



Summary of S. 1895, Lower Health Care Costs Act

(as approved by the Senate HELP Committee)

Updated July 2, 2019

Yellow: New Sections in the Managers Amendment Released on June 24, 2019

Green: Amendments approved during HELP Committee Mark-up on June 26, 2019

Section	Summary
Title 1: Ending Surprise Medical Bills	
101. Protection Against Out of Network Deductibles	<p>Expands the existing patient protections for emergency services that apply to the emergency department of a hospital included in the Public Health Service Act also apply to freestanding emergency.</p> <p>Expands existing law to apply in-network deductible. For out of network care in a hospital emergency department or in a freestanding emergency room, the cost-sharing requirement (expressed as a copayment amount, coinsurance rate or deductible) is the same requirement that would apply if such services were provided in-network.</p>
102. Protection Against Surprise Medical Bills	<p>Patients are held harmless from surprise medical bills.</p> <p><i>Out of Network Ancillary Services.</i> For emergency care, patients are only required to pay the in-network cost-sharing amount for out-of-network ancillary services at an in-network facility including any referrals for diagnostic services at in-network facilities.</p> <p><i>Notice before non-emergency services.</i> Out-of-network, non-emergency services that are not ancillary services, from an out-of-network provider at an in-network facility, and such services would be covered under such plan or coverage if provided in-network, the cost-sharing requirement (expressed as a copayment amount, coinsurance rate, or deductible) shall be the same requirement that would apply if such services were provided by an in-network practitioner, and any coinsurance or deductible shall be based on in-network rates, unless, as soon as practicable, and in no case later than 48 hours prior to providing non-emergency services that are not ancillary services the enrollee consents acknowledging that out of network services may require higher cost sharing.</p>

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	<p><i>Enrollees Admitted to the Hospital for Emergency Services Prior to Stabilization.</i> Similar protections apply in the case of an enrollee in a group health plan or group or individual health insurance coverage who receives emergency services, or maternal care for a woman in labor, in the emergency department of an out-of-network facility admitted to the hospital but prior to stabilization.</p> <p>Rulemaking is required 6 months after enactment including clarification on whether an individual is considered stabilized and the timing of required notices.</p> <p>Balance billing is prohibited during emergency services, out of network ancillary services at an in-network facility, services furnished by an out-of-network provider after an enrollee has been admitted to the hospital for emergency services but prior to stabilization, and out of network services after stabilization at a facility where consent was not received.</p> <p><i>Existing State Laws.</i> Nothing in this section shall prevent a State from establishing or continuing in effect, with respect to health insurance issuers, facilities, or practitioners, an alternate method under State law for determining the appropriate compensation for services. However, this section shall apply to group health plans not subject to state regulation (i.e., self-funded plans).</p> <p><i>Definitions.</i> Ancillary, non-emergency services shall mean non-emergency services provided in a facility by anesthesiologists, pathologists, radiologists, neonatologists, assistant surgeons, hospitalists, intensivists, or other providers as determined by the Secretary. The term shall not include non-emergency services provided in a facility by a primary surgeon.</p> <p><i>Enforcement.</i> Facility or practitioners subject to civil monetary penalties not more than \$10,000 for each violation. Safe harbor is provided if facility or practitioner with 30 days of the violation withdraws the bill and reimburses the group health plan, issuer or enrollee the difference between the amount billed and the amount allowed to be billed plus interest. The Secretary may establish a hardship exemption.</p> <p><i>Applicability.</i> Applies to grandfathered health plans for plan years beginning the second plan year after enactment and the Federal Employees Health Benefits Program.</p>
103. Benchmark for Payment	For surprise bills, health plans would pay providers the local median contracted commercial amount under that plan or coverage that insurers have negotiated with other providers and agreed upon in that geographic area. Payments must be made in a timely fashion.

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	<p>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 including consideration of adequate access to rural areas and health professional shortage areas in consultation with the National Association of Insurance Commissioners.</p> <p>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. Such databases shall be free of conflicts of interest and have sufficient information reflecting allowed amounts.</p>
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.
105. Ending Surprise Air Ambulance Bills	<p>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.</p> <p>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. Notice and comment rulemaking is required 6 months after enactment and shall include the information the plan used to calculate payment and geographic regions.</p> <p>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.</p> <p><i>Effective Date.</i> One year after enactment.</p>
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, 103 and 105 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 Price of Prescription Drugs	
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.”

