TITLE I: Ending Surprise Medical Bills	
Sec. 101. Protecting patients against out-of-network deductibles in emergencies.	• Requires that emergency health care charges to a patient are counted toward the patient's in-network deductible. • Ensures that patient protections for emergency services apply in all relevant settings of care.
Sec. 102. Protection against surprise bills.	• Patients are held harmless from surprise medical bills. Patients are only required to pay the in-network cost-sharing amount for out-of-network emergency care and for care provided by ancillary out-of-network practitioners, and for out-of-network diagnostic services at in-network facilities. Facilities and practitioners are barred from sending patients "balance" bills for more than the in-network cost-sharing amount. • If a patient is stabilized after entering a facility through the emergency room, the patient must be given advance notice of any out-of-network care, an estimate of the patient's costs for out-of-network care, and referrals for alternative options for in-network care. If a patient is not given adequate notice, the patient would be protected from surprise bills or out-of-network cost-sharing.
Sec. 103. Benchmark for payment.	• For surprise bills, health plans would pay providers the local median contracted commercial amount that insurers have negotiated with other providers and agreed upon in that geographic area. • HHS will use notice and comment rulemaking to define geographic areas and establish a consistent methodology for health plans to use in calculating their own median contracted rates. • Health plans without sufficient internal data in a given geographic area will have the option of accessing unbiased external data sources (such as a state's all-payer claims database) to calculate an appropriate median rate for that market.
Sec. 104. Effective date.	• Sections 101, 102, and 103 shall take effect beginning in the second plan year that begins after the date of enactment of this Act.

Sec. 105. Ending surprise air ambulance bills.	• Patients are held harmless from surprise air ambulance bills. Patients are only required to pay the in-network cost sharing amount for air ambulance transport, and air ambulance providers are barred from sending patients balance bills for more than the in-network cost-sharing amount. • For surprise air ambulance bills, health plans would pay air ambulance providers the local median contracted commercial amount that the insurer negotiated with other providers and agreed upon in that geographic area. • Health plans without enough internal data to calculate median contracted rates in a particular geographic area have the option of using unbiased external data sources, such as a state's all-payer claims database, to establish a benchmark.
Sec. 106. Report.	• Directs the Secretary of HHS, in consultation with the Federal Trade Commission and Attorney General, to conduct a study on the effects of sections 101, 102, and 103 on vertical and horizontal integrations, on overall health care costs, and on recommendations for effective enforcement of section 103, including potential challenges to addressing anti-competitive consolidation by health care facilities, providers, group health plans, or health insurance issuers.

	TITLE II: Reducing the Prices of Prescription Drugs
Sec. 201. Biological product patent transparency.	• Increases transparency of patent information for biological products by requiring information to be submitted to the Food and Drug Administration (FDA) and published in the "Purple Book." • Codifies the publication the "Purple Book" as a single, searchable list of information about each licensed biological product, including marketing and licensure status, patent information, and relevant exclusivity periods. • Requires the Secretary, in consultation with the Director of the U.S. Patent and Trademark Office, to publish a list of any holders of biological product licenses that failed to submit such information.
Sec. 202. Orange Book modernization.	• Clarifies the information that FDA must include in the Orange Book about patents and exclusivities for drugs approved under Section 505 of the Federal Food, Drug, and Cosmetic Act. • Requires FDA to remove patents and patent claim information from the Orange Book when the U.S. Patent and Trademark Office determines a patent or patent claim is invalid or inoperative to encourage drug development in the area no longer patented.
Sec. 203. Ensuring timely access to generics.	• Maintains the use of citizen petitions to allow interested stakeholders, including drug companies, to notify FDA of concerns with pending generic and other follow-on drug applications. • Addresses the abuse of the citizen petition process, which can be used to unnecessarily delay the approval of a drug application. • Provides that FDA may deny a citizen petition that is submitted with the primary purpose of delaying the approval of an application and clarifies criteria that FDA may use to make this determination. • Requires a petition to be submitted within 60 days after the petitioner knew, or reasonably should have known, the information that forms the basis of the petition. • Requires HHS to establish procedures for referring a petitioner to the Federal Trade Commission if determined that a petition was submitted with the primary purpose of delaying the approval of another application.
Sec. 204. Protecting access to biological products.	• Clarifies that biological products, including insulin products, that will transition from the drugs pathway to the biologics pathway in March 2020, cannot receive new, extended market exclusivities. • Preserves certain unexpired exclusivities for biological products as FDA transitions the regulation of such products from the drugs pathway to the biologics pathway.

