The Fair Care Act of 2020

Introduced by Rep. Bruce Westerman (AR-04)

Title, Subtitle and Section Summary

TITLE I: Medisave

Subtitle A—Medisave Accounts and Contributions

This subtitle consolidates HSAs, HRAs, FSAs and MSAs into one Medisave Account where pre-tax dollars can be used to purchase qualified medical expenses, direct pay arrangements with primary care physicians and monthly insurance premiums. The subtitle also expands eligible contributions to CSR payments and APTCs.

Section 101. Establishment of Medisave Accounts

This section establishes Medisave Accounts (MDAs) for eligible individuals to save and spend pre-tax earnings towards qualified medical expenses. There will be a yearly contribution limit ranging from $5,000 to $3,600 for individuals on a sliding scale with an accruing total of $50,000. Individuals with insurance plans that are above 80% actuarial value are not eligible for MDAs unless those plans meet high deductible health plan (HDHP) thresholds, or if the individual has an income below 250% FPL. Unused advance premium tax credits (APTCs) can be directly deposited into MDAs and employers may make contributions tax free if the individual is not already receiving APTCs. MDA funds that are used to purchase non-qualified medical expenses will have a 20% tax and no payment for a qualified medical expense shall count toward the Medical Expense Deduction.

Section 102. Consolidation of HSAs, HRAs, FSAs and MSAs into Medisave Accounts

This section establishes that within one year of enactment, holders of legacy health care savings accounts like Health Savings Accounts, Health Reimbursement Arrangements, Flexible Spending Accounts and Medical Savings Accounts will need to deposit these monies into MDAs in order to preserve their tax-free status. There will be no contribution limit for this one-time transition. Employers will be required to allow workers to convert their employer-owned HRA balances into the new employee-owned MDAs.

Section 103. Health Reimbursement Arrangements and Other Account-Based Group Health Plans

This section codifies the Administration's June 2019 rule allowing employers to offer their workers Health Reimbursement Accounts (HRAs) that, if structured in a certain way, can be used by workers to purchase individual-market insurance. The section also modernizes the provision to reflect the newly created MDAs.

Section 104. Cost Sharing Reduction Payments as Eligible Contributions

This section stabilizes exchange premiums by authorizing funding to reinstate cost sharing reduction (CSR) payments and provides states with greater flexibility to use these payments. Specifically, it allows states with a waiver to receive equivalent amounts to be deposited into MDAs of individuals and families with incomes below 250% FPL.

Section 105. Direct Primary Care

This section offers a concrete definition of expands the use of Direct Primary Care Arrangements (DPC) and allows MDA funds to pay for DPC services.

Subtitle B—Assistance to Medisave Accounts

This subtitle provides incentives to establish Medisave Accounts including a 50% federal match for the first year, requiring new business and all federal employees to offer MDAs to employees and authorizing educational grant programs.

Section 111. Support in Implementation

This section provides incentives to help the implementation of and transition to MDAs. Specifically, it provides individuals less than 400% FPL with a 100% match on all contributions during the first year up to $1,000 as a refundable tax credit. Individuals greater than 400% FPL will receive a 33% match as a non-refundable credit.

Section 112. New Corporations Required to Offer Medisave Accounts

New businesses (i.e., incorporated on or after December 31, 2021) that wish to sponsor tax-advantaged health insurance for their workers, must do so by offering MDAs to their workers so that their workers can choose the coverage that is best for them.

Section 113. Federal Employee Health Benefits and Medisave

This section eliminates Federal Employee Health Benefits Program (FEHBP) eligibility for most federal employees, encouraging them to enroll in individual exchange plans. Instead of offering federal health plans, benefits will be converted into MDA deposits that may be used to buy exchange-based coverage. MDA deposits will be benchmarked to the cost of the second-lowest-cost Silver plan in a worker's ZIP code.

Section 114. Grants to States for Consumer Assistance

This section directs CMS to authorize $5 million for 5 years to establish a grant program that states and local organizations may apply for to educate the public and provide assistance with MDAs.

TITLE II: Improving Private Health Insurance

Subtitle A—Maintaining Protections for Patients with Preexisting Conditions

This subtitle maintains all of the preexisting condition protections offered in the Affordable Care Act, ensuring that those seeking health insurance in the individual market can do so without discrimination.

Section 201. Guaranteed Availability of Coverage; Prohibiting Discrimination
This section codifies all Affordable Care Act (ACA) preexisting protections under the Health Insurance Portability and Accountability Act (HIPAA) pending a Supreme Court ruling on the lawfulness of the individual mandate in the ACA. This section specifically codifies ACA language regarding guaranteed issue, essential health benefits, dependent child coverage through twenty-six years old, and a ban on annual or lifetime benefit limits.

Subtitle B—Expanding Coverage Options

This subtitle codifies Administrative policies relating to Association Health Plans (AHPs) and Short-Term Limited Duration Insurance (STLD). Promoting these plans will offer greater and more affordable coverage options for individuals.

Section 211. Definitions and Rules of Construction
This section codifies the Department of Labor's 2018 final rule on Association Health Plans (AHPs) that allow existing associations and the formation of new associations for purchasing group health insurance for their dues-paying members.

