaborative Research

(Sec. 2061) The CDC must: (1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, (2) incorporate obtained information into a National Neurological Conditions Surveillance System, and (3) ensure that the system facilitates further research on neurological diseases.

(Sec. 2062) HHS must: (1) continue to conduct or support research on vector-borne diseases, (2) establish the Tick-Borne Disease Working Group to review HHS efforts regarding tick-borne diseases.

(Sec. 2063) Researchers may remotely access protected health information if security and privacy safeguards are maintained and the information is not retained. HHS must: (1) issue guidance regarding an individual's authorization to use protected health information for future research, and (2) convene a working group to study the use of protected health information for research.

Subtitle G--Promoting Pediatric Research

(Sec. 2071) In carrying out the Pediatric Research Initiative, NIH must (currently, may) support a National Pediatric

Research Network and entities supporting pediatric research consortia.

TITLE III--DEVELOPMENT

Subtitle A--Patient-Focused Drug Development

(Sec. 3001) This bill amends the Federal Food, Drug, and Cosmetic Act to require the FDA, after approving an application for a new medication, to publish a brief statement on any patient experience data or related information that was part of the application. Patient experience data is information about the impact of a medical condition or a related therapy on a patient's life and the patient's preferences for treatment.

(Sec. 3002) The FDA must issue guidance on the collection and use of patient experience data.

(Sec. 3003) The Paperwork Reduction Act does not apply to voluntary collection of patient experience data.

(Sec. 3004) The FDA must report on its use of patient experience data in regulatory decision-making.

Subtitle B--Advancing New Drug Therapies

(Sec. 3011) The FDA must establish a process to qualify drug development tools (methods, materials, or measures that aid drug development and regulatory review) as reliable for use in supporting approval or investigational use of a drug.

(Sec. 3012) The FDA may permit the sponsors of new medications that target genes or variant proteins to treat rare, serious conditions to rely upon information submitted for an approved medication that uses the same technology. To rely upon submitted information, the sponsor must have developed, or have a right of reference to, the information.

(Sec. 3013) The priority review voucher program for rare pediatric disease medications is extended until the end of FY2020. (A priority review voucher is a transferable voucher that entitles the holder to have a new drug or biological product application acted upon by the FDA within six months.)

(Sec. 3014) The Government Accountability Office (GAO) must report on the effectiveness and impact of specified priority review voucher programs.

(Sec. 3015) This bill amends the Orphan Drug Act to authorize HHS to defray all the costs of development of orphan drugs (drugs for rare conditions), instead of only certain testing expenses.

(Sec. 3016) HHS may award grants to institutions of higher education and nonprofits to study and recommend improvements to the process of continuous manufacturing of medications. (Currently, most medications are manufactured in batches.)

Subtitle C--Modern Trial Design and Evidence Development

(Sec. 3021) The FDA must issue guidance addressing the use of novel clinical trial design in the development and review of drugs.

(Sec. 3022) The FDA must evaluate and issue guidance on the use of evidence from sources other than clinical trials to support approval of a drug for a new indication.

(Sec. 3023) HHS must revise the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules to: (1) reduce regulatory duplication and unnecessary delays; (2) modernize the provisions;

and (3) protect vulnerable populations, incorporate local considerations, and support community engagement.

(Sec. 3024) Clinical testing of investigational medical devices and drugs no longer requires the informed consent of the subjects if the testing poses no more than minimal risk to the subjects and includes safeguards.

Subtitle D--Patient Access to Therapies and Information

(Sec. 3031) For certain indications, the FDA may rely upon a summary of clinical data to approve a supplemental application for a medication.

(Sec. 3032) The manufacturer or distributor of an investigational drug for a serious condition must publish a policy for compassionate use of the drug.

(Sec. 3033) Upon request, the FDA must facilitate development and expedite review of regenerative advanced therapies, including cell therapies, therapeutic tissue engineering products, and human cell and tissue products. For a therapy to be eligible, there must be preliminary clinical evidence that the therapy has the potential to address an unmet medical need for a serious condition.

(Sec. 3034) The FDA must issue guidance on its evaluation of medical devices used in the recovery, isolation, or delivery of regenerative advanced therapies.

(Sec. 3036) HHS must facilitate the development of standards to support development and review of regenerative medicine and advanced therapies.

(Sec. 3037) Health care economic information provided to an entity selecting medications for coverage or reimbursement, such as the formulary committee of a health insurer, must describe any differences between the information provided regarding a medication and the FDA-approved labeling for that medication.

(Sec. 3038) The bill revises provisions regarding combination products, which are a combination of a drug, medical device, or biological product.

The FDA may not determine that a combination product is a drug or biological product solely because the product has a chemical action. (Combination products are regulated based on their primary mode of action.) If the sponsor of a combination product disagrees with the FDA's determination of the primary mode of action of the product, the FDA must provide the rationale for its determination and the sponsor and the FDA may agree to studies to inform a reevaluation of the product.

The FDA's Office of Combination Products must coordinate reviews of combination products and oversee feedback regarding such reviews.

The FDA must: (1) issue guidance that describes the process and best practices for review of combination products, and (2) propose that certain types of combination products may adopt good manufacturing practices that vary from requirements in regulations.

Subtitle E--Antimicrobial Innovation and Stewardship

(Sec. 3041) HHS must encourage the health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service to report on antimicrobial drug use, microbial resistance to antimicrobial drugs, and antimicrobial stewardship programs.

HHS must: (1) annually publish information on antimicrobial resistance and antimicrobial stewardship; (2) disseminate guidance and materials regarding antimicrobial stewardship; (3) continue working with state and local public health departments on antimicrobial resistance programs; and (4) collect, evaluate, and publish data from the antimicrobial stewardship activities of health care facilities.

(Sec. 3042) The FDA may, at the request of the drug's sponsor, approve an antibiotic or antifungal drug for use in a limited population if the drug is intended to treat a serious infection in a limited population of patients with unmet medical needs. The FDA's determination of the safety and effectiveness of such a drug must reflect the drug's use in the intended limited population.

The label and prescribing information of such a drug must indicate that the drug has been approved for use only in a limited population. The sponsor of such a drug must submit promotional materials for the drug to the FDA prior to dissemination. The FDA may remove these requirements for such a drug that is approved for broader use.