Sec. 205. Preventing blocking of generic drugs.	• Prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market. • Triggers the start of first-to-file generic drug applicants' 180-day exclusivity when a subsequent applicant has been tentatively approved and no first-to-file applicant has received final approval within 33 months of submission of its application.
Sec. 206. Education on biological products.	• Requires FDA to establish an internet website to provide educational materials for health care providers, patients, and caregivers on biological products, including biosimilar and interchangeable biological products. • Provides that the Secretary may develop and improve continuing medical education for health care providers regarding biological products.
Sec. 207. Biological product innovation.	• Excludes all biological products subject to regulation under the Public Health Service Act from requirements to follow U.S. Pharmacopeial compendial standards, which were originally drafted to apply to drugs approved under Section 505 of the Federal Food, Drug, and Cosmetic Act. • Prevents delays related to compliance with USP standards, in the licensure of biosimilar and interchangeable products.
Sec. 208. Clarifying the meaning of new chemical entity.	• Clarifies that eligibility for five-year new chemical entity (NCE) exclusivity is available only for a drug containing no active moiety that has been previously approved in the United States • Ensures that drug manufacturers cannot receive NCE exclusivity for making small tweaks to old drugs – that only the most innovative or novel drugs qualify for exclusivity.
Sec. 209. Streamlining the transition of biological products.	• In March 2020, a small subset of biological products, including insulin, will transition from the drugs pathway to the biologics pathway, opening the biological products up to biosimilar competition. • Ensures that FDA can continue to review drug applications submitted six months prior to the transition date that have not received approval – making clear that applications will not have to be resubmitted under the biologics pathway, and avoiding delays in generic product availability.
Sec. 210. Orphan drug clarification.	• Clarifies that the clinical superiority standard applies to drugs with an orphan drug designation that are approved after the FDA Reauthorization Act of 2017 in order to be awarded 7 years of orphan drug exclusivity, regardless of the date of the orphan drug designation.

Sec. 211. Prompt approval of drugs related to safety information.	• Gives FDA authority to more promptly approve a follow-on or generic drug and include a statement of necessary safety information in its labeling even if certain safety information is protected by a brand drugs exclusivity.
Sec. 212. Conditions of use for biosimilar biological products.	• Clarifies that biosimilar applicants can include information in biosimilar submissions to show that the proposed conditions of use for the biosimilar product have been previously approved for the reference product.
Sec. 213. Modernizing the labeling of certain generic drugs.	• Gives FDA new authorities to address outdated drug labeling for generic drugs that contain incomplete or incorrect information because there is no longer a brand drug on the market. • Allows FDA to require changes to the labeling of generic drugs to reflect new information and scientific evidence about a generic drug in accordance with FDA's gold standard of approval.

TITLE III: Improving Transparency in Health Care	
Sec. 301. Increasing transparency by removing gag clauses on price and quality information.	• Bans gag clauses in contracts between providers and health plans that prevent enrollees, plan sponsors, or referring providers from seeing cost and quality data on providers. • Bans gag clauses in contracts between providers and health insurance plans that prevent plan sponsors from accessing de-identified claims data that could be shared, under HIPAA business associate agreements, with third parties for plan administration and quality improvement purposes.
Sec. 302. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.	• Prevents "anti-tiering" and "anti-steering" clauses in contracts between providers and health plans that restrict the plan from directing or incentivizing patients to use specific providers and facilities with higher quality and lower prices. • Prevents "all-or-nothing" clauses in contracts between providers and health plans that require health insurance plans to contract with all providers in a particular system or none of them. • Prevents "most-favored-nation" clauses in contracts between providers and health plans that protect an insurance company's dominant position in a market by requiring that the insurance company be given the most favorable pricing of any health plan in the market. • Prohibits obligations on plan sponsors to agree to terms of contracts that the sponsor is not party to and cannot review, which could conceal anti-competitive contracting terms.
Sec. 303. Designation of a nongovernmental, nonprofit transparency organization to lower Americans' health care costs.	• Designates a nongovernmental, nonprofit entity to improve the transparency of health care costs. • The nonprofit entity, in compliance with current privacy and security protections, will use de-identified health care claims data from self-insured plans, Medicare, and participating states to help patients, providers, academic researchers, and plan sponsors better understand the cost and quality of care, and facilitate state-led initiatives to lower the cost of care, while prohibiting the disclosure of identifying health data or proprietary financial information. • Creates an advisory committee composed of public and private sector representatives to advise the entity on the format, scope, and uses of this data, and establish the entity's research and reporting objectives. • Creates custom reports for employers and employee organizations seeking to utilize the database to lower health care costs. • Authorizes grants to states to maintain or create similar transparency initiatives.
Sec. 304. Protecting patients and improving	• Requires health plans to have up-to-date directories of their in-network providers, which shall be available to patients online, or within 24 hours of an inquiry.