Section 212. Clarification of Treatment of Single Employer Arrangement
This section amends the Employee Retirement Income Security Act of 1974 (ERISA) to allow AHPs to consist of organizations from different industries so long as the organizations are under common control.

Section 213. Enforcement Provisions Relating to Association Health Plans
This section establishes penalties for violating the rules described in this subtitle regarding AHPs.

Section 214. Cooperation Between Federal and State Authorities
This section enables the formation of AHPs that can offer plans across state lines.

Section 215. Effective Date and Transitional and Other Rules
This section states that the new rules for association health plans will go into effect one year after the enactment of this Act and establishes transitional rules for certain existing health benefits programs.

Section 216. Short-Term Limited Duration Insurance
This section codifies short-term limited duration insurance (STLD) policies; enforces a 12-month option for such plans; and provides they are exempt from Affordable Care Act requirements such as Essential Health Benefits (EHB) coverage and specified enrollment periods.

Subtitle B—Improving Commercial Health Insurance

This subtitle enacts provisions to strengthen and increase enrollment in the commercial marketplace, provides flexibility to states wishing to improve their exchanges and restructures risk sharing policies to encourage healthy individual participation while protecting those with preexisting conditions.

Section 221. Invisible Guaranteed Coverage Pool Reinsurance Program

This section implements a reinsurance program using an invisible high-risk pool approach. It authorizes $200B over ten years ($20B annually) to HHS for establishment of such a program. States shall participate in a nationwide, federally-operated pool, or choose to receive a block grant composed of an appropriately portioned amount determined by the Secretary to run separate pools. Additionally, a $4 fee attached to exchange policies will contribute to funding the pool and an HHS report, in collaboration with the GAO, will be published after 5 and 10 years to provide oversight on the funding of this pool.

Insurance companies in states that participate in the federal program will designate policies for placement in the pool and may do so at any time. They may place individual policies as well as family policies into the pool, but they cannot separate one individual from a family policy for placement in the pool. When an insurance company places a policy in the pool, that policy takes on a "high-risk" designation, but policyholders are not notified of the designation.

From insurers' perspective, two features of high-risk plans separate them from the rest. First, insurers retain only 10% of the monthly premiums paid for these high-risk policies. The remaining 90% shall be submitted to the fund sustaining the pool. In return, insurers are responsible only for the first $10,000 in annual medical costs incurred by individuals on high-risk policies. Subsequent costs are payable at the Medicare Advantage rate and are reimbursed by the fund sustaining the pool. For services not covered by Medicare, the Secretary may establish an appropriate dollar amount.

Section 222. Employer Health Insurance Mandate Repeal

This section repeals the monetary penalty—implemented under the Affordable Care Act— imposed on employers who do not provide minimum essential coverage, eliminating employer requirements to provide health insurance as an employee benefit.

Section 223. Refundable Credits for Coverage Under Employer-Sponsored Insurance Plans

This section allows those with employee-sponsored health insurance (ESI) offers to opt out and receive Advanced Premium Tax Credits (APTCs), if eligible, to find affordable coverage in the individual market. This section also repeals rules for employer-sponsored minimum essential coverage such that coverage must be affordable, provide minimum value, and the employee or family must not be covered under employer plan. The cost of providing more APTCs are offset by the non-uptake of an ESI tax break if an individual switches from an ESI plan to exchange plan.

Section 224. Establishing a Standard Tax Deduction for Employer-Sponsored Insurance

This section establishes a standard tax deduction for employer-sponsored health insurance of up to $10,200 for individual coverage or $27,500 for family coverage. This section also clarifies the definition of "cost basis" for the purpose of capital gains by creating clear statutory authority for the Treasury Secretary to write such a definition, inclusive of the effects of inflation.

Section 225. Promoting Health Plans for Younger Individuals Through Lower Premiums

This section restores the 5:1 ratio in which insurers can charge their most to least costly plans. This will reduce premiums for young people, encouraging a healthier risk pool in the individual market, which will also lower premiums for older enrollees.

Section 226. Premium Assistance Adjustment to Reflect Age
This section adjusts premium assistance to incorporate both means-tested and age-adjusted tax credits. The new schedule also increases premium assistance eligibility for individuals from current ACA levels (400% Federal Poverty Level) to 600% of the Federal Poverty Level. See table below.

Federal Poverty Level (FPL)	Up to Age 29		Ages 30-39		Ages 40-49		Ages 50-59		Over Age 59	
	Initial %	Final %	Initial %	Final %	Initial %	Final %	Initial %	Final %	Initial %	Final %
Up to 100%	0	0	0	0	0	0	0	0	0	0
100%-133%	2	2	2	2	2	2	2	2	2	2
133%-150%	3	4.3	3	4.3	3	4.3	3	4.3	3	4.3
150%-200%	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7
200%-250%	6.7	6.7	6.7	7.6	6.7	8.5	6.7	8.5	6.7	8.5
250%-300%	6.7	6.7	7.6	7.6	8.3	9.8	8.3	9.8	8.3	9.8
300%-400%	6.7	7	7.6	8	9.8	10	9.8	10	9.8	10
400%-600%	7	9	8	10	10	15	10	15	10	15

Section 227. Calculation of Premium Assistance
This section assigns premium assistance eligibility based on the previous year's tax return, opposed to a forward-looking projection of monthly income. Additionally, this would align the open enrollment period with tax return filing.

