

## TITLE I: Improving Public Health

<p>Sec. 111. Improving awareness of disease prevention.</p>	<ul style="list-style-type: none"> <li>• Authorizes a national campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, to combat misinformation, and to disseminate scientific and evidence-based vaccine-related information.</li> <li>• Directs the Department of Health and Human Services (HHS) to expand and enhance, and, as appropriate, establish and improve, programs and activities to collect, monitor, and analyze vaccination insurance coverage data.</li> <li>• Requires the National Vaccine Advisory Committee to update, as appropriate, the report entitled, “Assessing the State of Vaccine Confidence in the United States: Recommendations from the National Vaccine Advisory Committee.”</li> <li>• 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.</li> </ul>
<p>Sec. 112. Guide on evidence-based strategies for public health department obesity prevention programs.</p>	<ul style="list-style-type: none"> <li>• Authorizes 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.</li> </ul>
<p>Sec. 113. Expanding capacity for health outcomes.</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<p>Sec. 114. Public health data system modernization.</p>	<ul style="list-style-type: none"> <li>• Requires HHS to expand, enhance, and improve public health data systems used by the Centers for Disease Control and Prevention (CDC).</li> <li>• Requires HHS to award grants to State, local, Tribal, or territorial public health departments for the modernization of public health data systems in order to assist public health departments in assessing current data infrastructure capabilities and gaps; to improve secure public health data collection, transmission, exchange, maintenance, and analysis; to enhance the interoperability of public health data systems; to support and train related personnel; to support earlier disease and health condition detection; and to develop and disseminate related information and improved electronic case reporting.</li> <li>• Requires the Secretary of HHS to develop and submit to Congress a coordinated strategy and accompanying implementation plan that identifies and demonstrates measures utilized to carry out such activities.</li> </ul>

Maternal Health

	<ul style="list-style-type: none"><li>• Requires HHS to consult with State, local, Tribal, and territorial health departments and other appropriate public or private entities regarding the plan and grant program to modernize public health data systems pursuant to this section.</li></ul>
Sec. 115. Native American suicide prevention.	<ul style="list-style-type: none"><li>• Ensures states consult with Indian tribes, tribal organizations, urban Indian organizations, and Native Hawaiian Health Care Systems in developing youth suicide early intervention and prevention strategies.</li></ul>
Sec. 121. Innovation for maternal health.	<ul style="list-style-type: none"><li>• Directs HHS to establish or continue a grant program for the purpose of improving maternal health care quality and outcomes, eliminating preventable maternal mortality and severe maternal morbidity, and improving infant health outcomes, including by identifying, developing, and disseminating best practices and information to improve maternal health outcomes.</li></ul>
Sec. 122. Training for health care providers.	<ul style="list-style-type: none"><li>• Establishes an HHS grant program for the training of health care professionals to reduce and prevent discrimination, including training related to implicit and explicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.</li><li>• Allows the Secretary of HHS to identify and disseminate best practices for such training.</li></ul>
Sec. 123. Study on training to reduce and prevent discrimination.	<ul style="list-style-type: none"><li>• Requires HHS, through a contract with an independent research organization, to conduct a study and make recommendations for best practices associated with training for health care professionals to reduce and prevent discrimination, including training related to implicit and explicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.</li></ul>
Sec. 124. Perinatal quality collaboratives.	<ul style="list-style-type: none"><li>• Requires HHS, acting through the Director of CDC, 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.</li></ul>
Sec. 125. Integrated services for pregnant and postpartum women.	<ul style="list-style-type: none"><li>• 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.</li><li>• 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.</li></ul>