the accuracy of provider directory Information.	• If a patient provides documentation that they received incorrect information from an insurer about a provider's network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount.
Sec. 305. Timely bills for patients.	• Requires health care facilities and providers to give patients a list of services received upon discharge. • Requires all bills to be sent to a patient within 45 days. If bills are received more than 45 days after receiving care, the patient is not obligated to pay. • Requires providers and facilities to give patients at least 30 days to pay bills upon receipt.
Sec. 306. Health plan oversight of pharmacy benefit manager services.	• Requires that plan sponsors receive a quarterly report on the costs, fees and rebate information associated with their PBM contracts. Reporting will be structured to prevent the release of information that could lead to higher drug prices. • Prohibits PBMs from engaging in spread pricing, or charging a plan sponsor, health insurance plan, or patient more for a drug than the PBM paid to acquire the drug. Includes reporting and pricing requirements for PBMs that own mail-order, specialty, or retail pharmacies. • Requires the PBM to pass on 100% of any rebates or discounts to the plan sponsor.
Sec. 307. Government Accountability Office study on profit- and revenue-sharing in health care.	• Requires a GAO study on profit-sharing relationships between hospitals, contract management groups, and physician and ancillary services, and the Federal oversight of such relationships.
Sec. 308. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health plans and enrollees in plans on the individual market.	• Requires health benefit brokers and consultants to disclose to plan sponsors any direct or indirect compensation the brokers and consultants may receive for referral of services, using a reporting format similar to a regulation proposed in 2007 by the Bush Administration for health and pension plan brokers. • Requires health benefit brokers to disclose to enrollees in the individual market any direct or indirect compensation the brokers may receive for referral of coverage. • Establishes a disclosure requirement for compensation that is not known at the time a contract is signed.
Sec. 309. Ensuring	• Requires providers and health plans to give patients good faith estimates of their expected out-

enrollee access to cost sharing information.	of-pocket costs for specific health care services, and any other services that could reasonably be provided, within two business days of a request.
Sec. 310. Strengthening parity in mental health and substance use disorder benefits.	• Requires group health plans and health insurance coverage to conduct comparative analysis of nonquantitative treatment limitations used for medical and surgical benefits as compared to mental health and substance use disorder benefits. • Requires the Secretary of Labor to request that a group health plan or coverage submit the comparative analysis if they receive a complaint from an enrollee and that the Secretary request random submissions from 50 plans per year. • If, upon review of the analysis, the Secretary finds that a plan or coverage is out of compliance with mental health parity law, the Secretary must specify actions for the plan or coverage to come into compliance.
Sec. 311. Technical Amendments.	• Clarifies the application of Public Health Service Act requirements on group health plans and health insurance coverage under the Employee Retirement Income Security Act and the Internal Revenue Code.
Sec. 312. Third-Party Administrators.	• Clarifies the obligations of third-party administrators to group health plans regarding compliance with Federal law.

