



## Abridged Summary of “Improving Access To Affordable Prescription Drugs Act”

### TITLE I—TRANSPARENCY

#### **Sec.101.Drug manufacturer reporting.**

Section 101 would require prescription drug corporations to disclose a variety of information, ranging from research and development expenditures, marketing and advertising, and acquisitions, to profits, pricing information, and executive compensation, among other factors. It would require reported information to be made available online, and noncompliant corporations would face a civil penalty.

#### **Sec.102.Determining the public and private benefit of copayment coupons and other patient assistance programs.**

Section 102 would require 501(c)(3) organizations to disclose to the Internal Revenue Service the total amount of patient assistance provided to patients who are prescribed drugs manufactured by any contributor to that 501(c)(3) organization.

It would also require the Government Accountability Office (GAO) to conduct a study and report for Congress on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures, including adherence to Office of Inspector General (OIG) of HHS guidance on the avoidance of waste, fraud and abuse, among other factors.

### TITLE II—ACCESS AND AFFORDABILITY

#### **Sec.201.Negotiating fair prices for Medicare prescription drugs.**

Section 201 would allow the Secretary of HHS to negotiate Medicare Part D prescription drug prices with prescription drug companies through use of techniques the Secretary deems appropriate. In the event of a failure of negotiations, the Secretary could establish a price that is the lower of the price paid by the Department of Veterans Affairs or the ‘Big Four’. The negotiated or established price would provide a ceiling for how much Part D plan sponsors may be charged.

It would require the Secretary to submit regular reports to Congress and the public on the impacts of such negotiations. It would further require the Comptroller General to conduct a study on the negotiations, including recommendations on how to improve the negotiations. Lastly, it would mandate the Center for Medicare and Medicaid Innovation to conduct testing of at least three models to improve the value provided through drug and biologic prices.

#### **Sec.202.Prescription drug price spikes.**

Section 202 would impose a tax on prescription drug companies that raise drug prices beyond the rate of medical inflation over one year or between two and five years. They would be required to submit sales information to the HHS OIG for the purposes of determining applicable fines. Noncompliant companies would be penalized by a percentage of the product's gross revenues. Collected revenues would be appropriated to the HHS Secretary for the purposes of funding or conducting research on economic and policy implications of price patterns of prescription drugs; or increasing funding to the National Institutes of Health for drug research and development.

**Sec.203.Acceleration of the closing of the Medicare Part D coverage gap.**

Section 203 would accelerate the closing of the Part D coverage gap, aka "donut hole". Generic drug coinsurance in the coverage gap would be reduced to 25% in 2018 (rather than 2020, as under current law). Starting in 2018, for brand-name drugs, beneficiaries' coinsurance would be reduced to 25%, and the level of manufacturer discount would be increased from 50% to 75%.

**Sec.204.Importing affordable and safe drugs.**

Section 204 would instruct the Secretary of HHS to issue regulations allowing for the import of qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years it would allow imports from other select countries that meet comparable U.S. statutory or regulatory standards. The Secretary would be given the authority to suspend importation of a product that is in violation of this section, and impose penalties for persons selling counterfeit products. In order for foreign distributors or pharmacies to export to the U.S. under this section they would be required to meet an extensive series of certification requirements.

This section would require the Secretary to issue a report to Congress and the public within one year of finalizing of all rules called for in this section, and for the GAO to conduct a study within 18 months of the final rule to analyze the implementation of this section and review its impacts on drug safety and cost savings as well as its importation shipment and tracing processes.

**Sec.205.Requiring drug manufacturers to provide drug rebates for drugs dispensed to low-income individuals.**

Section 205 would amend Medicare Part D by requiring drug manufacturers to grant drug rebates to HHS for low-income individuals at the level provided in Medicaid. Drugs or biologics by a manufacturer that fails to enter into a rebate agreement would be excluded from Part D coverage. It would exclude rebates from Medicaid's calculation of best and average manufacturer price.

**Sec.206.Cap on prescription drug cost-sharing.**

Section 206 would amend the essential health benefit requirements of the Affordable Care Act by specifying that requirements relating to cost-sharing apply to prescription drugs offered by insurance plans. For plan years beginning in 2019 or later, prescription drug cost sharing would be capped at \$250 for individuals or \$500 for families. The caps would be adjusted in subsequent years in accordance with the medical care component of the consumer price index.