Section 228. Copper Plans on Exchanges
This section adds to the platinum, gold, silver, and bronze tier options a new "copper" tier. Copper-level plans will have an actuarial value of 50% and will have out-of-pocket limits that are 30% higher than bronze plans.

Section 229. Expanded Premium Assistance for Copper and Bronze Plans
This section allows premium assistance subsides and cost sharing reductions (CSRs), or the Medisave equivalents, to be used to purchase copper and bronze plans. Currently, CSRs can only be used when purchasing silver plans; this section establishes CSRs would apply at an actuarial value 10% lower for Bronze plans and 20% lower for Copper plan.

Section 230. Waivers for State Innovation
This section allows governors to pursue ACA requirement waivers without state legislature approval; expedites the approval of states seeking a previously approved waiver; increases the default length of a waiver from five years to six; and alters the standard for approval of changes related to health coverage and cost sharing from "at least as affordable" to "of comparable affordability."

Section 231. Flexible Enrollment Periods
Currently, individuals may enroll in exchange plans only during established periods—annual open enrollment or special enrollment circumstances. This section allows insurers to enroll individuals in exchange plans outside of open enrollment periods if they wish, and to charge late enrollment penalties for doing so.

Section 232. Flexibility for State-Operated Exchanges
This section grants states with a waiver the option to hold open enrollment periods every 24 or 36 months to increase stability in the marketplace.

Section 233. Promoting Health Plans that Cover Individuals in Different States
This section authorizes $10 million to the Center for Medicare and Medicaid Innovation (CMMI) to fund grants aimed at increasing competition among insurers in different states. Applicants must demonstrate plans for "new research or pilot programs dedicated to pursuing viable methods of enrolling individuals in health insurance programs that cross State lines."

TITLE III: Competition, Transparency and Accountability

Subtitle A—Provider and Insurer Competition

This subtitle enacts provisions that promote provider competition, reduce incentives for hospital mergers, and increase anti-competitive authority relating to hospitals, providers and insurers.

Section 301. Action to Address Hospital Consolidation
This section requires hospitals serving a significant population to accept Medicare Advantage reimbursement rates from commercial payers, with the exemption of hospitals in Census Bureau Medicare-designated rural areas or less expensive rates for services provided to Medicaid patients. To further support rural providers, the Critical Access Hospital formula increases allowable cost reimbursements phases up from 101% to 110%.

Additionally, this section provides $1 billion annually in grants to states that take specific actions to improve hospital competition. This section also authorizes a 400% increase in Federal Trade Commission (FTC) funding ($160 million) for the exclusive purpose of increasing the size of its antitrust staff investigating hospital consolidation.

Section 302. Authority of the Federal Trade Commission over Certain Tax-Exempt Organizations
This section provides the Federal Trade Commission (FTC) jurisdiction over certain tax-exempt organizations, allowing the FTC to evaluate anti-competitive actions perpetrated by non-profit hospitals.

Section 303. Restoring Federal Antitrust Laws Relating to the Business of Health Insurance
This section reverses anti-competitive practices by amending the McCarran-Ferguson Act to ensure that those in the business of health insurance or dental insurance are not exempted from federal antitrust laws.

Section 304. Leveling the Playing Field Between Payers and Providers
This section creates a safe harbor from antitrust liability to allows one or more private health insurer issuers to jointly negotiate prices of hospital services with a hospital provider and reimbursement policies of the insurers for those services.

Section 305. Removing Gag Clauses in Health Insurance Contracts
This section 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. Additionally, this section bans gag clauses in contracts that prevent plan sponsors from accessing de-identified claims data that could be used for plan administration and quality improvement purposes.

Section 306. Banning Anti-Competitive Terms in Facility and Insurance Contracts
This section prevents *"anti-tiering" and "anti-steering"* clauses in contracts between providers and health plans that restrict incentives directing patients to use providers and facilities with higher quality and lower prices. It also prevents *"all-or-nothing"* clauses that require plans to contract with all providers in a particular system or none of them and bans *"most-favored-nation"* clauses that protect an insurance company's dominant position in a market by requiring that the insurer be given favorable pricing. Lastly, this section prohibits obligations to agree to terms of contracts that the sponsor is not party to, which could conceal anti-competitive contracting terms.

Section 307. Repeal of Incentives for Hospital Consolidation via Accountable Care Organizations
This section repeals incentives to form hospital-led Accountable Care Organizations (ACOs) that encourage consolidation among providers. Incentives would remain for physician-led Accountable Care Organizations.

Section 308. Permitting the establishment of New Physician-Owned Hospitals
This section repeals provisions of the ACA that prevent the establishment of new physician-owned hospitals.

Section 309. Alternative Payment Model for Certain Shoppable Procedures
This section gives the HHS Secretary the authority to waive EHB rules and allow insurers for both individual and group health plans the option to pay a flat, cash payment to the insured individual for specific medical procedures. The price of such procedure must be posted by the provider for prior review by the beneficiary and the cash payment can be no less than the median negotiated rate for such geographic region.