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	<p>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.</p> <p>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.</p>
202. Orange Book Modernization	<p>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.</p> <p>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.</p>
203. Ensuring Timely Access to Generics	<p>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.</p> <p>Addresses the abuse of the citizen petition process, which can be used to unnecessarily delay the approval of a drug application.</p> <p>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.</p> <p>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.</p> <p>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.</p>
204. Protecting Access to Biological Products	<p>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.</p> <p>Preserves certain unexpired exclusivities for biological products as FDA transitions the regulation of such products from the drugs pathway to the biologics pathway.</p>
205. Preventing Blocking of Generic Drugs	<p>Prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market.</p>

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	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.
206. Education on Biological Products	<p>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.</p> <p>Provides that the Secretary may develop and improve continuing medical education for health care providers regarding biological products.</p>
207. Biological Product innovation	<p>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.</p> <p>Prevents delays related to compliance with USP standards, in the licensure of biosimilar and interchangeable products.</p>
208. Clarifying the Meaning of New Chemical Entity	<p>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</p> <p>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.</p>
209. Streamlining the Transition of biological products	<p>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.</p> <p>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.</p>
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.
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.
212. Conditions of Use for Biosimilars 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.

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<p>213. Modernizing the Labeling of certain generic drugs</p>	<p>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.</p> <p>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.</p>
<p>214. Actions for Delays of Generic Drugs and Biosimilar biological products (CREATES Act)</p>	<p>Allows generic drug manufacturers to sue brand-name manufacturers for not selling them samples for testing. Allows generic companies to use separate safety protocols than those in place for the branded drug. The generic maker would have to prove that the brand-name maker hasn’t delivered sufficient quantities generally within 31 days of a request.</p> <p>Courts would be authorized to award monetary damages sufficient to deter future gaming.</p> <p>Clarifies FDA’s discretion to allow generic manufacturers to operationalize equivalent safety protocols in a separate system instead of entering a shared safety protocol with brand manufacturers, provided that such separate protocol meets the same safety standard as the original system.</p>
<p>215. Reducing the Price of Prescription Drugs (FAIR Drug Pricing Act) Legislative Text</p>	<p>Requires a drug manufacturer to submit a report to the Health and Human Services Secretary for each price increase of certain drugs of which the wholesale acquisition cost increase is equal to 10 percent or more over a 12-month period or 25 percent or more over a 36-month period. The report must be submitted no later than 30 days prior to the planned price increase date.</p> <p>With respect to the drug in question, the report must include:</p> <ul style="list-style-type: none"> • The percentage that the wholesale acquisition cost will be raised; • The justification for the increase; • The initial developer’s identity; • A description of the price increase history; • The current list price; • The total expenditures of materials and manufacturing as well as acquired patents and licensing; • Expenditures on research and development; • Total revenue and profit generated; and, • Marketing and advertising costs. <p>With respect to the manufacturer, the report must include:</p> <ul style="list-style-type: none"> • Total revenue and net profit for the appropriate time periods before the price increase; • Stock-based performance metrics during that period; and, • Any additional metrics the manufacturer or Secretary deem appropriate.

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	<p>Subject to \$100,000 per day penalty for failing to submit the report.</p> <p>The report must be posted publicly on the Health and Human Services' website within 30 days.</p>
Title III: Improving Transparency in Health Care	
<p>301. Increasing Transparency by Removing Gag Clauses on Price and Quality Information</p>	<p>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.</p> <p>Agreements cannot restrict the providing of provider-specific cost or quality of care information through a consumer engagement tool or other means or the electronic access to de-identified claims and encounter data for each enrollee as long as consistent with HIPAA, GINA and the ADA (includes allowed mounts, provider information, service codes or any other information normally in a claim)</p> <p>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.</p> <p>Issuers offering individual may not enter into an agreement with a health care provider, network or association of providers, or other service provider offering access to a network of providers that would, directly or indirectly restrict the health insurance issuer from:</p> <ul style="list-style-type: none"> • providing provider-specific price or quality of care information, through a consumer engagement tool or any other means; or • sharing, for plan design, plan administration, and plan, financial, legal, and quality improvement activities with a HIPAA business associate <p>Nothing shall prevent reasonable restrictions on the public disclosure of this information</p> <p>Effective 18 months after enactment.</p>
<p>302. Banning Anti-competitive Terms in Facility and Insurance Contracts that Limit Access to Higher Quality, Lower Cost Care</p>	<p>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.</p> <p>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.</p>