	<ul style="list-style-type: none"> <li>• Requires HHS to disseminate information on best practices and models of care used by grantees under this section to relevant stakeholders.</li> </ul>
Sec. 126. Improving rural maternal and obstetric care data.	<ul style="list-style-type: none"> <li>• Includes “preventable maternal mortality and severe maternal morbidity” in the maternal health-related activities that CDC is required to coordinate.</li> <li>• Updates the CDC Office of Women’s Health to ensure consideration of the impact of geography on women’s health, and the health of female American Indians, Native Hawaiians, and Alaska Natives.</li> <li>• Improves data collected under the Safe Motherhood program, including related to race, ethnicity, and other demographic information, and encourages research on maternal health outcomes in rural areas.</li> <li>• Requires the National Institutes of Health (NIH) Office of Research on Women’s Health to identify research projects and multidisciplinary research opportunities related to pregnancy, especially related to reducing preventable maternal mortality and severe maternal morbidity.</li> </ul>
Sec. 127. Rural obstetric network grants.	<ul style="list-style-type: none"> <li>• Requires HHS to award grants for networks in rural and frontier areas, or Indian Tribal jurisdictions, to improve maternal and infant health outcomes and reduce maternal mortality.</li> <li>• Such networks may use funds to improve coordination and access to care; implement evidence-based and sustainable delivery models; develop models for cross-setting collaboration, which may utilize telehealth; train health professionals in settings without specialty care on-site; and address disparities in health outcomes.</li> </ul>
Sec. 128. Telehealth network and telehealth resource centers grant programs.	<ul style="list-style-type: none"> <li>• Amends the telehealth network and telehealth resource centers grant program to include maternal care providers and improve care for high-risk pregnancies.</li> </ul>
Sec. 129. Rural maternal and obstetric care training demonstration.	<ul style="list-style-type: none"> <li>• Requires HHS to award grants to accredited health professional schools and training programs to establish programs to train health care professionals and other professionals to provide maternal health care services in rural, community-based settings.</li> <li>• Requires grant recipients to ensure that training programs under this section are evidence-based and address maternal mental health, maternal substance use disorder, social determinants of health impacting rural communities, and implicit and explicit bias to improve maternal health outcomes.</li> </ul>
Sec. 131. Short title.	<ul style="list-style-type: none"> <li>• Names this subtitle of the legislation the Kay Hagan Tick Act.</li> </ul>

<p>Sec. 132. Combating vector-borne diseases.</p>	<ul style="list-style-type: none"> <li>• Requires HHS to ensure the development and implementation of a national strategy for vector-borne diseases, including tick-borne diseases, to identify strategic goals and address gaps and unnecessary duplication in federal activities related to vector-borne diseases.</li> <li>• Requires HHS, in coordination with CDC, to make awards to academic institutions to support the establishment or continuation of regional centers of excellence to address vector-borne diseases.</li> </ul>
<p>Sec. 133. Enhancing capacity to address vector-borne diseases.</p>	<ul style="list-style-type: none"> <li>• Allows HHS, through CDC, to enter into cooperative agreements with State, local, and territorial health departments and Tribes and Tribal organizations in areas at high-risk of vector-borne diseases, in order to improve the ability of health departments to identify, report, prevent, and respond to such diseases and related outbreaks.</li> </ul>
<p>Sec. 141. Extension for community health centers, the national health service corps, and teaching health centers that operate GME programs.</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<p>Sec. 142. Diabetes programs.</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

## TITLE II: Improving Transparency In Health Care

<p>Sec. 201. Increasing transparency by removing gag clauses on price and quality information.</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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 Health Insurance Portability and Accountability Act (HIPAA) business associate agreements, with third parties for plan administration and quality improvement purposes.</li> </ul>
<p>Sec. 202. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• Provides an opportunity for state officials to waive the prohibition for arrangements that do not lessen competition.</li> </ul>
<p>Sec. 203. State All Payer Claims Databases.</p>	<ul style="list-style-type: none"> <li>• Establishes a grant program to create and improve State All Payer Claims Databases.</li> <li>• Requires recipients of the grants from this program to make data available to authorized users, including researchers, employers, health insurance issuers, third-party administrators, and health care providers for quality improvement and cost-containment purposes.</li> <li>• Requires the Secretary of Labor to establish a standard national format that states must use in order to require self-insured plans to report to the state’s database.</li> </ul>
<p>Sec. 204. Protecting patients and improving the accuracy of provider directory information.</p>	<ul style="list-style-type: none"> <li>• Requires health plans to have up-to-date directories of their in-network providers, which shall be available to patients online, or within one business day of an inquiry.</li> <li>• 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.</li> </ul>

