Improving Access to Affordable Prescription Drugs Act

Title I: Transparency

Section 101: Drug manufacturer reporting.
Some drug makers claim that high drug prices are necessary, as they simply reflect the high cost of bringing new drugs to market. But the actual amount that companies spend on research and development is small compared to other expenses such as marketing, and that much of the biomedical innovation motivating new drug discovery is supported by the National Institutes of Health (NIH) and other federal programs.

To better understand how research and development costs, manufacturing and marketing costs, acquisitions, federal investments, revenues and sales, and other factors influence drug prices, this section requires drug manufacturers to disclose this information, by product, to the Secretary of the Department of Health and Human Services (HHS), who, in turn, will make it publicly available in a searchable format.

Section 102: Determining the public and private benefit of copayment coupons and other patient assistance programs.
Drug makers offer coupons for prescription drug co-payments and other patient assistance programs to build brand loyalty and keep drug prices high. While these programs provide temporary relief to patients, public and private payers are left paying for these expensive drugs, which drive up health care costs for insurers, taxpayers, and patients in the form of higher premiums and higher cost sharing.

To better understand how patient assistance programs affect drug prices and the extent to which drug makers are using independent charity assistance programs to drive up profits, this section requires independent charity assistance programs to disclose to the IRS the total amount of patient assistance provided to patients who are prescribed drugs manufactured by any contributor to the independent charity assistance program. It also requires a GAO study on the impact of patient assistance programs on prescription drug pricing and expenditures.

Title II: Access and Affordability

Section 201: Negotiating fair prices for Medicare prescription drugs.
Medicare is one of the largest purchasers of prescription drugs in the country but, unlike Medicaid and the Department of Veterans Affairs (VA), it is not allowed to leverage its purchasing power to negotiate lower drug prices and bring down costs.

This section would allow the Secretary of HHS to negotiate with drug companies to lower prescription drug prices, and directs the Secretary to prioritize negotiations on specialty and other high-priced drugs. If, after a year, the Secretary and drug manufacturers fail to successfully negotiate a fair price, the Secretary will use the price that the Department of Veterans Affairs or other federal agencies that purchase prescription drugs use.

The section also requires the Medicare Payment Advisory Commission to conduct a study how negotiations affect prices in Medicare and the private market, and make recommendations on how to improve negotiations. It also requires the Center for Medicare and Medicaid Innovation to test new value-based and outcomes-based pricing models emerging from the private market.

Section 202: Prescription drug price spikes.
Prescription drugs are priced in the United States according to whatever the market will bear and are sometimes subject to drastic and frequent price increases without apparent justification. This makes drugs increasingly unaffordable and creates significant uncertainty for patients' and insurers' budgets.

This section requires the HHS Office of the Inspector General (HHS OIG) to monitor changes in drug prices and take steps to prevent drug manufacturers from engaging in price gouging. Under this provision, if a drug company increases the price of a drug beyond medical inflation (over a one year period or cumulatively), the drug manufacturer is subject to a graduated excise tax that depends on the size of the price increase. However, prior to enforcement of the tax, HHS OIG and the FTC would work with drug companies to assess the extent to which an increase in price was due to changes in a drug's supply chain or for other justifiable reasons.

Acceleration of the closing of the Medicare Part D coverage gap.
When Medicare Part D passed in 2003, the law provided a basic level of coverage for all beneficiaries below a certain threshold of costs (about $3,300 in 2016); it also provided coverage for seniors with the highest drug costs (costs above about $7,500 in 2016). This left a coverage gap (otherwise known as the "donut hole"), in which many seniors had to pay for the full cost of their drugs. The Affordable Care Act (ACA) included provisions to close this coverage gap by 2020.

This section closes the Medicare Part D prescription coverage gap in 2018, two years earlier than under current law, providing faster financial relief to seniors, and requires drug manufacturers to pay a larger share of the costs during the coverage gap.

Section 204: Importing affordable and safe drugs.
This section allows wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers and, after two years, from OECD countries that meet standards comparable to U.S. standards. Imported drugs must have the same active ingredient, route of administration, and strength as drugs approved in the U.S., and the Secretary has suspension authority when sellers do not meet standards. FDA-certified foreign sellers must comply with criteria including requiring a valid prescription for sale to individuals and a requirement to transmit product tracing and transaction history information to U.S. importers. The Secretary and GAO must report on the implementation of the Act.

Section 205: Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.
Prior to the creation of Medicare Part D, dual-eligible seniors received drug coverage through the Medicaid program, which requires drug manufacturers to offer discounts on their products in the

form of rebates. When Medicare Part D was introduced, dual-eligible beneficiaries were enrolled in the low-income subsidy program, and drug manufacturers no longer had to pay rebates for drugs provided to dual-eligible seniors.

This section restores prescription drug rebates for seniors who are dually eligible for Medicare and Medicaid and extends these rebates to other Medicare patients in Medicare low-income-subsidy (LIS) plans.

Section 206: Cap on prescription drug cost-sharing.
Increasingly, consumers are having to pay more out-of-pocket for their prescription drugs. Higher deductibles and higher cost-sharing are straining family budgets, especially for individuals who need expensive, specialty drugs.

For plan years beginning in 2019 and later, this section caps prescription drug cost sharing at $250 per month for individuals and $500 a month for families enrolled in Qualified Health Plans and employer-based plans.