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	<p>Providers an exception for certain group model issuers including HMOs or a value-based network arrangement.</p> <p>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.</p> <p>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.</p> <p>Effective 18 months after enactment</p>
<p>303. Designation of a Non Governmental Nonprofit Transparency Organization to Lower Americans’ Health Care Costs</p>	<p>Designates a nongovernmental, nonprofit entity to improve the transparency of health care costs.</p> <p>Directs HHS to contract with said nonprofit entity within one year of the passage of the legislation.</p> <p>Establishes and appoint members to a 13-person advisory committee within 180 days after passage of the legislation. There is no designated seat on the committee for health plans.</p> <p>Directs the nonprofit entity, in consultation with the committee, to define data elements to be collected as well as the format and standards of reporting for insurers. The nonprofit entity would also be responsible for creating privacy and security parameters/encryption in order to de-identify personal data and protect proprietary information.</p> <p>Requires an “applicable self-insured group health plan” to submit - through TPA, PBM, or other designated entity - all requisite medical and prescription drug claims data. Although the legislation specifically addresses self-insured group health plans, it also allows states to require issuers to submit data to the entity in a standardized format. An applicable self-insured group health plan is defined as a plan or a plan’s TPA that administers benefits for more than 50,000 enrollees and/or is one of the 5 largest administrators or issuers, by aggregate number of enrollees in plans administered by that administrator in the state.</p> <p>Allows for the sharing of data with state-based APCDs at cost if the state contributes claim data to the nonprofit entity.</p> <p>Provides for the use of data by employers, employee organizations, researchers and policymakers assuming certain data security criteria are met.</p>

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	<p>Authorizes grants to states to maintain or create similar transparency initiatives. Authorizes appropriations of 100 million dollars for these grants for fiscal years 2020-2029.</p>
<p>304. Protecting Patients and Improving the Accuracy of Provider Directory Information</p>	<p><i>Network Status of Providers.</i> Requires health plans to have up-to-date directories of their in-network providers, which shall be available to patients online, through oral confirmation kept in an enrollees file for a minimum of 2 years and provided in writing within 1 business day of a telephone inquiry. Print directories should include an accurate as of date disclaimer.</p> <p><i>Business Processes.</i> Health plans must verify and update at least once every 90 days the information for all providers in the online directory and remove any provider from such online directory if they have not verified their information within the previous 6 months or the plan is unable to verify the provider's network participation.</p> <p><i>Cost Sharing Limitations.</i> If a patient provides documentation that they received incorrect information from an insurer (based on electronic, written information or provided orally) about a provider's network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount and providers shall reimburse enrollees for the full amount paid in excess of the in-network cost sharing amount plus interest.</p> <p><i>Enforcement.</i> Health care providers in violation or takes actions to prevent a group health plan from complying from requirements to verify information shall be subject to a civil monetary penalty of not more than \$10,000 for each act of violation.</p> <p><i>Savings Clause.</i> Nothing shall prevent a provider from requiring contract terms that they be removed at the time of contract termination from the provider directory or that the plan bear financial responsibility for providing inaccurate network status information.</p> <p>Effective date is plan years beginning 18 months after enactment.</p>
<p>305. Timely Bills for Patients</p>	<p>Requires health care facilities and providers to give patients a list of services received upon discharge or at the end of the visit or by postal or electronic mail as soon as practicable and not later than 5 calendar days after discharge or date of visit.</p> <p>Requires all adjudicated bills to be furnished to a patient within 45 days. If bills are received more than 45 days after receiving care, the patient is not obligated to pay.</p>