<p>Sec. 205. Timely bills for patients.</p>	<ul style="list-style-type: none"> <li>• Requires health care facilities and practitioners to give patients a list of services received upon discharge or end of a visit or by postal or electronic communication as soon as practicable and not later than 15 calendar days after discharge or date of visit.</li> <li>• The health care facility or practitioner shall submit to the health plan the bill not later than 20 calendar days after discharge or date of visit of the individual. A health plan, after receiving the bill from the health care facility or practitioner, shall complete adjudication of the bill not later than 20 calendar days after receiving the bill. The health care facility or practitioner shall send the adjudicated bill to the patient not later than 20 calendar days after receiving the adjudicated bill from the health plan.</li> <li>• If a patient receives a bill more than 60 calendar days after receiving care, the patient is not obligated to pay.</li> <li>• The Secretary of HHS shall promulgate regulations to account for any extenuating circumstances or types of billing (such as global packages) that may prevent a provider, facility, or health plan from complying with this provision.</li> <li>• Requires facilities and practitioners to give patients at least 35 days after the postmark date to pay bills.</li> </ul>
<p>Sec. 206. Health plan oversight of pharmacy benefit manager services.</p>	<ul style="list-style-type: none"> <li>• Requires that group health plan sponsors receive a semi-annual report on the costs, fees, and rebate information associated with their pharmacy benefit manager (PBM) contracts. Reporting will be structured to prevent the release of information that could lead to higher drug prices.</li> <li>• 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 the pharmacy for the drug.</li> <li>• Requires the PBM to pass on 100% of any rebates or discounts to the plan sponsor.</li> <li>• Requires Government Accountability Office (GAO) to conduct a study on PBMs that own mail-order, specialty, or retail pharmacies.</li> </ul>
<p>Sec. 207. Government Accountability Office study on profit-and revenue-sharing in health care.</p>	<ul style="list-style-type: none"> <li>• Requires GAO to conduct a study on profit-sharing relationships between hospitals, contract management groups, and physician and ancillary services, and the Federal oversight of such relationships.</li> </ul>
<p>Sec. 208. Disclosure of direct and indirect compensation for brokers and consultants to employer-sponsored health</p>	<ul style="list-style-type: none"> <li>• 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 <u>in 2007 by the Bush Administration</u> for health and pension plan brokers.</li> </ul>