Subtitle B—Price Transparency

This subtitle promotes transparency among hospitals, providers, insurers and directly benefits patients.

Section 321. Hospital Price Transparency
This section requires hospitals to publish, in a standardized digital format, volume-weighted average prices for their 100 most common services. It also requires hospitals to publish and honor price lists for related bundles of discrete services that represent a category or episode of care, as defined by the Secretary of Health and Human Services, such as prenatal care and childbirth.

This section also grants the Secretary of Health and Human Services the authority to grant exceptions to the Affordable Care Act's essential health benefits requirements, in cases where insurers choose to offer a reference-based payment for certain health care services, equal to insurers' average in-network payment for the same services.

Section 322. Price Transparency Requirements
This section codifies the two price transparency rules from President Trump's Improving Price and Quality Transparency in American Healthcare Executive Order. These rules will require hospitals and insurers to reveal their low, discounted cash prices and negotiated rates to consumers before they receive medical care.

Section 323. Designation of Non-Profit Transparency Organizations to Lower Costs (All-Payer Claims Database)
This section designates at least two nongovernmental, nonprofit entities to improve the transparency of health care costs. Specifically, the nonprofit entities will use de-identified health care claims data from self-insured plans, Medicare, and participating states to create reports to better understand the cost and quality of care, and facilitate state-led initiatives to lower costs, while prohibiting the disclosure of identifying health data or proprietary financial information.

Additionally, this section establishes grants for states to create or maintain similar transparency initiatives and establishes an advisory committee composed of public and private sector representatives to advise the entities on the research and reporting objectives.

Section 324. Protecting Patients and Improving the Accuracy of Provider Directory Information
This section 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. 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.

Section 325. Ensuring Enrollee Access to Cost-Sharing Information
This section 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.

Section 326. Patient Access to Protected Health Information
This section establishes patient ownership of all diagnostic tests and objective clinical measurements conducted on their behalf.

Section 327. Timely Bills for Patients
This section requires health care facilities and providers to give patients a list of services received upon discharge. All bills are required to be sent to a patient within 45 days of receiving care, the patient is not obligated to pay if received after the 45-day period. Additionally, the patient will have at least 30 days to pay bills upon receipt.

Section 328. Advisory Group on Reducing Hospital Administrative Burdens
This section requires Health and Human Services (HHS) to establish an advisory group to provide recommendations on how the federal government can reduce the burden of federal administrative requirements on hospitals.

Sections 329. Data Reporting to Improve Transparency within the 340B Program
This section requires participating 340B entities to report to HHS the number of individuals dispensed drugs under this program, whether they belong to Medicare, Medicaid or other insurance, the total costs incurred and reimbursements received. This data will be made public on the HHS website and the OIG, GAO and Comptroller General will provide subsequent reports based on the data.

Sections 330. Low-income Utilization Rate Reports in the 340B Program
These sections require participating 340B entities to report to HHS the low-income utilization rates of specific outpatient hospital services. Additionally, the Health Resource Services Administration (HRSA) will provide a report based on the data.

Section 331. Employer Health Benefits Reporting
This section requires employers who provide health insurance for 100 or more employees to provide certain information to those beneficiaries. On an annual basis, each beneficiary will be informed of the amount the employer paid for their coverage for that plan year, as well as any previous plan years in which the employer paid for their coverage.

Section 332. Group Health Plan Reporting Requirements
This section requires health insurers to report to the Secretary detailed information including the most prescribed and most costly prescription drugs, total health expenditures broken down by hospital and provider cost, the average monthly premium, and impact of rebates

Section 333. Government Accountability Office Study on Profit and Revenue-Sharing in Health Care
This section 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.

Subtitle C—Prescription Drug Competition and Innovation

This subtitle addresses many problems in the pharmaceutical approval process, prescribing habits, and post-market practices that lead to increased costs to patients and the health care system as a whole. Specifically, provisions in this subtitle will increase access to generic drugs and biologics, allow innovative therapies to treat a wider base of patients, and ensure drug manufacturers and payors engage in fair negotiations.

Section 341. Expedited Development and Priority Review for Generic Complex Drug Products
This section amends the Federal Food, Drug, and Cosmetic Act to establish a program to expedite and increase flexibility for the development and priority review of generic complex drug products that do not clearly fit the definition of a drug or device, or that operate as a combination product.

Section 342. Preventing Blocking of Generic Products
This section prevents drug companies from practicing anti-competitive behavior, like pay-for-delay, when generic drug companies file abbreviated new drug applications. Specifically, it prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market. The 180-day exclusivity period of a first-to-file generic drug applicant will start 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.

Section 343. Ensuring Timely Access to Generics
This section addresses the abuse of citizen petitions to delay drug approval and allows FDA to deny a citizen's petition that is submitted with the primary purpose of delaying the approval of an application. This section requires the HHS to establish a procedure for referring a petitioner to the FTC if determined that a petition was submitted with the primary purpose of delaying a different drug's approval process.

Section 344. Preemption of State Barriers to the Substitution of Biosimilar Products
This section requires states to allow pharmacists to substitute a more affordable biosimilar in place of a brand name (reference) product, so long as FDA has designated the biosimilar as an interchangeable product.