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	<p>Requires providers and facilities to give patients at least 35 days after postmark date to pay bills upon receipt.</p> <p>Provides for civil monetary penalties of up to \$10,000 a day for facilities that fail provide a list of services 10 times.</p> <p>Effective date is 6 months after enactment.</p>
<p>306. Health Plan Oversight of PBMs</p>	<p><i>Reports to Group Health Plan Sponsors.</i> Requires that plan sponsors receive a twice annual report on the costs, fees and rebate information associated with their PBM contracts in a machine-readable format. Reports include:</p> <ul style="list-style-type: none"> • information from drug manufactures on co-pay assistance paid • for each covered drug: the number of enrollees, the number of prescription fills, the total number of dosage units and the dispensing channel, wholesale acquisition cost, total out-of-pocket spending by enrollees on such drug, and for any drug exceeding \$10,000 during the reporting period, a list of other available drugs and the rationale for preferred pharmacy placement • a list of each therapeutic category or class: along with the total gross spending by the plan before rebates, fees or other manufacturer remuneration; the number of enrollees who filled a prescription for a drug in that category or class, a description of the tiers (including utilization mechanisms such as prior-authorization or step therapy), and the total out of pocket spending. • for classes which 3 or more drugs are included on the formulary the amount received or expected to be received from drug manufacturers in rebates, fees, alternative discounts or other remuneration. • total gross spending on prescription drugs before rebates or other fees or remuneration • total amounts received in rebates, fees, alternative discounts and all other remuneration from the manufacturer or other third party other than the plan sponsor related to utilization of drug or drug spending • total net spending on prescription drugs • amounts paid directly or indirectly in rebates, fees or another type of remuneration to brokers, consultants, advisors or any other individual or firm who referred the group health plans business to the PBM. <p><i>Privacy.</i> Information shared shall be consistent with the HIPAA privacy, security and breach notification regulations. Information may be disclosed to business associates. Reasonable restrictions may be placed on public disclosure, except to governmental agencies pursuant to an investigation or enforcement action. The Secretary may define a limited report to meet these requirements for plan sponsors who are drug</p>

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	<p>manufacturers, drug wholesalers, or other direct participants in the drug supply chain to prevent anti-competitive behaviors.</p> <p><i>Spread Pricing.</i> 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 to require the pricing not exceed the lesser of the amount paid to the pharmacy for acquisition of the drug or the median price charged when the same drug is dispensed by other similarly-situated pharmacies not wholly or partially owned by the health insurance issuer or the PBM.</p> <p><i>Full Pass Through Rebate to the Plan.</i> Requires the PBM to pass on 100% of any rebates or discounts to the plan sponsor. Rebate contracts with drug manufactures to be made available to plan sponsors or designated third parties no later than 90 days after the end of such period.</p> <p>Rebate contracts with drug manufactures shall be available for audit subject to confidentiality agreements to prevent re-disclosure.</p> <p>Rule of construction. Nothing shall be construed as to prohibit payments to PBMs for bona fide services using a fee structure not contemplated by this section, provided such fees are transparent.</p>
307. GAO Study on Profit and Revenue Sharing 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 no later than 1 year after enactment.
308. Disclosure of Direct and Indirect Compensation for Brokers and Consultants to Employer Sponsored Health Plans and Enrollees in Plans on the Individual Market	<p><i>Group Health Plans.</i> 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.</p> <p><i>Individual Market Coverage.</i> Requires health insurance issuers to disclose annually to the Secretary prior to the beginning of open enrollment any direct or indirect compensation provided to brokers for referral of coverage.</p> <p>Requires health insurer to disclose to enrollees the amount of direct or indirect compensation to a broker or agent for a specific plan selection: (1) prior to the individual finalizing plan selection; and (2) in any documentation conforming enrollment.</p>