<p>plans and enrollees in plans on the individual market.</p>	<ul style="list-style-type: none"> <li>• Requires health benefit brokers to disclose to enrollees in the individual market or enrollees purchasing short-term limited duration insurance any direct or indirect compensation the brokers may receive for referral of coverage.</li> <li>• Establishes a disclosure requirement for compensation that is not known at the time a contract is signed.</li> </ul>
<p>Sec. 209. Ensuring enrollee access to cost-sharing information.</p>	<ul style="list-style-type: none"> <li>• Requires providers and health plans to give patients good faith estimates of their expected out-of-pocket costs for specific health care services, and any other services that could reasonably be provided, within two days of a request.</li> </ul>
<p>Sec. 210. Strengthening parity in mental health and substance use disorder benefits.</p>	<ul style="list-style-type: none"> <li>• Requires group health plans and health insurance issuers offering coverage in the individual or group markets to conduct comparative analyses of the nonquantitative treatment limitations used for medical and surgical benefits as compared to mental health and substance use disorder benefits.</li> <li>• Requires the Secretary of Labor to request that a group health plan or coverage offered by an issuer submit the comparative analysis of at least 20 plans per year. The Secretary shall use a risk-based approach for conducting the requests.</li> <li>• If, upon review of the analysis, the Secretary finds that a plan or coverage offered by an issuer is out of compliance with mental health parity law, the Secretary must specify corrective actions for the plan or coverage to come into compliance within 45 days.</li> <li>• If the plan is still not in compliance, the plan shall notify all individuals enrolled in noncompliance plans within 7 days.</li> <li>• Requires the Secretary of Labor to publish an annual report with a summary of the comparative analyses.</li> </ul>
<p>Sec. 211. Third-party administrators.</p>	<ul style="list-style-type: none"> <li>• Clarifies the obligations of third-party administrators to group health plans regarding compliance with Federal law.</li> </ul>
<p>Sec. 212. Group health plan reporting requirements.</p>	<ul style="list-style-type: none"> <li>• Requires health plans to report information on plan medical costs and prescription drug spending to the Secretary of HHS.</li> <li>• The Assistant Secretary of Planning and Evaluation, in coordination with the Office of the Inspector General, shall publish a report on the HHS website on prescription drug pricing trends and the contribution to health insurance premiums 18 months after the date of enactment, and every two years thereafter.</li> </ul>

Sec. 213. Study by  
Comptroller General of  
United States.

- Requires GAO to conduct a study on the role of PBMs and issue a report to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives three years after the date of enactment.



### TITLE III: No Surprises Act

Sec. 301. Short title.	<ul style="list-style-type: none"> <li>• This title may be cited as the “No Surprises Act”.</li> </ul>
Sec. 302. Preventing surprise medical bills.	<ul style="list-style-type: none"> <li>• Relocates existing emergency care protections in 2719A(b) of the Public Health Service Act into a new Part D of Title XXVII of that Act.</li> <li>• Adds new protections that hold patients harmless from surprise medical bills. Patients are only required to pay the in-network cost-sharing amount for out-of-network emergency care, for certain ancillary services provided by out-of-network providers at in-network facilities, and for out-of-network care provided at in-network facilities without the patient’s informed consent. Requires that out-of-network surprise bills are attributed to a patient’s in-network deductible.</li> <li>• Resolves payment between providers and insurers by requiring that the insurer pay at minimum the market-based median in-network negotiated rate for the service in the geographic area where the service was delivered.</li> <li>• If the median in-network rate payment is above \$750, the provider or insurer may elect to go to baseball-style, binding arbitration – referred to as Independent Dispute Resolution (IDR).</li> <li>• If a bill goes to arbitration, the arbitrator is required to consider information brought by the parties related to the training, education, and experience of the provider, the market share of the parties, and other extenuating factors such as patient acuity and the complexity of furnishing the item or service.</li> <li>• Following arbitration, the party that initiated the arbitration may not take the same party to arbitration for the same item or service for 90 days following a determination by the arbitrator.</li> </ul>
Sec. 303. Preventing certain cases of balance billing.	<ul style="list-style-type: none"> <li>• Prohibits out-of-network facilities and providers from sending patients “balance” bills for more than the in-network cost-sharing amount, in the surprise billing circumstances defined in section 302.</li> <li>• Prohibits certain out-of-network providers from balance billing patients unless the provider gives the patient notice of their network status and an estimate of charges 72 hours prior to receiving out-of-network services and the patient provides consent to receive out-of-network care.</li> </ul>
Sec. 304. Ending surprise air ambulance bills.	<ul style="list-style-type: none"> <li>• Patients are held harmless from surprise air ambulance medical bills. Patients are only required to pay the in-network cost-sharing amount for out-of-network air ambulances. Air ambulances are barred from sending patients “balance” bills for more than the in-network cost-sharing amount.</li> </ul>