Section 345. Increasing Pharmaceutical Options to Treat "Under-met" Medical Needs
Currently, when a disease or condition cannot be treated with existing products (there is an unmet need), FDA can fast-track the approval process for new drugs treating these conditions. To increase the speed at which additional products may join the market, this section allows FDA to also use the fast-track process when a disease or condition is currently treatable by only one or two FDA-approved products (there is an "under-met" need).

Section 346: Provisional Approval of Innovative Drugs
This section creates a "provisional approval pathway" within FDA where a drug that has cleared early stage clinical trials with substantial data proving safety and efficacy can apply for an expedited, conditional approval under strict supervision to enter the market and treat patients with life-threatening conditions that have few to no other therapies available. This time-limited approval would still be subject to full FDA approval after a maximum of 5 years. This section also establishes the position of Patient Advocate General within FDA.

Section 347. Consolidating Exclusivity for Drugs Treating Rare Diseases and Conditions
This section amends the market exclusivity period for drugs treating rare diseases and conditions by limiting orphan drug manufactures to two periods of exclusivity—one 7-year period of exclusivity for the initial designation and one 3-year period of exclusivity for the following designation.

Section 348. Exclusivity Period for Brand Name Biological Products
This section decreases the market exclusivity period for reference products (brand name drugs) from 12 years to 5 years—the same market exclusivity period time for both small molecule and biologic drugs.

Section 349. Protecting Access to Biological Products
This section 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.

Section 350. Streamlining the transition of biological products
This section clarifies that products submitted under the drugs pathway but are now classified as biologics will not need to resubmit under the new pathway so long as the application was six months before March 2020.

Section 351. Regulation of Manufacturer-Sponsored Copay Contributions
This section authorizes the HHS to prohibit drug manufacturers from providing financial contributions to patient copays and allows HHS to penalize drug manufacturers that engage in this behavior.

Section 352. Antitrust Exemption for Negotiation of Drug Prices
This section creates a safe harbor from antitrust liability for private health insurers that jointly negotiate with drug manufacturers for wholesale acquisition prices and formulary access.

Section 353. Biological Product Innovation
This section excludes all biological products from requirements to follow U.S. Pharmacopeia compendial standards, which were originally drafted to apply to small molecule drugs. This will prevent delays related to compliance with USP standards, in the licensure of biosimilar and interchangeable products.

Section 354. Clarifying the Meaning of New Chemical Entity
This section clarifies that eligibility for a 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.

Section 355. Prompt Approval of Drugs Related to Safety Information
This section gives FDA authority to more promptly approve a follow-on or generic drug by allowing safety information in its labeling that may be protected by a brand drugs exclusivity.

Section 356. Conditions of Use for Biosimilar Biological Products
This section 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.

Section 357. Education on Biologic Products
This section requires FDA to establish a website to provide educational materials for health care providers, patients, and caregivers on biological and biosimilar products to promote their use and uptake.

Section 358. Congressional Review of Costly FDA Rulemaking
This subtitle establishes a requirement that Congress vote on all major actions proposed by FDA—those that would have an economic impact of $100 million or more. The action shall be approved with a simple majority of both the House and Senate.

Section 359. Government Accountability Office Study of Rules
This section requires the Comptroller General to submit a report to Congress within 1 year after the enactment of this Act on the number of rules and major rules in effect and the total estimated economic cost imposed by these rules.

Subtitle D—Prescription Drug and Pharmacy Benefit Manager Transparency

This subtitle enacts provisions that promote transparency regarding drug manufacturers patents and other information and Pharmacy Benefit Managers' misleading practices and role in the drug supply chain.

Section 361. Transparency for Biologic Drug Patents
This section requires branded biologic manufacturers to disclose their patents in a timely and transparent manner, promoting competition with biosimilars.

Section 362. Biological Product Patent Transparency
This section increases transparency of patent information for biological products by requiring information to be submitted to FDA and published in the "Purple Book." Additionally, it 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.

Section 363. Orange Book Modernization
This section clarifies the information that FDA must include in the Orange Book in regard to drug patents and exclusivities including the removal of patents and patent claim information when it is determined to be invalid or expired.

Section 364. Modernizing the Labeling of Certain Generic Drugs
This section addresses outdated generic drug labels that contain incomplete or incorrect information because there is no longer a brand drug on the market.

Section 365. Elimination of PBM Rebates in the Commercial Market
This section amends the Public Health Service Act to prohibit group health plans from receiving a price reduction on prescription drugs from a drug manufacturer unless the price reduction is reflected at the point of sale and the fees are transparent to the health plan or health plan provider.

Section 366. Pharmacy Benefits Manager Reform
This section offers transparency and prohibits anti-competitive practices that are common among Pharmacy Benefit Managers (PBMs). Specifically, this section prohibits retroactive fees and payment reductions imposed on retail pharmacies (DIR fees); bans PBMs from requiring PDP enrollees to solely use pharmacies, including mail order, in which the PBM is involved in ownership; and requires the establishment and regular update of a prescription drug pricing standard to be used by PBMs.