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	Requires rulemaking within one year of enactment. Effective two years after enactment.
309. Ensuring Enrollee Access to Cost Sharing Information	<p>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 business days of a request.</p> <p>Provision effective 18 months after enactment.</p>
310. Strengthening Parity in Mental Health and Substance Use Disorder Benefits	<p><i>NQTL Compliance.</i> Requires group health plans and health insurance issuers to conduct comparative analyses of nonquantitative treatment limitations (NQTLs) used for mental health and substance use disorder benefits as compared to medical and surgical benefits, upon request by the applicable state or federal authority. The analyses must be available 60 days after request beginning 6 months after enactment.</p> <p>The analyses are to include the following information:</p> <ol style="list-style-type: none"> 1. The specific plan or coverage terms regarding the NQTL and a description of all MH/SUD and medical/surgical benefits to which it applies in each respective benefits classification. 2. The factors used to determine that an NQTL will apply to MH/SUD and medical/surgical benefits. 3. The evidentiary standards used for each of the factors identified in item 2 and any other sources or evidence relied upon to design and apply the NQTL to MH/SUD and medical/surgical benefits. 4. The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to design and apply NQTLs to MH/SUD benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design and apply the NQTL, as written and in operation, to medical/surgical benefits. 5. A disclosure of the specific findings and conclusions reached by the plan that the results of the analyses indicate that the plan is in compliance. <p>The Secretary shall request not fewer than 20 comparative analyses per year. The Secretary may request additional information if it is concluded that the plan has not provided sufficient information for the Secretary to review the comparative analyses. If, upon review of the analysis, the Secretary finds that a plan is out of compliance, the plan shall specify the actions it will take to come into compliance.</p> <p>Not later than 1 year after enactment (and annually thereafter), the Secretary shall submit a report to the following congressional committees: House Ed & Labor and the Senate HELP Committee. The report must contain the following information:</p> <ol style="list-style-type: none"> 1. Summary of the comparative analyses requested. Plan identities will be redacted.

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	<ol style="list-style-type: none"> 2. The Secretary’s conclusions on whether the plans submitted sufficient information for the Secretary to review the comparative analyses requested. 3. For those that did submit sufficient information, the Secretary’s conclusions on whether the plans are in compliance with the disclosure requirements under this section. 4. For those that did not submit sufficient information, the additional information the Secretary requested. 5. The corrective actions the Secretary specified if plans were determined to be noncompliant. <p>The Secretary will provide deidentified examples of noncompliant plans in the compliance program guidance document as it is updated every 2 years. The Secretary shall also share information on findings of compliance and noncompliance with the State where the group health plan is located or issuer is licensed.</p>
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.
312. Third Party Administrators	Clarifies the obligations of third-party administrators to group health plans regarding compliance with Federal law.
313. Group Health Plan reporting requirements	<p>Requires prior to March 1 of each year the following information:</p> <ul style="list-style-type: none"> • The number of enrollees • Each State in which the plan is offered. • The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the issuer, and the total number of paid claims for each such drug. • The 50 most costly prescription drugs with respect to the plan by total annual spending, and the annual amount spent by the plan for each such drug. • The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan in each such plan year. • Total spending on health care services by such group health plan, broken down by certain categories • The average monthly premium • Any impact on premiums by rebates • Any reduction in premiums and out-of-pocket costs associated with rebates <p><i>Report.</i> Not later than 18 months after the date on which the first report is required and biannually thereafter, the Secretary shall make available a report on prescription drug reimbursements under group health plans, prescription drug pricing trends, and the role of prescription drug costs in contributing to</p>

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	premium increases or decreases under such plans, aggregated in such a way as no drug or plan specific information will be made public.
314. Study by the Comptroller General	<p>Comptroller General may examine various qualitative and quantitative aspects of the role of pharmacy benefit managers no later than 3 years after enactment including:</p> <ul style="list-style-type: none"> (1) The role that pharmacy benefit managers play in the pharmaceutical supply chain. (2) The state of competition among pharmacy benefit managers, including the market share for the Nation's largest pharmacy benefit managers. (3) The use of rebates and fees by pharmacy benefit managers (4) Whether pharmacy benefit managers structure their formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives. (5) The average prior authorization approval time for pharmacy benefit managers. (6) Factors affecting the use of step therapy by pharmacy benefit managers.
Title IV: Improving Public Health	
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.
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.
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.
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.
405. Public health data system modernization.	<p>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.</p> <p>Authorizes the Centers for Disease Control and Prevention (CDC) to update and improve public health data systems used by the agency</p>