TITLE IV: Improving Public Health	
Sec. 401. Improving awareness of disease prevention.	• Authorizes a national campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation, and disseminate scientific and evidence-based vaccine-related information.
Sec. 402. Grants to address vaccine-preventable diseases.	• Authorizes grants for the purpose of planning, implementation, and evaluation of activities to address vaccine-preventable diseases, and for research on improving awareness of scientific and evidence-based vaccine-related information.
Sec. 403. Guide on evidence-based strategies for public health department obesity prevention programs.	• Requires HHS to develop and disseminate guides on evidence-based obesity prevention and control strategies for State, territorial, and local health departments and Indian tribes and tribal organizations.
Sec. 404. Expanding capacity for health outcomes.	• Authorizes the provision of technical assistance and grants to evaluate, develop, and expand the use of technology-enabled collaborative learning and capacity building models to increase access to specialized health care services in medically underserved areas and for medically underserved populations.
Sec. 405. Public health data system modernization.	• Requires HHS to award grants to state and local public health departments for the expansion and modernization of public health data systems to improve data collection, simplify reporting by health care providers, enhance interoperability of current public health data systems with health information technology, support earlier disease detection, and support electronic case reporting. • Authorizes the Centers for Disease Control and Prevention (CDC) to update and improve public health data systems used by the agency.
Sec. 406. Innovation for maternal health.	• Establishes an HHS grant program for the training of health care professionals to reduce and prevent discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care. • Allows the Secretary to identify and disseminate best practices for such training.

Sec. 407. Training for health care providers.	• Establishes an HHS grant program for the training of health care professionals to reduce and prevent discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.
Sec. 408. Study on training to reduce and prevent discrimination.	• Requires HHS, through a contract with an independent research organization, to study and make recommendations for best practices associated with training for health care professionals to reduce and prevent discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.
Sec. 409. Perinatal quality collaboratives.	• Requires HHS, acting through the Director of the Centers for Disease Control and Prevention, to award grants for the establishment or support of state perinatal quality collaboratives to improve perinatal care and perinatal health outcomes for pregnant and postpartum women and their infants.
Sec. 410. Integrated services for pregnant and postpartum women.	• Authorizes HHS to award grants to states for the purpose of establishing or operating evidence-based or innovative, evidence-informed programs that deliver integrated health care services to pregnant and postpartum women to optimize the health of women and their infants, including by addressing issues that contribute to adverse maternal health outcomes, pregnancy-related deaths, and related health disparities, including disparities associated with racial and ethnic minority populations. • Requires HHS to submit a report to Congress that describes the outcomes of activities supported by grants under this section on maternal and child health, including best practices and models of care utilized, obstacles identified, and strategies used by grantees to deliver care, improve maternal and child health, and reduce related health disparities. • Requires HHS to disseminate information on best practices and models of care used by grantees under this section to relevant stakeholders.
Sec. 411. Extension for community health centers, the National Health Service Corps,	• Extends mandatory funding for community health centers, the National Health Service Corps, and the Teaching Health Center Graduate Medical Education Program at current levels for each of fiscal years 2020 through 2024.

and Teaching Health Centers that operate GME programs.	
Sec. 412. Other programs.	• Extends mandatory funding for the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians at current levels for each of fiscal years 2020 through 2024.

TITLE V: Improving the Exchange of Health Information	

Sec. 501. Requirement to provide health claims, network, and cost information.	• Expands on the success of the Center for Medicare and Medicaid Services Blue Button Initiative by requiring commercial health insurers to make information available to patients through application programming interfaces, including:
	  ○ health insurance claims data;
	  ○ in-network practitioners; and
	  ○ expected out-of-pocket costs.
	• To help patients pick the best health insurance plan for their family and then navigate that plan when they need care, this ensures that patients have full, electronic access to their own health information and information on what the patient would pay out of pocket for specific care.
	• Emphasizes that all existing privacy and security protections for patient health data under the Health Insurance Portability and Accountability Act (HIPAA) and state laws apply.

Sec. 502. Recognition of security practices.	• Incentivizes health care entities to adopt strong cybersecurity practices by encouraging the Secretary of Health and Human Services to consider entities' adoption of recognized cybersecurity practices when conducting audits or administering fines related to the Health Insurance Portability and Accountability Act (HIPAA) Security Rule.
Sec. 503. GAO study on the privacy and security risks of electronic transmission of individually identifiable health information to and from entities not covered by the Health Insurance Portability and Accountability Act.	• Requests a Government Accountability Office study to better understand existing gaps in privacy and security protections for health information as patients move their information to third parties, such as mobile applications, that are not covered by the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules. The study would identify potential opportunities for improving the privacy and security protections for that health information.
Sec. 504. Technical corrections.	• Clarifies the Department of Health and Human Services Office of the Inspector General's authority to investigate and enforce the information blocking provisions in the 21st Century Cures Act.