(Sec. 3044) The FDA must identify and publish susceptibility test interpretive criteria for antimicrobial drugs. (These criteria characterize the drug resistance of microbes.) Under specified conditions, the FDA may waive certain requirements for medical devices that characterize the drug resistance of microbes using these criteria.

Subtitle F--Medical Device Innovations

(Sec. 3051) The bill revises requirements regarding priority review of breakthrough medical devices.

Upon a sponsor's request, the FDA must determine whether a device meets the criteria for designation as a breakthrough device. To expedite the development and review of designated medical devices, the FDA must:

- assign a team of staff for each device,
- adopt an efficient process for dispute resolution,
- provide for interactive and timely communication with the device sponsor,
- expedite review of manufacturing and quality systems compliance,
- disclose to the sponsor in advance the topics of any consultation between the FDA and external experts or an advisory committee and provide the sponsor the opportunity to recommend external experts,
- assign staff to address questions by institutional review committees concerning investigational use of the device.

The FDA may take additional steps to expedite the development and review of designated medical devices.

(Sec. 3052) The humanitarian device exemption is expanded to allow the FDA to exempt from effectiveness requirements certain medical devices intended to benefit up to 8,000 individuals. (Currently, a device must be intended to benefit fewer than 4,000 individuals to qualify for this exemption.)

(Sec. 3053) The bill revises provisions related to medical device performance standards.

(Sec. 3054) The bill revises provisions related to medical device reporting requirements.

(Sec. 3055) The bill revises provisions related to medical device classification panels.

(Sec. 3056) The bill eliminates the requirement for the Institutional Review Board supervising the clinical testing of an investigational or humanitarian medical device to be local.

(Sec. 3057) The FDA must revise the guidance entitled “Recommendations for Clinical Laboratory Improvement

Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices."

(Sec. 3058) The FDA must ensure that employees who review premarket submissions of medical devices receive training on least burdensome means requirements. (Currently, the FDA is required to consider the least burdensome appropriate means for a sponsor to demonstrate the effectiveness of a medical device or demonstrate a device's substantial equivalence to an approved medical device.)

The FDA must consider the least burdensome means requirements when requesting additional information from a medical device sponsor to support a premarket approval application.

The FDA's documented rationale for a significant decision regarding a medical device must include a statement on how the least burdensome means requirements were considered and applied.

(Sec. 3059) The FDA must: (1) identify types of medical devices for which premarket notification must include validated instructions for cleaning, disinfection, and sterilization; and (2) issue final guidance regarding when a premarket notification is required for a modification to a medical device.

(Sec. 3060) Certain software is exempted from requirements for medical devices, including software that provides medical recommendations and the basis for those recommendations to health care professionals. Software remains subject to regulation as a medical device if: (1) the software acquires, processes, analyzes, or interprets medical information; or (2) the FDA identifies use of the software as reasonably likely to have serious adverse health consequences.

When assessing a medical device that includes a software function exempted from medical device requirements, the FDA may assess the impact of the software on the functioning of the device.

The FDA must classify a medical device accessory based on its intended function, not based on the classification of the medical device with which it is used.

Subtitle G--Improving Scientific Expertise and Outreach at FDA

(Sec. 3071) The bill revises the Silvio O. Conte Senior Biomedical Research Service to: (1) increase the limit on the number of members, (2) expand eligibility for appointment, (3) set a maximum pay rate, and (4) remove the option for members to contribute to the retirement system of an institution of higher education.

(Sec. 3072) The bill grants the FDA additional hiring authority for scientific, technical, or professional positions that support the development, review, and regulation of medical products.

(Sec. 3073) The FDA must establish one or more Intercenter Institutes. Each institute must coordinate activities applicable to a major disease area among the FDA centers that review products.

(Sec. 3074) Scientific meetings directly related to the duties of a HHS professional must not be considered conferences for purposes of certain reporting requirements and restrictions on conference travel.

(Sec. 3075) The bill revises provisions regarding: (1) FDA screening of the Adverse Event Reporting System, and (2) evaluation of elements to assure safe use of drugs.

(Sec. 3076) The bill revises provisions regarding the Reagan-Udall Foundation for the FDA's Board of Directors

membership, Executive Director compensation, and accounting.

Subtitle H--Medical Countermeasures Innovation

(Sec. 3081) HHS must ensure the issuance of timely and accurate guidelines regarding the use of medical products for countering public health emergencies or material threats. HHS must report on funding for procurement of medical countermeasures when available funds are below a specified amount.

(Sec. 3082) The Biomedical Advanced Research and Development Authority's (BARDA's) contracting authority for procurement of medical countermeasures under Project BioShield is codified.

(Sec. 3083) The Office of the Assistant Secretary for Preparedness and Response must annually publish its budget plan for medical countermeasures.

(Sec. 3084) BARDA may enter an agreement with an independent, nongovernmental nonprofit to foster and accelerate the development and innovation of medical countermeasures and related technologies. BARDA must direct and oversee the nonprofit's work and ensure transparency and accountability.

(Sec. 3085) BARDA's procurement of medical countermeasures no longer requires Presidential approval or an agreement between HHS and the Department of Homeland Security.

(Sec. 3086) The FDA must award, upon approval, a priority review voucher to the sponsor of a drug or biological product that: (1) is a significant improvement in the prevention, diagnosis, or treatment of a serious condition; and (2) can be used as a medical countermeasure to a material threat. The transferable voucher entitles the holder to have an application for a new medication acted upon by the FDA within six months. The FDA may not issue vouchers after FY2023.

(Sec. 3087) The Paperwork Reduction Act does not apply to voluntary collection of information during a public health emergency or while determining whether there is a public health emergency.

(Sec. 3088) The bill revises provisions regarding FDA authorization of emergency use of unapproved products to include animal drugs and veterinary feed directive drugs.

Subtitle I--Vaccine Access, Certainty, and Innovation

(Sec. 3091) The Advisory Committee on Immunization Practices must: (1) consider the use of newly licensed vaccines at each regularly scheduled meeting, and (2) make timely recommendations for vaccines designated as breakthrough therapies and vaccines that could be used in a public health emergency.

(Sec. 3092) The CDC must review the processes of the Advisory Committee on Immunization Practices.