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406. Innovation for maternal health.	<p>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.</p> <p>Allows the Secretary to identify and disseminate best practices for such training.</p>
407. Training for health care providers.	<p>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.</p>
408. Study on training to reduce and prevent discrimination.	<p>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.</p>
409. Perinatal quality collaboratives.	<p>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.</p>
410. Integrated services for pregnant and postpartum women.	<p>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.</p> <p>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.</p> <p>Requires HHS to disseminate information on best practices and models of care used by grantees under this section to relevant stakeholders.</p>
411. Extension for community health centers, the National Health Service Corps, and Teaching Health Centers that operate GME programs.	<p>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.</p>
412. Other programs.	<p>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.</p>

Section	Summary
413. Native American Suicide Prevention	Requires states applying for federal youth suicide early intervention and prevention grants to confer with federally recognized Indian tribes or tribal organizations in developing youth suicide prevention strategies.
414. Minimum Age of Sale of Tobacco Products	<p>Raises the national tobacco-purchasing age from 18 to 21. Violations are subject to penalties.</p> <p>Requires the Secretary of Health and Human Services to update relevant regulations within 180 days on age verification requirements for tobacco sales to require age verification for individuals under the age of 30. Effective 90 days after the rule is published. The Secretary shall notify the Congressional committees of jurisdiction regarding promulgation of the rule within 90 days.</p>
415. Sale of Tobacco Products to Individuals under the age of 21	<p>A state must conduct random, unannounced inspections to ensure retailers do not sell tobacco products to individuals under 21 and submit a report to the Health and Human Services Secretary on these activities. If the state does not comply, they are subject to lose up to 10 percent of their federal grants to fight substance abuse and addiction. The state is not subject to grant withholding if it commits that additional state funds will be used to prevent the sale of tobacco products to individuals under 21, it successfully negotiate an agreement with the Department of Health and Human Services, or it is a territory that receives less than \$1 million in relevant grant funding for a fiscal year.</p> <p>Provides four-year optional grant for states to transition enforcement efforts from age 18 to age 21. Authorizes \$18.6 million annual appropriations from fiscal year 2020 through fiscal year 2024. Requires the Secretary to provide technical assistance to states. Requires the Secretary to submit a report to Congressional committees of jurisdiction within 3 years of enactment.</p>
Title V: Improving the Exchange of Health Information	
501. Requirement to provide health claims, network, and cost information.	<p><i>Health Claims, Network and Cost Information via API.</i> Expands on CMS' Blue Button Initiative and proposed regulations for federal health programs by requiring commercial health insurers to make information available to patients through application programming interfaces, including: health insurance claims data, provider encounter data and payment data; in-network practitioners; and expected out-of-pocket costs. Data to be available to an enrollee or former enrollees, the enrollee's providers or any third-party applications or services authorized by the enrollee.</p> <p>Including identifying directory information for all in-network providers, including the capability to return the information necessary to establish a list of participating in-network facilities, practitioners in a given specialty or at a particular facility type within a geographic radius. Per Cassidy amendment, the plan must provide a list of ancillary services categories that the plan has no in-network providers.</p> <p>Emphasizes that all existing privacy, security protections and breach notification laws for patient health data under HIPAA and state laws apply</p>

Section	Summary
	Effective 18 months after enactment.
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 covered entities' adoption of recognized cybersecurity practices when conducting audits or administering fines related to the HIPAA Security Rule.
503. GAO Study on Privacy and Security Risk of Electronic Transmission of Individually-Identifiable Health Information to and from Entities not covered by HIPAA	GAO study one year after enactment 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 HIPAA privacy and security rules. The study would identify potential opportunities for improving the privacy and security protections for that health information.
504. Technical Corrections	Clarifies the HHS IG's authority to investigate and enforce the information blocking provisions in the 21st Century Cures Act.
505. Public Meeting on Patient Matching Metrics	180 days after enactment HHS shall convene a meeting to discuss and provide input on public-matching metrics to enable interoperability and the exchange of health information across health care organizations.