	<ul style="list-style-type: none"> <li>• Resolves payment between air ambulance providers and insurers by requiring that the insurer pay at minimum the market-based median in-network negotiated rate for the service in the geographic area where the service was delivered.</li> <li>• If the median in-network rate payment is above \$25,000, the air ambulance provider or insurer may elect to go to IDR.</li> <li>• If a bill goes to arbitration, the arbitrator is required to consider information brought by the parties related to the training, education, and experience of the provider, location where the patient was picked up, and the population density of that location, air ambulance vehicle type and medical capabilities, and other extenuating factors such as patient acuity and the complexity of furnishing the item or service.</li> </ul>
Sec. 305. Reporting requirements regarding air ambulance services.	<ul style="list-style-type: none"> <li>• Requires air ambulance providers to submit two years of cost data to the Secretary of HHS and the Secretary of Transportation and insurers to submit two years of claims data related to air ambulance services to the Secretary of HHS. Requires the Secretaries to publish a comprehensive report on the cost and claims data submitted.</li> <li>• Establishes an advisory committee on air ambulance quality and patient safety.</li> </ul>
Sec. 306. Transparency regarding in-network and out-of-network deductibles and out-of-pocket limitations.	<ul style="list-style-type: none"> <li>• A group or individual health plan shall include on their plan or insurance identification card issued to the enrollee the amount of the in-network and out-of-network deductibles and the in-network and out-of-network out-of-pocket maximum limitation.</li> </ul>
Sec. 307. Reports.	<ul style="list-style-type: none"> <li>• Requires the Secretary of HHS, in consultation with the Federal Trade Commission and Attorney General, to conduct a study no later than January 1, 2023 and annually thereafter for the following 4 years on the effects of the provisions in the Act.</li> <li>• Requires the Secretary of Labor, not later than one year after enactment and annually for five years, to conduct a study on the effects of the provisions in the Act on premiums, out-of-pocket costs, and network adequacy in group health plans.</li> <li>• Requires GAO to submit to Congress a report on the impact of the provisions in the Act on access to care and State All Payer Claims Databases.</li> </ul>

#### TITLE IV: Improving Competition to Lower Drug Costs

<p>Sec. 401. Biological product patent transparency.</p>	<ul style="list-style-type: none"> <li>• Increases transparency of patent information for biological products by requiring patent information to be submitted to Food and Drug Administration (FDA) and published in the “Purple Book.”</li> <li>• Codifies the publication of 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.</li> </ul>
<p>Sec. 402. Protecting access to biological products.</p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Preserves certain unexpired exclusivities for biological products as FDA transitions the regulation of such products from the drugs pathway to the biologics pathway.</li> </ul>
<p>Sec. 403. Streamlining the transition of biological products.</p>	<ul style="list-style-type: none"> <li>• Requires FDA to continue reviewing, under the drugs pathway, pending biological product applications that were submitted before the transition to the biologics pathway in March 2020 and are under review by the agency at the time of the transition. Prevents such pending applications from having to be resubmitted under the biologics pathway.</li> <li>• Requires FDA, upon approval of a pending application, to fully transition such product to the biologics pathway.</li> </ul>
<p>Sec. 404. Conditions of use for biosimilar biological products.</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<p>Sec. 405. Education on biological products.</p>	<ul style="list-style-type: none"> <li>• Requires FDA to maintain and operate an Internet website to provide educational materials for health care providers, patients, and caregivers on biological products, including biosimilar biological products and interchangeable biosimilar biological products.</li> <li>• Provides that the Secretary of HHS may develop and improve continuing education for health care providers regarding biological products.</li> </ul>
<p>Sec. 406. Orange Book modernization.</p>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