(Sec. 3093) HHS must: (1) report on ways to promote innovation in the development of vaccines, and (2) revise the Vaccine Injury Table to include information on vaccines recommended by the CDC for pregnant women. A mother and child are individually considered for compensation for a vaccine injury from a vaccine administered during pregnancy.

Subtitle J--Technical Corrections

(Sec. 3101) The bill revises provisions regarding:

- movement of impounded drugs,

pediatric study plans,
- reporting on drug shortages,
- reporting on inspections of establishments manufacturing drugs or medical devices,
- requests to classify medical devices,
- priority review of qualified infectious disease products,
- use of clinical investigation data from outside the United States, and
- medical gasses.

The bill makes technical changes to various provisions regarding medical products.

TITLE IV--DELIVERY

(Sec. 4001) This bill amends the Health Information Technology for Economic and Clinical Health Act to require HHS to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of electronic health records (EHR).

The Office of the National Coordinator for Health Information Technology (ONC) must encourage, keep, or recognize the certification of health information technology (IT) for use in medical specialties. HHS must adopt certification criteria to support health IT for pediatrics.

HHS must publish attestation statistics for the Medicare and Medicaid EHR Incentive Programs. (Health care providers in these programs must attest to meaningful use of EHR to avoid a penalty.)

(Sec. 4002) The bill requires developers of health IT, for their health IT to be certified, to meet certain requirements, including that the developer not engage in information blocking, which is preventing, discouraging, or interfering with the access, exchange, or use of information.

A health care provider whose adopted health IT is decertified is exempted from penalties under the Medicare EHR Incentive program.

HHS must support the convening of stakeholders to develop reporting criteria for health IT developers.

(Sec. 4003) The ONC must: (1) convene stakeholders to develop or support a framework and agreement for the secure exchange of health information between networks, (2) provide for testing of the framework and agreement, and (3) publish a list of networks that adopt the agreement.

HHS must establish an index of digital contact information for health professionals, health facilities, and others to encourage the exchange of health information.

The bill replaces the Health IT Policy Committee and the Health IT Standards Committee with the Health IT Advisory Committee. The ONC must periodically convene the Health IT Advisory Committee to report on priority uses of health IT and standards and implementation specifications that support the use and exchange of electronic health information.

(Sec. 4004) Developers of health IT and health care providers may be penalized for engaging in information blocking.

The ONC must issue guidance on the secure exchange of electronic health information.

(Sec. 4005) To be certified, EHR must be capable of transmitting to and receiving from data registries certified by the ONC.

HHS must report on best practices and current trends provided by patient safety organizations to improve the integration of health IT into clinical practice.

(Sec. 4006) HHS must: (1) encourage partnerships between health information exchanges and others to offer patients access to their electronic health information, (2) educate providers on health information exchanges, (3) issue guidance to health information exchanges on best practices, and (4) promote policies to facilitate patient communication with providers.

The ONC must ensure patient access to health information in a convenient form.

The HHS Office for Civil Rights must assist individuals and health care providers in understanding a patient's rights to access and protect their personal health information.

The ONC may require health IT certification criteria support certain usability features.

(Sec. 4007) The GAO must review the policies and activities of the ONC and stakeholders to ensure correct matching of a patient to electronic health information.

(Sec. 4008) The GAO must report on patient access to their protected health information, including difficulties providers experience in providing such access.

(Sec. 4009) Medicare administrative contractors must publish local coverage determinations.

(Sec. 4010) A pharmaceutical and technology ombudsman within the Centers for Medicare and Medicaid Services (CMS) must receive and respond to complaints from manufacturers of medical products regarding Medicare coverage of their products.

(Sec. 4011) The CMS must publish estimated Medicare beneficiary prices for items and services provided by either hospital outpatient departments or ambulatory surgical centers.

(Sec. 4012) The CMS and the Medicare Payment Advisory Commission must provide information to Congress regarding Medicare telehealth services.

TITLE V--SAVINGS

(Sec. 5001) The bill increases the funds available to the Medicare Improvement Fund for services provided during and after FY2021.

(Sec. 5002) The effective date of the limit on Medicaid reimbursement to states for durable medical equipment, to Medicare payment rates, is changed from January 1, 2019, to January 1, 2018.

(Sec. 5003) For HHS agreements, monetary penalties are established for fraudulent claims, fraudulent statements, and failure to provide timely access to the Inspector General of HHS.

(Sec. 5004) The bill revises Medicare payments for infusion medications delivered through durable medical equipment. These medications are excluded from Medicare competitive bidding programs.

(Sec. 5005) The bill amends titles XIX (Medicaid) and XXI (Children's Health Insurance Program [CHIP]) of the Social Security Act to prohibit Medicaid payment for nonemergency services furnished by providers whose participation in CHIP

has been terminated. (Currently, states must exclude from Medicaid participation any provider that has been terminated under any state's Medicaid program or under Medicare.)

States must exclude from CHIP participation any provider that has been terminated under Medicaid or Medicare.

States must require Medicaid and CHIP providers to submit identifying information to the state. States must submit this information when notifying HHS that a provider has been terminated under a state plan.

The bill prohibits federal payment under Medicaid or CHIP for services provided by a managed care organization (MCO) unless: (1) the state notifies MCOs when a provider is terminated under Medicaid, Medicare, or CHIP; and (2) any contract between the state plan and an MCO requires such providers be excluded from participation in the MCO provider network.

(Sec. 5006) A state must publish and annually update a directory of physicians participating in its Medicaid program if the program provides assistance on a fee-for-service basis or through a primary care case-management system.

(Sec. 5007) The supplemental needs trust exemption, which excludes a supplemental needs trust from treatment as resources available to an individual for purposes of Medicaid eligibility, is extended to supplemental needs trusts established by individuals for themselves.

(Sec. 5008) The bill eliminates federal payment under Medicaid for drugs used for cosmetic purposes or hair growth, unless medically necessary.

(Sec. 5009) The bill reduces funding for the Prevention and Public Health Fund for FY2018-FY2024.

(Sec. 5010) The Department of Energy must sell crude oil from the Strategic Petroleum Reserve. The bill reduces the minimum amount of oil that must be kept in the reserve under certain circumstances that allow for a drawdown.