## TITLE III—INNOVATION

### **Sec.301.Prize fund for new and more effective treatments of bacterial infections.**

Section 301 would establish in the U.S. Treasury an Antibiotics Prize Fund of two billion dollars in FY2018. The Director of NIH would establish public criteria and goals that contribute to the advancement of research in the field in order to qualify for the prizes, in addition to reasonable pricing, waiving of patent rights, and government authority to clawback the prize from noncompliant awardees.

The Director would enter into an agreement with the National Academies of Sciences, Engineering, and Medicine to conduct a study on the efficacy of prize funds and models of delinking the costs of research and development from drug prices.

### **Sec.302.Public funding for clinical trials.**

Section 302 would establish at the NIH a Center for Clinical Research, for the purpose of conducting clinical trials on drugs. The Director of the Center would establish and publish criteria for acquiring patent rights and selecting drugs to ensure they address an existing or emerging need. When said drug receives FDA approval, the Director would execute non-exclusive license for manufacturers to manufacture the drug or enter into purchasing contracts. Data and findings from the Center's studies would be made publically available.

### **Sec.303.Rewarding innovative drug development.**

Section 303 would reduce the periods and applicability of certain FDA-granted exclusivities. New Chemical Entity data exclusivity would be reduced from five to three years, while new drug application marketing exclusivity would be maintained for five years after approval. Biologic exclusivity would be reduced from 12 to seven years. The award of exclusivity for a new clinical study would be restricted to supplements of applications that show a significant clinical benefit over existing therapies manufactured by the applicant during a certain timeframe.

This section would also require the GAO to conduct a study and submit to Congress a report on orphan drugs, including Medicare and Medicaid expenditures on such products and more in-depth pricing and usage information for a sample of products.

### **Sec.304.Improving program integrity.**

Section 304 would rescind FDA granted exclusivities to a person who is found to have committed a violation under this section with respect to that drug. Violations range from the misbranding of a drug, to defrauding the federal or state government, among other areas. Failure to report violations would result in a fine of \$200,000 per day so long as the violation persists.

## TITLE IV—CHOICE AND COMPETITION

### **Sec.401.Preserving access to affordable generics.**

Section 401 would amend the Federal Trade Commission Act to authorize the Federal Trade Commission (FTC) to initiate proceedings against parties to any agreement resolving or settling a patent infringement claim in connection with the sale of a drug. Agreements would be considered in violation of this section if the abbreviated new drug application (ANDA) filer agrees to delay development or sale of the implicated generic drug in exchange for anything of value, with some exclusions. Entities subject to FTC enforcement may petition the order to be reviewed in federal court within 30 days of the order's issuance. Violations of this section would result in civil penalties no greater than three times the value given to the responsible party.

**Sec.402.180-Day exclusivity period amendments regarding first applicant status.**

**Sec.403.180-Day exclusivity period amendments regarding agreements to defer commercial marketing.**

Sections 402 and 403 would amend the Federal Food, Drug and Cosmetic Act by disqualifying a generic drug applicant from receiving "first applicant" 180-day exclusivity under certain circumstances that would delay marketing of the generic drug, also known as "pay for delay". It would expand the definition of "first applicant" to certain subsequent applicants. A "first applicant" that has entered into a disqualifying agreement would be prohibited from beginning marketing for a specified period of time.

**Sec.404.Increasing generic drug competition.**

Section 404 would require the FDA commissioner to publish on the FDA website a complete list of all generic drugs and related pertinent information to increase generic drug competition. It would also require entities engaged in the production of drugs or devices to register any contract. Manufacturers of all drugs would be required to notify the Secretary of any discontinuance or interruption of the production of any drug that is likely to lead to a disruption of its U.S. supply. If the Secretary determines that there are less than two manufacturers of an approved drug or biologic, the Secretary may take specific measures intended to increase the number of manufacturers and establish related guidelines.

**Sec.405.Disallowance of deduction for advertising for prescription drugs.**

Section 405 would disallow tax deductions for expenses relating to direct-to-consumer advertising, including advertisements in regard to a prescription drug product primarily directed toward consumers in publications, broadcast media, over the internet and through patient assistance programs.

**Sec.406.Product Hopping.**

Section 406 would require the FTC to submit a report to Congress on the extent to which manufacturers of drug and biologic products engage in product hopping, a form of evergreening in which a manufacturer reformulates an existing product to attain a new FDA approval for a product that treats the same condition, and takes action to shift patients to the new product. It would also require the FTC to issue guidelines on circumstances in which product hopping raises anticompetitive concerns or is considered a violation of antitrust laws.