	<ul style="list-style-type: none"> <li>Requires FDA to remove patents and patent claim information from the Orange Book when the U.S. Patent and Trademark Office or a court determines a patent or patent claim is cancelled or invalid to encourage drug development in the area no longer patented.</li> </ul>
Sec. 407. Change conditions of first-to-file generic applicants' 180-day exclusivity to spur access and competition.	<ul style="list-style-type: none"> <li>Prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market.</li> <li>Triggers the start of first-to-file generic drug applicants' 180-day exclusivity when no first-to-file applicant has received final approval within 30 months of submission of its application, and a subsequent applicant has been tentatively approved.</li> </ul>
Sec. 408. Clarifying the meaning of new chemical entity.	<ul style="list-style-type: none"> <li>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.</li> <li>Ensures that drug manufacturers cannot receive NCE exclusivity for making small tweaks to old drugs – and that only the most innovative or novel drugs qualify for exclusivity.</li> <li>Clarifies requirements specific to biological products and the use of active ingredients for such applications.</li> </ul>
Sec. 409. Orphan drug clarification.	<ul style="list-style-type: none"> <li>Clarifies that the clinical superiority standard applies to all drugs with an orphan drug designation for which an application is approved after the FDA Reauthorization Act of 2017, regardless of the date of the orphan drug designation.</li> </ul>
Sec. 410. Prompt approval of drugs related to safety information.	<ul style="list-style-type: none"> <li>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 drug's exclusivity.</li> </ul>
Sec. 411. Actions for delays of generic drugs and biosimilar biological products.	<ul style="list-style-type: none"> <li>Provides for a process that allows biosimilar or generic drug developers to obtain samples of reference product biologics or drugs for the purposes of developing and seeking approval of a biosimilar or generic drug.</li> <li>Gives FDA new authorities to address efforts to use restricted distribution programs to delay generic competition.</li> </ul>
Sec. 412. Reporting on explanation for drug price increases.	<ul style="list-style-type: none"> <li>Requires manufacturers of certain prescription drugs to report information to the Secretary of HHS regarding the price of the drug, an explanation for the increase, and information regarding the development and approval of the drug if the price of the drug increases 10 percent or more in a single year, or 25 percent or more within three consecutive years.</li> </ul>

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|  | <ul style="list-style-type: none"><li>• The Secretary of HHS is then required to publicly post the reports from manufacturers of qualifying drugs the day the price increase is scheduled to go into effect.</li></ul> |
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### TITLE V: Updating Tobacco Product Regulation

<p>Sec. 501. Minimum age of sale of tobacco products.</p>	<ul style="list-style-type: none"> <li>• Updates the Federal Food, Drug, and Cosmetic Act to increase the minimum age of sale of tobacco products from 18 to 21 years of age.</li> <li>• Requires HHS to update regulations issued under Chapter IX of the Federal Food, Drug, and Cosmetic Act within 180 days of enactment, including with regards to age verification requirements, and provide an update to Congress within 90 days of enactment on progress toward the final rule.</li> </ul>
<p>Sec. 502. Sale of tobacco products to individuals under the age of 21.</p>	<ul style="list-style-type: none"> <li>• As a condition for receiving block grant funding under Section 1921 of the Public Health Service Act, continues a requirement that states conduct inspections to ensure retailers do not sell tobacco products to individuals under a certain age, updates that age to 21 years of age, and requires reporting on relevant activities. Provides flexibility for states found to be in non-compliance, including adding an option for a negotiated corrective action plan.</li> <li>• Prohibits the Secretary from withholding funds under Section 1926 for three years after enactment and allows the Secretary to use discretion for two additional years to provide states time to transition to compliance with updated age requirements.</li> <li>• Requires the Secretary to update related regulations and provide technical assistance to States.</li> <li>• Provides a time-limited grant program that ends in 2024 to help states comply with the new requirements</li> </ul>
<p>Sec. 503. Improving Age Verification.</p>	<ul style="list-style-type: none"> <li>• Requires the Secretary to establish standards for approved retailer training programs, as defined by the Family Smoking Prevention and Tobacco Control Act, to include effective methods for age verification, to prevent the sale of tobacco products to any person under the minimum age of sale.</li> </ul>
<p>Sec. 504. Penalties.</p>	<ul style="list-style-type: none"> <li>• Increases the amount of civil penalties for retailers who sell tobacco products to individuals under the minimum age of sale.</li> </ul>
<p>Sec. 505. Advertising and sales requirements for all tobacco products.</p>	<ul style="list-style-type: none"> <li>• Requires the Secretary, as appropriate and applicable, to update relevant regulations to account for age verification technology, deemed tobacco products, and social media platforms, and to <u>apply certain labeling and advertising e restrictions to electronic nicotine delivery systems.</u></li> </ul>
<p>Sec. 506. Preventing online sales of e-cigarettes to children.</p>	<ul style="list-style-type: none"> <li>• Requires age verification for purchase and deliveries of online or mail order electronic nicotine delivery system products.</li> <li>• Directs the United States Postal Service to promulgate regulations within 120 days of enactment to clarify the applicability of the prohibition on mailing of cigarettes to include electronic nicotine delivery systems.</li> </ul>