(Sec. 5011) The bill rescinds a specified amount of funding related to health insurance exchanges for U.S. territories.

(Sec. 5012) Medicare coverage is expanded to include home infusion therapy, including training and monitoring.

DIVISION B--HELPING FAMILIES IN MENTAL HEALTH CRISIS

Helping Families in Mental Health Crisis Reform Act of 2016

TITLE VI--STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A--Leadership

(Sec. 6001) This bill amends the Public Health Service Act to rename the position of Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) to Assistant Secretary for Mental Health and Substance Use.

(Sec. 6002) The bill revises SAMHSA authorities, including to expand SAMHSA’s authority to develop educational materials and intervention strategies to reduce the risks of communicable diseases among individuals with mental or substance use disorders.

The bill establishes new requirements for SAMHSA, including that SAMHSA must: (1) improve mental and substance use

disorder services provided by the Department of Defense (DOD) and the Department of Veterans Affairs, (2) improve mental and substance use disorders services for chronically homeless individuals and individuals who have been arrested or incarcerated, and (3) develop and support activities to recruit and retain a workforce addressing mental and substance use disorders.

(Sec. 6003) The bill creates the position of Chief Medical Officer within SAMHSA.

(Sec. 6004) SAMHSA must maintain a Center for Behavioral Health Statistics and Quality to: (1) carry out existing data collection requirements, (2) provide statistical and analytical support for SAMHSA activities, (3) recommend performance metrics to evaluate SAMHSA activities, and (4) coordinate with others to improve SAMHSA services and evaluation of SAMHSA activities.

(Sec. 6005) Every four years, SAMHSA must develop, publish, and carry out a strategic plan.

(Sec. 6006) The bill revises requirements regarding SAMHSA’s biennial report on its activities.

(Sec. 6007) The bill revises provisions regarding SAMHSA’s Center for Mental Health Services, Center for Substance Abuse Prevention, and Center for Substance Abuse Treatment, including to require the centers to ensure consistent documentation of the application of grant criteria.

(Sec. 6008) The bill revises membership requirements for SAMHSA advisory councils.

(Sec. 6009) The bill revises membership requirements for SAMHSA peer review groups.

Subtitle B--Oversight and Accountability

(Sec. 6021) The Office of the Assistant Secretary for Planning and Evaluation must ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(Sec. 6022) This bill amends the Protection and Advocacy for Individuals with Mental Illness Act to require state protection and advocacy systems to publish their annual reports. The Department of Health and Human Services (HHS) must include in its biennial reports detailed accounting for each system.

(Sec. 6023) The Government Accountability Office (GAO) must report on protection and advocacy systems for individuals with mental illness.

Subtitle C--Interdepartmental Serious Mental Illness Coordinating Committee

(Sec. 6031) HHS must establish the Interdepartmental Serious Mental Illness Coordinating Committee to report on research, evaluate the effect of federal programs, and recommend agency actions to better coordinate administration of mental health services.

TITLE VII--ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

(Sec. 7001) SAMHSA's Office of Policy, Planning, and Innovation is renamed the National Mental Health and Substance Use Policy Laboratory. The bill specifies responsibilities for the laboratory, including that the laboratory must: (1) facilitate the implementation of policy changes likely to have a significant effect on mental health; (2) collect information from SAMHSA grantees to evaluate and disseminate information on evidence-based practices; and (3) identify SAMHSA

activities that are duplicative or that are not evidence-based, effective, or efficient.

SAMHSA may award grants for the development of evidence-based interventions for mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders.

(Sec. 7002) SAMHSA must review and publish information on evidence-based programs and practices.

(Sec. 7003) The bill revises and extends through FY2022 SAMHSA support for addressing regionally and nationally significant needs regarding mental health, substance use disorder treatment, and substance use disorder prevention.

TITLE VIII--SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

(Sec. 8001) The bill revises and extends through FY2022 block grants for community mental health services. States must use at least a specified amount of a block grant to support evidence-based programs for individuals with early serious mental illness. The bill revises the block grant requirement that a state maintain spending on community mental health services.

(Sec. 8002) The bill revises and extends through FY2022 block grants for prevention and treatment of substance abuse. The bill eliminates the block grant requirements for states to: (1) maintain spending on services for individuals with tuberculosis or HIV, and (2) submit an assessment of need for a block grant. The bill revises the block grant requirement for a state to maintain spending on prevention and treatment of substance abuse.

(Sec. 8003) In the case of a public health emergency, HHS may grant extensions or waive requirements for block grants for transition from homelessness, community mental health services, and prevention and treatment of substance abuse.

SAMHSA must permit states to apply jointly for block grants.

(Sec. 8004) SAMHSA must report on the funding formulas for block grants for community mental health services and prevention and treatment of substance abuse.

TITLE IX--PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A--Helping Individuals and Families

(Sec. 9001) The bill revises and extends through FY2022 grants for mental health and substance abuse services for homeless individuals.

(Sec. 9002) The bill revises and extends through FY2022 grants to divert individuals with a mental illness from the criminal justice system to community-based services. In awarding grants, SAMHSA must give special consideration to entities proposing to support services for veterans. Grant funding may be used to develop programs to divert individuals prior to booking or arrest.

(Sec. 9003) SAMHSA may provide support for improvement of integrated primary care and behavioral health care.

(Sec. 9004) The bill revises and extends through FY2022 block grants for transition from homelessness. SAMHSA must report on the funding formula for these block grants.

(Sec. 9005) SAMHSA must maintain the existing National Suicide Prevention Lifeline program.

(Sec. 9006) SAMHSA must maintain the existing National Treatment Referral Routing Service to assist individuals and families in locating treatment providers for mental and substance use disorders.

(Sec. 9007) SAMHSA must award grants to enhance community-based crisis response systems or for a database of available beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities.

(Sec. 9008) The bill revises and extends through FY2022 a technical assistance resource center to prevent suicides. The center’s focus is expanded from youth suicides to suicides among all ages, particularly among groups that are at high risk for suicide.

A program to provide support for youth suicide early intervention and prevention strategies is also revised and extended through FY2022.

(Sec. 9009) SAMHSA must award grants for suicide prevention and intervention programs for adults.

(Sec. 9010) The bill revises and extends through FY2022 SAMHSA's training grant program. The program is expanded to include additional categories of trainees.