Section 367. Health Plan Oversight of PBMs
This section requires that plan sponsors receive a quarterly report on the costs, fees and rebate information associated with their PBM contracts. Additionally, this section prohibits PBMs from engaging in spread pricing and requires the PBM to pass on 100% of any rebates or discounts to the plan sponsor.

Section 368. Study by Comptroller General of the United States on PBMs
This section requires The Comptroller General to conduct a study on the role of PBMs to determine what industry practices may be increasing or decreasing drug costs.

Subtitle E—Medicare and Medicaid Prescription Drug Reform

This subtitle enacts provisions to lower the cost of drugs directly purchased by the federal government while promoting market-based pricing models.

Section 371. Medicare Part B Rebate by Manufacturers for Drugs or Biologics with Prices Increasing Faster Than Inflation

This section would require manufacturers to pay a rebate for drugs and biologicals for which the average sales price (ASP) increases faster than inflation, beginning in January 1, 2021. Manufacturers would provide mandatory rebates to the Secretary for each quarter that the ASP of a drug increased faster than inflation. The rebate amount would be equal to the difference between the inflation-adjusted ASP and the actual ASP during the quarter. The Secretary would be prohibited from making payments for a drug if the manufacturer fails to comply with the rebate requirements for that drug.

Section 372. Market Based Medicare Part B International Pricing Index

This section would direct HHS to make Medicare Part B drug payments based on an international pricing index, so long as countries with market-based drug prices are weighted heavier than those with government-controlled markets or prices.

Section 373. Innovation Model Testing of Medicare Drug Payments

This section directs the Center for Medicare and Medicaid Innovation to conduct a pilot program to determine the efficiency and effectiveness of an integrated drug benefit for individuals enrolled in Medicare parts A, B, D and Social Security for the elderly and disabled.

Section 374. Modification of Maximum Rebate Amount Under Medicaid Drug Rebate Program

This section increases the current 100% AMP cap on Medicaid rebates to 125% beginning in October 2022 and establishes there will be no cap on the rebate amount for drugs whose prices exceed inflation.

Subtitle F—Medical Malpractice Reform

This subtitle enacts provisions that reform costly litigation surrounding health care lawsuits where the care was provided or subsidized by the federal government. Specifically, this subtitle establishes liability protections for providers and a statute of limitations on the lawsuits; defines eligible medical expert witnesses, and caps compensation and ensures it is delivered to the patient.

Section 381. Definitions

This section defines medical terminology referred to under this subsection.

Section 382. Encouraging Speedy Resolution of Claims

This section encourages speedy resolution of medical malpractice lawsuits by implementing a statute of limitations of no longer than (a) 3 years after the date of the occurrence of the breach or tort; (b) 3 years after the date of medical treatment that is the subject of the claim; or (c) 1 year after the claimant discovers that he or she is injured, whichever comes first, unless the claim involves fraud, intentional concealment, or the presence of a foreign body in the injured person.

Section 383. Compensating Patient Injury

This section limits the amount of noneconomic damages awarded in a health care lawsuit to $250,000, regardless of the number of parties involved. This section makes each party liable for their share of the damages based on their percentage of responsibility.

Section 384. Maximizing Patient Recovery
This section empowers courts to restrict attorney's contingency fees so that patients are the beneficiaries of any recoveries in malpractice litigation. In no event shall contingent fees exceed: (1) 40% of the first $50,000 recovered; (2) 33% of the next $50,000 recovered; (3) 25% of the next $500,000 recovered; and (4) 15% of any amount recovered in excess of $600,000.

Section 385. Authorization of Payment of Future Damages to Claimants in Health Care Lawsuits
This section allows payment of future damages that are $50,000 and over to be paid by periodic payments.

Section 386. Product Liability for Health Care Providers
This section prevents health care providers who prescribes or provides an FDA approved medical product from being named as a party to a product liability lawsuit involving the product they provided, or as a claimant in a class action lawsuit against the product.

Section 387. Vaccine Product Liability for Health Care Providers
This section clarifies that this subtitle does not preempt federal laws regarding vaccine-related injuries or death and does not affect any defense available to a defendant in a health care lawsuit.

Section 388-389. Expert Witness Qualifications
These sections limit acceptable expert witnesses in a health care lawsuit to appropriately licensed health professionals that specialize in the relevant field of care and are involved in an active clinical practice or clinical instruction. Additionally, this section limits health care expert witness qualifications in other lawsuits to appropriately licensed professionals with specialties relevant to the injury in question.

Section 390. Communications Following Unanticipated Outcome
This section establishes that any evidence of a health care provider expressing apologies, compassion, or condolence following an unanticipated injury or death is inadmissible as an admission of liability or evidence of an admission against interest.

Section 391. Affidavit of Merit
This section requires the plaintiff's attorney to file an affidavit of merit signed by a health professional who meets the requirements for an expert witness under this subsection at the same time they file the health care lawsuit.

Section 392. Notice of Intent to Commence Lawsuit
This section requires any person intending on commencing a health care lawsuit give the health care provider 90 days written notice before the action is commenced.

Section 393. Limitation on Liability for Volunteer Health Care Professionals
This section limits the ability of individuals to sue physicians for certain actions that occur while providing charity care.