Title III: Innovation
Section 301: Prize fund for new and more effective treatments of bacterial infections.
New ways to incentivize antibiotic development are necessary to fight the global health crisis posed by antibiotic resistance.

This section creates a $2 billion prize fund at the National Institutes of Health to fund entities that develop superior antibiotics that treat serious and life-threatening bacterial infections and to fund research that advances such treatments and is made publicly available. In order to receive prize funds, recipients must commit to offering their products at a reasonable price, share clinical data, take steps to promote antibiotic stewardship and waive applicable exclusivity periods. The National Academy of Medicine will study the extent to which the prize fund model fosters innovation and research.

Section 302: Public funding for clinical trials.
One of the barriers to new drug innovation is the high cost of clinical trials, which are necessary to demonstrate the safety and efficacy of new products to gain FDA approval.

This section creates a Center for Clinical Research within the NIH to conduct all stages of clinical trials on drugs that may address an existing or emerging health need. The bill provides $10 billion in funding over 10 years. If these trials support a drug that receives FDA approval, the Center for Clinical Research will execute non-exclusive licenses with drug manufacturers or enter into purchasing contracts to manufacture the approved drug.

Section 303: Rewarding innovative drug development.
The U.S. rewards pharmaceutical companies for innovative new drugs by granting exclusive marketing rights. Reducing certain exclusivity periods and increasing the standards for award of others will promote generic competition and lower drug prices.

This section amends various exclusivity periods awarded by the FDA to brand-name pharmaceutical companies in an effort to accelerate competition in the generic and biologics market. First, the bill modifies the New Chemical Entity (NCE) exclusivity period to allow FDA to accept a generic drug application for the branded product after three years rather than five, but maintains market exclusivity for five years.

Second, this section would add in a requirement that products awarded the 3-year New Clinical Investigation Exclusivity must show significant clinical benefit over existing therapies manufactured by the applicant in the 5-year period preceding the submission of the application.

Third, this section reduces the biological product exclusivity from 12 years to 7 years. Finally, the section directs GAO to conduct a study on orphan drug development, awarding of exclusivities, and revenues generated from orphan drugs.

Section 304: Improving program integrity.
The federal government awards drug exclusivities to innovative new products. But, under current law, even when drug companies defraud the government, they continue to reap the benefits of government-granted market exclusivity.

This section would terminate any remaining market exclusivity periods on any product found to be in violation of criminal or civil law through a federal or state fraud conviction or settlement in which the company admits fault.

Title IV: Choice and Competition
Section 401: Preserving access to affordable generics.
Pay-for-delay agreements occur when a brand-name pharmaceutical drug company pays a generic competitor to keep the generic drug off the market as part of a patent settlement. These deals delay access to cost-saving generic drugs and cost consumers and the government billions of dollars in higher drug costs.

This legislation would make it illegal for brand-name and generic drug manufacturers to enter into anti-competitive agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep more affordable generic equivalents off the market.

Section 402 and 403: 180-Day exclusivity period amendments regarding first applicant status and agreements to defer commercial marketing.
Under current law, the first generic company to submit a generic drug application automatically receives a 180-day exclusivity period once the generic enters the market; no other generic competitor can bring a generic to market until the exclusivity period has expired or been forfeited.

This section builds on section 401 and enables FDA to take away the 180-day generic drug exclusivity period from any generic company that enters into anti-competitive pay-for-delay settlements with brand-name drug manufacturers.

Section 404: Increasing generic drug competition.
While competition in most of the generic market has been robust, a segment of the generic drug market has seen a spike in drug prices. In some instances, these price increases are the result of generic drug manufacturers exiting the market, leaving little competition or limited capacity to meet market demand.

This section introduces new reporting requirements and financial incentives to promote and sustain competitive generic markets. It requires the HHS Secretary to maintain a public, up-to-date list of generic drugs and their manufacturers (including distributors, labelers, and compounders) to more quickly identify drugs at risk of shortage or drugs with a limited number of competitors. This section also directs generic drug manufacturers to report a discontinuance or interruption in the production of a drug at least 180-days prior to the event or as soon as practicable. Lastly it also authorizes the federal government to enter into purchase contracts with generic drug manufacturers if the number of manufacturers for essential medicines, as defined by the World Health Organization or another similar entity, falls below two.

Section 405: Disallowance of deduction for advertising for prescription drugs.
Pharmaceutical companies spend billions of dollars every year on television, magazine, and internet advertisements and receive tax credits from the federal government gives those companies a tax break every time you see a drug advertisement. Direct-to-consumer (DTC) advertisements drive up demand for new and higher-cost prescriptions and treatments, which increases medical costs for American families and seniors.

This section eliminates the tax breaks drug companies receive from the federal government for expenses related to direct-to-consumer advertising.

Section 406: Product hopping.
Manufacturers will introduce slightly modified versions of existing drugs to extend monopoly protections for their drug products and prevent generic competition. In some cases, drug manufacturers will take further action to shift patient demand to these more expensive drugs, especially when generic competitors hit the market. This practice is called "product hopping."

This section establishes a definition for the term "product hopping" and instructs the FTC to submit a report to Congress on the extent to which companies engage in these anti-competitive practices and their effects on company profits, consumer access, physician prescribing behavior, and broader economic impacts.