(Sec. 9012) SAMHSA must provide technical assistance and disseminate information regarding mental health and substance use disorders among geriatric populations.

(Sec. 9013) The Centers for Disease Control and Prevention is encouraged to improve the National Violent Death Reporting System.

(Sec. 9014) This bill amends the Protecting Access to Medicare Act of 2014 to extend through FY2022 a pilot program for assisted outpatient treatment programs for individuals with serious mental illness.

(Sec. 9015) SAMHSA must award grants for assertive community treatment programs for adults with a serious mental illness. (Patients in assertive community treatment programs receive care in their community from a multidisciplinary team of providers.)

(Sec. 9016) The bill extends SAMHSA programs to reduce underage drinking through FY2022 and expands the programs to permit SAMHSA to award grants to pediatric health care providers.

(Sec. 9017) The bill repeals various expired SAMHSA programs.

Subtitle B--Strengthening the Health Care Workforce

(Sec. 9021) The bill revises and extends through FY2022 mental and behavioral health education and training grants. Grantees must be able to place students in areas with a high need and high demand population.

(Sec. 9022) HHS must establish a training demonstration program for mental and substance use disorders to award grants for: (1) training medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings with integrated care; (2) training other providers to provide services in such settings; and (3) academic units or programs that train students or faculty or develop practices or recommendations for the design of such units or programs.

(Sec. 9023) The Health Resources and Services Administration (HRSA) must clarify the eligibility of pediatric

psychiatrists for the National Health Service Corps Loan Repayment Program.

(Sec. 9024) HHS must maintain a Minority Fellowship Program for mental and substance use disorder treatment professionals to improve services for racial and ethnic minority populations.

(Sec. 9025) A health professional volunteer providing primary health care to an individual at a community health center or through programs or events carried out by a center is deemed to be an employee of the Public Health Service for purposes of any civil action that may arise from providing services to patients. For a volunteer to be covered by this liability protection, HHS must approve the center's application to sponsor the volunteer.

(Sec. 9026) HRSA must publish a report on the adult and pediatric mental health and substance use disorder workforce.

Subtitle C--Mental Health on Campus Improvement

(Sec. 9031) The bill revises and extends through FY2022 SAMHSA grants for mental and behavioral health services at institutions of higher education.

(Sec. 9032) HHS must establish a College Campus Task Force to discuss mental and behavioral health concerns at institutions of higher education.

(Sec. 9033) SAMHSA must convene a working group regarding a public education campaign focused on mental and behavioral health at institutions of higher education.

TITLE X--STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

(Sec. 10001) The bill revises and extends through FY2022 a grant program to provide comprehensive community mental health services to children with a serious emotional disturbance.

(Sec. 10002) HRSA must award grants to promote integration of behavioral health with pediatric primary care.

(Sec. 10003) The bill revises and extends through FY2022 SAMHSA support for substance use disorder treatment services for children. The program is expanded to include support for early identification and services for children at risk of substance use disorders and assistance to pregnant and parenting women with substance use disorders.

(Sec. 10004) The bill revises and extends through FY2022 a grant program to address violence-related stress. The program must support the continued operation of the National Child Traumatic Stress Initiative (NCTSI). The NCTSI coordinating center must report on child treatment and outcomes and facilitate training in evidence-based and trauma-informed treatments, interventions, and practices.

(Sec. 10005) HHS must award grants to states for screening, assessment, and treatment services for maternal depression.

(Sec. 10006) HHS must award grants for infant and early childhood mental health promotion, intervention, and treatment programs.

TITLE XI--COMPASSIONATE COMMUNICATION ON HIPAA

(Sec. 11002) After finalizing regulations on the confidentiality of alcohol and drug abuse patient records, HHS must

convene stakeholders to determine the effect of the regulations on patient care, health outcomes, and patient privacy.

(Sec. 11003) The HHS Office for Civil Rights must ensure that entities involved in mental or substance use disorder treatment, including patients and their families, have adequate, accessible, and easily comprehensible resources regarding use and disclosure of protected health information under the Health Insurance Portability and Accountability Act. HHS must issue guidance clarifying the circumstances under which an entity may use or disclose protected health information.

(Sec. 11004) HHS must identify, or recognize entities to develop and disseminate, model programs and materials for training: (1) health care providers regarding the use and disclosure of the protected health information of patients seeking or undergoing mental or substance use disorder treatment, and (2) patients and their families regarding their rights to protect and obtain such information.

TITLE XII--MEDICAID MENTAL HEALTH COVERAGE

(Sec. 12001) The bill declares that current law allows a state Medicaid plan to pay for a primary care service and a mental health service furnished to an individual on the same day by providers at the same facility.

(Sec. 12002) The Centers for Medicare and Medicaid Services (CMS) must report on Medicaid coverage of services provided through Medicaid managed care organizations or prepaid inpatient health plans to certain enrollees receiving treatment in institutions for mental diseases.

(Sec. 12003) The CMS must notify state Medicaid programs regarding opportunities to design innovative service delivery systems for adults with a serious mental illness or children with a serious emotional disturbance.

(Sec. 12004) The CMS must collect and report specified information from states with Medicaid emergency psychiatric demonstration projects, including the extent to which there is a reduction in spending under demonstration projects.

(Sec. 12005) This bill amends title XIX (Medicaid) of the Social Security Act to provide for federal payment under Medicaid for early and periodic screening, diagnostic, and treatment services for children in inpatient psychiatric hospitals, effective January 1, 2019.

(Sec. 12006) Federal payment under Medicaid for in-home personal care services or home health care services is reduced for states that do not require the use of an electronic visit verification system for such services, effective January 1, 2019. The CMS must pay a specified share of state expenditures attributable to such a system.

HHS must disseminate to states best practices for electronic visit verification systems, including training for users.

TITLE XIII--MENTAL HEALTH PARITY

(Sec. 13001) HHS, the Department of Labor, and the Department of the Treasury must: (1) issue guidance to improve the compliance of group health plans and health insurance coverage with requirements for parity between mental health and substance use disorder benefits and medical and surgical benefits, (2) publish feedback from the public on the disclosure request process for documents regarding parity requirements, and (3) audit the plan documents of group health plans and health insurers that repeatedly violate parity requirements.