Section 394. Rules of Construction
This section clarifies that except where specified, the provisions in this subtitle preempt state laws that may enable costly malpractice litigation.

Section 395. Effective Date
This section specifies that all health care lawsuits brought to court after the enactment date of this Act are subject to the provisions under this subtitle and exempts cases in which the injury occurred prior to the enactment date.

TITLE IV: Medicare and Medicaid Reforms

Subtitle A—Medicaid Reforms

This subtitle enacts provisions that provide greater flexibility to states' Medicaid programs and close the gap in coverage for people on the border of eligibility for Medicaid and premium assistance in the individual market.

Section 401. Flexible Medicaid Population
This section gives states the option to receive a per-capita allotment for coverage of their legacy (i.e. pre-ACA) Medicaid population. States that choose this option will have the flexibility to determine who qualifies for Medicaid in their state and will receive federal funds reflecting to the number of enrollees in the program.

Section 402. Eligibility for Premium Tax Credits
In states that have elected the Flexible Medicaid Population option, individuals whose incomes are below 600% FPL and above the threshold for eligibility in the state's Medicaid program as of January 1, 2009, shall be eligible for premium subsidies from the federal government. This will ensure low-income individuals can adequately receive Medicaid services, while those earning more can find affordable exchange plans.

Section 403. Medicaid Eligibility Determinations
This section allows states to hire outside contractors to conduct Medicaid eligibility redeterminations and allows states to asses an individual's Medicaid eligibility every 6 months or more frequently.

Section 404. Lowering Safe Harbor Threshold with Respect to State Taxes on Providers
Under current federal regulation, states can use provider taxes for the state's share of Medicaid spending and creates a safe harbor from the hold-harmless test for taxes where provider tax collections are 6% of less of net patient revenues. This section transitions from the maximum federally allowable safe harbor limit of 6%, decreasing for the next 25 years until no safe harbor exists.

Section 405. Direct Primary Care and Medicaid
This section allows for states, through an 1115 waiver, to design programs to allow direct primary care arrangements (DPC) for low-income individuals enrolled in their state Medicaid program.

Section 406. Deduction for Qualified Charity Care
This section creates a new tax deduction that may be utilized by primary care physicians who provide certain medical services to individuals enrolled in Medicaid or CHIP free of charge. The deduction shall be a predetermined amount, in most cases equivalent to the Medicare's physician fee schedule.

Subtitle B—Medicare Reforms

This subtitle enacts provisions that equally promote medical services from different Medicare providers, and provide tax relief for beneficiaries, and promote Medicare solvency.

Section 411. Reimbursement Rates for Site Neutral Services
This section establishes equivalent reimbursement rates for Medicare Part A inpatient hospital care and Medicare Part B outpatient services for substantially similar services.

Section 412. Eliminating FEHBP Eligibility for Annuitants
This section eliminates such FEHBP eligibility and coverage for those who qualify for Medicare Advantage.

Section 413. Eliminating Medicare Eligibility for Multimillionaires
This section prohibits individuals 65 and older, with lifetime reported earnings exceeding $10 million, from enrolling in Medicare Part B and Part D coverage, or other Medicare supplemental policies. However, they may still receive Medicare Part A coverage, as they have contributed to that fund throughout their lives.

Section 414. Medicare Part D Tax Deduction
This section allows employers to deduct business-expenses contributed toward prescription drug coverage for retires from their taxes without reductions due to federal subsidies.

Section 415. Repeal of Net Investment Income Tax
This section repeals the Unearned Income Medicare Contribution Surtax, which imposes a tax on certain net investment income of individuals, estates, and trusts.

Section 416. Medicare Coverage of Bad Debt
This section reduces the percent Medicare will cover for bad debt incurred by health institutions from 65% to 25% allowable bad debt coverage by increasing the reduction rate by 10% per year over the next four years.

Subtitle C—Medicare Choice and Competition

This subtitle modernizes and introduces market-based solutions to address the growing elderly health insurance market. Specifically, it establishes an online platform with a competitive bidding program to allow beneficiaries to easily compare fair coverage options.

Section 421. Competitive Bidding and Premiums for Medicare Plans
This section establishes an online platform for beneficiaries to enroll in easily comparable Medicare Advantage, Fee-For-Service (FFS), and Accountable Care Organization (ACO) plans. Medicare Advantage plans will be required to have an actuarial value equivalent to FFS coverage under Parts A and B and can only introduce two supplemental benefit plans, while FFS and ACO enrollees will still have access to Medigap plans. Competitive bidding markets will be tied to metropolitan statistical regions with benchmark premiums based on the weighted average (by enrollment in previous year) of the premium bids from Medicare Advantage plans, ACOs, and the per-person costs of FFS cost – minus the statutory Part B premium.

Beneficiaries enrolling in a Medicare Advantage plan will pay the difference above the benchmark rate for higher-cost plans or receive 100% of the savings for plans with premiums below the benchmark. Medicare Advantage plans can offer multiyear contracts with guaranteed premiums. For beneficiaries enrolling in FFS Medicare after the enactment of this Act, premiums can only increase $20/month year-over-year for 5 years to limit cost increases.