Sec. 507. Smoke-free schools	<ul style="list-style-type: none"> <li>• Includes electronic cigarettes and vaping products in the definition of tobacco products that are prohibited in schools and other childcare settings.</li> </ul>
Sec. 508 Labeling for electronic cigarettes.	<ul style="list-style-type: none"> <li>• Requires FDA to issue regulations requiring labeling directly on electronic nicotine delivery systems to identify that the product contains nicotine or may contain nicotine.</li> <li>• This labeling requirement will be in a format and size as determined by the Secretary.</li> </ul>
Sec. 509. Annual financial and performance reports.	<ul style="list-style-type: none"> <li>• Requires the Secretary to submit annual financial and performance reports to Congress for all tobacco products beginning with fiscal year 2020 and for each subsequent fiscal year for which user fees are collected.</li> </ul>
Sec. 510. Report to Congress on tobacco product advertising.	<ul style="list-style-type: none"> <li>• Directs the Federal Trade Commission, not later than two years after the date of enactment, and annually thereafter, to submit to Congress a report relating to each category of tobacco products that contains information on domestic sales and advertising and promotional activity by the manufacturers that have the largest market shares of the product category, and include recommendations from the Commissioner for consideration by Congress to help prevent marketing, advertisement, or promotion of tobacco products to individuals under the minimum age of sale.</li> </ul>
Sec. 511. Enforcement Against Illegally Marketed Tobacco Products.	<ul style="list-style-type: none"> <li>• Directs the Office of the Inspector General of the Department of Health and Human Services, not later than two years after the date of enactment, to submit to Congress a report on the tobacco products on the market that are not in compliance with the premarket review requirements of the Federal Food, Drug, and Cosmetic Act, as well as mechanisms used by the Food and Drug Administration to identify these products.</li> <li>• The report will also assess whether the Food and Drug Administration has taken enforcement actions against manufacturers in violation of the premarket review requirements and issue recommendations on how to bring these manufacturers into compliance.</li> </ul>

### TITLE VI: Improving the Exchange of Health Information

<p>Sec. 601. Recognition of security practices.</p>	<ul style="list-style-type: none"> <li>• Incentivizes health care entities to adopt strong cybersecurity practices by encouraging the Secretary of HHS to consider entities' adoption of recognized cybersecurity practices when conducting audits or administering fines related to the HIPAA Security Rule.</li> </ul>
<p>Sec. 602. 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.</p>	<ul style="list-style-type: none"> <li>• Requests a GAO 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 HIPAA privacy and security rules. The study would identify potential opportunities for improving the privacy and security protections for that health information.</li> </ul>
<p>Sec. 603. Technical corrections.</p>	<ul style="list-style-type: none"> <li>• Clarifies the HHS Inspector General's authority to investigate and enforce the information blocking provisions in the 21st Century Cures Act.</li> </ul>
<p>Sec. 604. Public meeting.</p>	<ul style="list-style-type: none"> <li>• Requires the Secretary of HHS to have a public meeting within 180 days of enactment on patient matching to enable interoperability and the exchange of health information.</li> </ul>