(Sec. 13002) HHS must convene stakeholders to produce an action plan for improved federal and state coordination regarding enforcement of parity requirements.

(Sec. 13003) The Employee Benefits Security Administration must report on closed federal investigations that found serious violations of parity requirements.

(Sec. 13004) The GAO must report on the extent to which group health plans, health insurers, Medicaid managed care organizations, and Children's Health Insurance Program (CHIP) health plans comply with parity requirements.

(Sec. 13005) The HHS Office on Women's Health may: (1) update published information on eating disorders, (2) incorporate public resources into its obesity prevention programs, and (3) advance public awareness of eating disorders.

(Sec. 13006) HHS may facilitate the identification of model programs and materials for educating and training health professionals regarding eating disorders.

TITLE XIV--MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A--Mental Health and Safe Communities

(Sec. 14001) This bill amends the Omnibus Crime Control and Safe Streets Act of 1968 to expand the Edward Byrne Memorial Justice Assistance Grant Program to support mental health programs and related law enforcement and corrections programs.

The public safety and community policing grant program is expanded to support training and programs for law enforcement and corrections officers regarding individuals with mental illness.

This bill amends the Federal Fire Prevention and Control Act of 1974 to expand Federal Emergency Management Agency (FEMA) grants for fire and emergency response to support training for first responders regarding individuals with mental illness.

(Sec. 14002) The bill revises the Department of Justice (DOJ) mental health courts program to require grantees to support court-ordered assisted outpatient mental health treatment.

(Sec. 14003) DOJ must establish a pilot program to determine the effectiveness of diverting certain offenders with mental illness or intellectual disabilities from federal prosecution, federal probation, or federal prison and placing the offenders in drug or mental health courts.

(Sec. 14004) DOJ may award grants for: (1) pretrial mental health screening of defendants and supervision of defendants on pretrial release, and (2) criminal justice system behavioral health assessments and intervention programs.

(Sec. 14005) DOJ may award grants for forensic assertive community treatment programs that provide services in the community for individuals with mental illness involved with the criminal justice system to prevent future incarcerations.

(Sec. 14006) The bill revises priority considerations for DOJ reentry demonstration project grants, including to prioritize applications that provide mental health treatment and transitional services to individuals with mental illness.

(Sec. 14007) The bill revises grants for drug courts and training for drug court personnel and officials to specify that the programs include activity regarding individuals with co-occurring substance abuse and mental health problems.

(Sec. 14008) HHS, DOD, the Department of Homeland Security, and the Department of Commerce must provide the uniformed services with training, technology, and programs for responding to individuals with mental illness.

(Sec. 14009) The bill revises priority considerations for DOJ reentry demonstration project grants, including to prioritize applications that target offenders with histories of homelessness, substance abuse, or mental illness.

The bill specifies that DOJ grants for transitional services may be used for mental health care.

(Sec. 14010) Grants awarded by the Office of Community Oriented Policing Services for improving school security may be used for crisis intervention teams.

(Sec. 14011) DOJ may provide safety training and technical assistance to local law enforcement agencies as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative.

(Sec. 14012) DOJ grants for residential substance abuse treatment programs for state prisoners may be used for programs for inmates with co-occurring mental health and substance abuse disorders or challenges.

(Sec. 14013) The bill revises a grant program for drug treatment alternatives to incarceration, including to expand the program to include mental health treatment alternatives.

(Sec. 14014) DOJ may award grants to establish a National Criminal Justice and Mental Health Training and Technical Assistance Center to conduct activities including: (1) training of law enforcement officers and others regarding individuals with mental illness, and (2) providing support for individuals with mental illness at risk of involvement with the criminal justice system.

(Sec. 14015) Data prepared by, or submitted to, the DOJ or the Federal Bureau of Investigation on homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers must include data on the involvement of mental illness in the incident.

(Sec. 14016) The GAO must report on the cost of imprisonment of individuals with serious mental illness and include: (1) the number and type of crimes committed by such individuals, and (2) strategies or ideas for preventing crimes by such individuals.

(Sec. 14017) The Department of Veterans Affairs, prior to determining a beneficiary is mentally incompetent, must provide the beneficiary with notice of the proposed determination and opportunities to request a hearing, be represented at the hearing, and present evidence.

(Sec. 14018) The bill extends though FY2021 the Justice and Mental Health Collaboration Program.

Subtitle B--Comprehensive Justice and Mental Health

(Sec. 14021) DOJ may award grants for sequential intercept mapping, which is aimed at minimizing criminal justice involvement for individuals with mental illness.

(Sec. 14022) DOJ may award grants to assist correctional facilities in addressing the needs of inmates with mental illness and training employees to respond to incidents involving inmates with mental illness.

(Sec. 14023) Justice and Mental Health Collaboration Program implementation grants may be used to support multidisciplinary teams that address frequent users of crisis services.

(Sec. 14024) DOJ grants to improve law enforcement response to mentally ill offenders may be used to support academy training and other programs that teach law enforcement personnel. Priority for these grants is given to programs that are

administered cooperatively by law enforcement personnel and mental health and substance abuse professionals.

(Sec. 14025) Regarding response to individuals with mental illness, DOJ must provide direction and guidance on: (1) training programs for federal first responders and tactical units, and (2) systems to provide timely information to federal law enforcement agencies and criminal justice agencies.

(Sec. 14026) The GAO must report on: (1) the practices used by federal first responders, tactical units, and corrections officers in responding to individuals with mental illness, (2) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses, and (3) how DOJ can expand and improve information sharing and dissemination of best practices.

(Sec. 14027) The bill revises priority considerations for Justice and Mental Health Collaboration Program grants to prioritize applications that: (1) propose interventions that reduce recidivism, and (2) target certain offenders with a moderate or high risk of recidivism and a need for treatment and services.

(Sec. 14028) The bill revises the Justice and Mental Health Collaboration Program to include certain veterans and violent offenders as preliminarily qualified offenders.

(Sec. 14029) The bill revises the Justice and Mental Health Collaboration Program to make grants subject to audits, prohibit certain nonprofits with offshore accounts from receiving grants, limit spending on conferences, and prevent duplicative grants.