Section 422. Eligibility and Enrollment Rules
This section allows individuals to opt out of Part A coverage without losing social security benefits and clarifies that an individual who opts out of Part A will also terminate benefits under Part B, and an individual that opts out of Part B terminates benefits under Part A. However, this section establishes a special open enrollment period, without a late enrollment penalty, for individuals who receive either Parts A or B coverage and wish to be enrolled in both. This section also establishes a process for autoenrollment in a Medicare Advantage plan for individuals with both Parts A and B eligibility

This section also establishes a process for autoenrollment in a Part D prescription drug plan (PDP) where the monthly premium does not exceed the weighted average premium of a respective Part C PDP and eliminates late enrollment fees for Medicare enrollees who were not previously enrolled in a Part D plan. This section also limits the benefits for full-benefit eligible individuals under Medicaid and allows states to receive subsidy payments from the federal government to enroll these individuals in Medicaid Managed Care Plans.

Section 423. Cost-sharing and Reporting Requirements
This section confirms that the out-of-pocket catastrophic limit and other cost-sharing measures will remain for all forms of Medicare. Additionally, PDPs will be required to report all enrollee out-of-pocket cost sharing for prescription drugs.

Section 424. Late Enrollment Penalty Not to Apply for Months of Any Health Coverage
This section clarifies that no late enrollment penalty will be assessed if new beneficiaries had any health coverage prior to enrollment.

Section 425. Medigap Reform
This section requires Medigap plans must offer guaranteed coverage, further protecting those with preexisting conditions.

Section 426. Accountable Care Organization Reform
This section subjects Accountable Care Organizations (ACOs) to competitive bidding similarly to Medicare Advantage plans with Fee-For-Service. They will be full risk bearing, and payments can go to a centralized entity rather than individual provider or supplier.

Section 427. Primary Care Options
This section allows Medicare Part B beneficiaries to select their own primary care physician and beneficiaries are not liable for more than $5 per visit to their selected physician. The physician may receive a monthly fee under Part B for providing services such as preventive care, vaccinations, and communications to the beneficiary. The Secretary is responsible for providing a list of standardized benefits that are included in the payment.

Section 428. General Provisions, Effective Date
This section defines terms and sets an effective date of Competitive Bidding at January 1, 2021.

Subtitle D—Telehealth Improvements and Expansion

This subtitle follows bipartisan and Trump administration policy to ease geographic limitations, provide for waiver flexibility and expand telehealth capabilities during emergency situations.

Section 431. Expanding Telehealth Health Professionals
This section expands allowable and billable telehealth coverage under Medicare to include applicable services furnished by a certified diabetes educator or licensed respiratory therapist, audiologist, occupational therapist, physical therapist or speech language pathologist. This section also allows for remote patient monitoring, a form of telehealth, for certain chronic conditions to be covered at Medicare rates.

Section 432. Expanding the Use of Telehealth Through the Waiver of Certain Requirements
This section provides the HHS Secretary authority to waive a variety of telehealth restrictions including geographic limitations, types of technology, types of providers, types of services when certain criteria are met and hold a public comment period for the waivers.

Section 433. Expanding the Use of Telehealth for Mental Health Services
This section removes geographic restrictions and adds the home as an originating site for mental health services.

Section 434. Use of Telehealth in Emergency Medical Care
This section removes geographic restrictions on certain originating sites for emergency medical care services furnished through telehealth.

Section 435. Improvements to the Process for Adding Telehealth Services
This section requires CMS to implement and clarify a process for adding covered telehealth services and increasing their access.

Section 436. Rural Health Clinics and Federally Qualified Health Centers
This section removes geographic restrictions on federally qualified ealth centers (FQHCs) and rural health clinics (RHCs) and that will allow FQHCs and RHCs to furnish telehealth services as both originating and distant sites.

Section 437. Native American Health Facilities
This section removes the geographic and originating site restrictions for facilities of the Indian Health Service or Native Hawaiian Health Care Systems.

Section 438. Waiver of Telehealth Restrictions During National Emergencies
This section allows for the waiver of telehealth restrictions
during national and public health emergencies, including COVID-19.

Section 439. Use of Telehealth in Recertification for Hospice Care
This section allows for beneficiaries recertifying the hospice benefit to do so via telehealth.

Section 440. Clarification for Fraud and Abuse Laws Regarding Technologies Provided to Beneficiaries
This section clarifies that the provision of technologies to a Medicare beneficiary for the purpose of furnishing services using technology is not considered “remuneration” under fraud and abuse laws.

Section 441. Study and Report on Increasing Access to Telehealth Services in the Home
This section requires MedPAC to study how different payers cover the home as an originating site and what services would be suitable for the home to be an originating site under Medicare.

Section 442. Analysis of Telehealth Waivers in Alternative Payment Models
This section requires an analysis of the impact of telehealth waivers in CMS Innovation Center models.

Section 443. Model to Allow Additional Health Professionals to Furnish Telehealth Services
This section authorizes a model to test allowing additional health professionals to furnish telehealth services.

Section 444. Testing of Models to Examine the Use of Telehealth Under the Medicare Program
This section encourages the CMS Innovation Center to test telehealth models in Medicare.