DIVISION C--INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

Increasing Choice, Access, and Quality in Health Care for Americans Act

TITLE XV--PROVISIONS RELATING TO MEDICARE PART A

(Sec. 15001) The bill amends title XVIII (Medicare) of the Social Security Act to require the Centers for Medicare & Medicaid Services (CMS) to develop, with respect to claims for hospital services, codes under the Healthcare Common Procedure Coding System (HCPCS) for similar inpatient and outpatient hospital services.

(Sec. 15002) The bill establishes processes for adjusting a hospital's Medicare payments based on the hospital's overall proportion of inpatients who are dually eligible for Medicare and Medicaid.

(Sec. 15003) The bill extends for five years the Rural Community Hospital Demonstration Program, through which Medicare pays certain rural hospitals on the basis of reasonable incurred costs rather than under the standard prospective payment system.

(Sec. 15004) With respect to long-term care hospitals (LTCHs), the bill lifts a moratorium on bed increases. The bill reduces rates for high-cost outlier payments, which are additional Medicare payments made in extraordinarily high-cost cases.

(Sec. 15005) The bill reduces the amount by which hospital payment rates for inpatient services increase in FY2018.

(Sec. 15006) The bill amends the Medicare, Medicaid, and SCHIP Extension Act of 2007 to revise the applicability of certain Medicare payment rules exempting LTCHs from negative payment adjustments for admissions from certain co-located hospitals beyond specified thresholds. These rules shall apply for an additional period beginning on October 1, 2016.

(Sec. 15007) In addition, the bill amends the Pathway for SGR Reform Act of 2013 to expand to all LTCHs the application of a payment rule that requires the exclusion of certain patients for purposes of calculating length of stay. Under current law, the payment rule applies only to a hospital that was classified as an LTCH as of a specified date.

(Sec. 15008) The bill removes certain hospitals specializing in neoplastic disease from their classification as LTCHs for purposes of Medicare payment.

(Sec. 15009) With specified exceptions, current law applies certain payment limits to inpatient services for LTCHs that do not meet specified discharge requirements. The bill: (1) establishes a new temporary exception to these limits for certain spinal cord specialty hospitals, and (2) expands an existing temporary exception with respect to certain discharges involving severe wounds.

TITLE XVI--PROVISIONS RELATING TO MEDICARE PART B

(Sec. 16001) The bill excludes certain off-campus outpatient departments (OPDs) from specified rules that mandate lower Medicare payments. Specifically, the exclusion applies to: (1) cancer hospitals in off-campus OPDs, and (2) mid-build OPDs. A "mid-build" OPD is one for which the provider had, before a certain date, a binding written agreement with an outside party for construction.

(Sec. 16003) With respect to payment reductions for failing to meet requirements for the meaningful use of electronic health records, the bill exempts eligible professionals who are based in ambulatory surgical centers.

(Sec. 16004) The bill requires the CMS to continue to instruct Medicare contractors not to enforce requirements for direct physician supervision of outpatient therapeutic services in critical access and small rural hospitals through 2016. The Medicare Payment Advisory Commission must report on the effect of extending this instruction on: (1) Medicare beneficiaries, and (2) hospital staffing needs.

(Sec. 16005) The bill amends the Patient Access and Medicare Protection Act to delay by six months the implementation of specified Medicare fee schedule adjustments with respect to certain accessories and seating systems used with complex rehabilitation technology wheelchairs.

(Sec. 16006) The bill allows physical therapists to utilize "locum tenens" arrangements (through which a substitute practitioner is retained when the regular practitioner is absent for a reason such as illness or pregnancy) under Medicare in the same manner as physicians are allowed to use utilize such arrangements under current law.

(Sec. 16007) The CMS shall: (1) delay by six months the full implementation of new Medicare payment rates for durable medical equipment (DME), and (2) study and report on the impact of applicable payment adjustments on the availability of DME to Medicare beneficiaries.

(Sec. 16008) Under current law, the CMS must use payment information from competitive acquisition programs to make payment adjustments for DME items furnished in areas outside of such programs. Current law also allows, but does not require, the CMS to make such adjustments with respect to certain orthotics (such as splints and braces) and parenteral and enteral nutrients, equipment, and supplies (such as feeding tubes). The bill requires the CMS, in making these adjustments, to account for stakeholder input. In addition, the CMS must account for a comparison of competitive acquisition areas and other areas with respect to the following factors:

- average travel distance and cost associated with furnishing items and services,
- average volume of items and services furnished by suppliers, and

number of suppliers.

TITLE XVII--OTHER MEDICARE PROVISIONS

(Sec. 17001) Until plan year 2019, the CMS may not terminate a Medicare Advantage (MA) plan solely because the plan failed to achieve a specified minimum quality rating.

(Sec. 17002) The CMS must annually report on specified Medicare enrollment data.

(Sec. 17003) The CMS shall: (1) request information and recommendations from stakeholders on information included in the Welcome to Medicare package, and (2) update the information included in the package accordingly.

(Sec. 17004) Current law allows the CMS to impose a temporary moratorium on the enrollment of new providers under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) if necessary to combat fraud, waste, or abuse. With specified exceptions, the bill prohibits payment under these programs to new providers in areas subject to such temporary moratorium.

(Sec. 17005) The bill expands and modifies enrollment and disenrollment options for MA-eligible individuals. Specifically, the bill extends the annual period in which an individual enrolled in MA may elect to instead receive benefits under the original Medicare fee-for-service (FFS) program as well as elect to change qualified prescription drug coverage. Furthermore, any MA-eligible individual (whether or not enrolled in MA) may once per period change a previous election with respect to receiving benefits through MA or Medicare FFS, including changing from one MA plan to another. Unsolicited marketing during this period is prohibited.

(Sec. 17006) The bill allows individuals with end-stage renal disease (ESRD) to be eligible for MA. Under current law, only individuals who develop ESRD while already enrolled in an MA plan may be considered eligible.

With respect to payment, the bill: (1) shifts responsibility for the cost of kidney acquisitions from MA plans to Medicare's FFS program, and (2) excludes such costs from the calculation of certain benchmarks that form the basis for payment under MA plans.

The CMS must conduct, and post online the results of, an evaluation of whether to include in a plan's

Actions Timeline

- **Dec 13, 2016:** Signed by President.
- **Dec 13, 2016:** Became Public Law No: 114-255.
- **Dec 8, 2016:** Presented to President.
- **Dec 7, 2016:** Considered by Senate (Message from the House considered). (consideration: CR S6769-6795)
- **Dec 7, 2016:** Resolving differences -- Senate actions: Senate agreed to the House amendment to the Senate amendment to H.R. 34 by Yea-Nay Vote. 94 - 5. Record Vote Number: 157.
- **Dec 7, 2016:** Senate agreed to the House amendment to the Senate amendment to H.R. 34 by Yea-Nay Vote. 94 - 5. Record Vote Number: 157.
- **Dec 7, 2016:** Message on Senate action sent to the House.
- **Dec 6, 2016:** Considered by Senate (Message from the House considered). (consideration: CR S6719-6730)
- **Dec 5, 2016:** Considered by Senate (Message from the House considered). (consideration: CR S6686-6696, S6697-6699)
- **Dec 5, 2016:** Cloture on the motion to concur in the House amendment to the Senate amendment to H.R. 34 invoked in Senate by Yea-Nay Vote. 85 - 13. Record Vote Number: 156. (consideration: CR S6697; text: CR S6697)
- **Dec 5, 2016:** Motion by Senator McConnell to refer to Senate Committee on Health, Education, Labor, and Pensions fell when cloture was invoked on the motion to concur in the House amendment to the Senate amendment to H.R. 34 in Senate.
- **Dec 5, 2016:** Pursuant to the provisions of H. Con. Res. 174, enrollment corrections on H.R. 34 have been made.
- **Dec 1, 2016:** Message on House action received in Senate and at desk: House amendment to Senate amendment.
- **Dec 1, 2016:** Measure laid before Senate by unanimous consent. (consideration: S6645-6646, S6646-6649, S6650-6658)
- **Dec 1, 2016:** Motion by Senator McConnell to concur in the House amendment to the Senate amendment to H.R. 34 made in Senate. (consideration: S6645)
- **Dec 1, 2016:** Cloture motion on the motion to concur in the House amendment to the Senate amendment to H.R. 34 presented in Senate. (consideration: S6645; text: CR S6645)
- **Dec 1, 2016:** Motion by Senator McConnell to concur in the House amendment to the Senate amendment to H.R. 34 with an amendment (SA 5117) made in Senate. (consideration: S6646)
- **Dec 1, 2016:** Motion by Senator McConnell to refer to Senate Committee on Health, Education, Labor, and Pensions the House message to accompany H.R. 34 with instructions to report back forthwith with the following amendment (SA 5119) made in Senate. (consideration: CR S6646)
- **Nov 30, 2016:** ORDER OF PROCEDURE - Mr. Upton asked unanimous consent that the question of adopting a motion to concur in the Senate amendment to H.R. 34 with an amendment be subject to postponement as though under clause 8 of rule 20. Agreed to without objection. (consideration: CR H6894-7006; H7046-7047)
- **Nov 30, 2016:** Mr. Upton moved that the House agree with an amendment to the Senate amendment.
- **Nov 30, 2016:** DEBATE - Pursuant to the provisions of H. Res. 934, the House proceeded with 80 minutes of debate on the motion to concur in the Senate amendment to H.R. 34, with an amendment.
- **Nov 30, 2016:** The previous question was ordered pursuant to the rule. (consideration: CR H7006)
- **Nov 30, 2016:** POSTPONED PROCEEDINGS - At the conclusion of debate on the amendment to the Senate amendment to H.R. 34, the Chair put the question on agreeing to the Senate amendment with an amendment and by voice vote, announced that the yeas had prevailed. Mr. McDermott demanded a recorded vote and the Chair postponed further proceedings until a time to be announced.
- **Nov 30, 2016:** Resolving differences -- House actions: On motion that the House agree with an amendment to the Agreed to by recorded vote: 392 - 26 (Roll no. 592).
- **Nov 30, 2016:** On motion that the House agree with an amendment to the Agreed to by recorded vote: 392 - 26 (Roll no. 592).
- **Nov 30, 2016:** Motion to reconsider laid on the table Agreed to without objection.
- **Nov 29, 2016:** Rules Committee Resolution H. Res. 934 Reported to House. Rule provides for consideration of H.R. 34 and H.R. 6392. Providing for consideration for the Senate amendment to H.R. 34 and for consideration of H.R. 6392.
- **Nov 30, 2015:** Star Print ordered on the errata sheet.
- **Oct 7, 2015:** Message on Senate action sent to the House.
- **Oct 6, 2015:** Measure laid before Senate by unanimous consent. (consideration: CR S7167-7171)
- **Oct 6, 2015:** The committee substitute as amended agreed to by Unanimous Consent. (text of committee substitute as

amended: CR S7167-7171)

- **Oct 6, 2015:** Passed/agreed to in Senate: Passed Senate with an amendment by Unanimous Consent.
- **Oct 6, 2015:** Passed Senate with an amendment by Unanimous Consent.
- **Sep 22, 2015:** Committee on Commerce, Science, and Transportation. Reported by Senator Thune with an amendment in the nature of a substitute. With written report No. 114-146.
- **Sep 22, 2015:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 237.
- **Sep 22, 2015:** An errata sheet on written report No. 114-146 was printed.
- **Feb 26, 2015:** Committee on Commerce, Science, and Transportation. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jan 8, 2015:** Received in the Senate and Read twice and referred to the Committee on Commerce, Science, and Transportation.
- **Jan 7, 2015:** Mr. Smith (TX) moved to suspend the rules and pass the bill.
- **Jan 7, 2015:** Considered under suspension of the rules. (consideration: CR H87-92)
- **Jan 7, 2015:** DEBATE - The House proceeded with forty minutes of debate on H.R. 34.
- **Jan 7, 2015:** Passed/agreed to in House: On motion to suspend the rules and pass the bill Agreed to by voice vote.(text: CR H87-90)
- **Jan 7, 2015:** On motion to suspend the rules and pass the bill Agreed to by voice vote. (text: CR H87-90)
- **Jan 7, 2015:** Motion to reconsider laid on the table Agreed to without objection.
- **Jan 6, 2015:** Introduced in House
- **Jan 6, 2015:** Referred to the House Committee on Science, Space, and Technology.