Key Provisions of Drug Pricing Proposals

April 26, 2021

By Josh LaRosa and Erin Slifer, Wynne Health Group

The following table reflects the Wynne Health Group's analysis of key provisions of the following bills. Specifically, we examine drug price negotiation, Medicare Part D redesign, Medicare Part B and Part D inflation rebates, international mechanisms, generic drug promotion and anticompetitive behavior, and manufacturer reporting.

- **Elijah E. Cummings Lower Drug Costs Now Act** (H.R.3, press release)
- **Lower Costs, More Cures Act** (Bill text; section-by-section, press release)
- **Prescription Drug Pricing Reduction Act** (S.2543, press release, section-by-section)
- **Prescription Drug Price Relief Act** (S.909/H.R.2148; Senate bill text; House bill text; summary; press release)
- **Medicare Drug Price Negotiation Act** (S.908/H.R.2139; Senate bill text; summary; press release)
- **Affordable and Safe Prescription Drug Importation Act** (S.920; legislative text; summary; press release)
- **Empowering Medicare Seniors to Negotiate Drug Prices Act** (S.62/H.R.2071; press release)
- **Protecting Consumer Access to Generic Drugs Act** (H.R.153)
- **FAIR Drug Pricing Act** (Senate bill text; summary; press release)
- **Consumer Health Options and Insurance Competition Enhancement (CHOICE) Act and Medicare-X Choice Act** (S.386; Senate bill text; summary; press release)

I. Drug Price Negotiation

	Elijah E. Cummings Lower Drug Costs Now Act	Medicare Drug Price Negotiation Act	Empowering Medicare Seniors to Negotiate Drug Prices Act	CHOICE Act and Medicare-X Choice Act
Covered drugs	Authorizes the HHS Secretary to establish a "Fair Price Negotiation Program" that would take effect in plan year 2024. HHS also may enter into a contract with one or more third parties to administer the negotiation process. The bill establishes the criteria for a drug to be eligible for negotiation: • is among the 125 covered Medicare Part D single-source drugs (i.e., brand-name drugs) with the highest	Authorizes the HHS Secretary to negotiate the prices of Medicare Part D drugs by eliminating the noninterference clause. HHS would be required to identify applicable covered Part D drugs through the following prioritization criteria: • the 40 Part D drugs with the highest total Medicare expenditures	Authorizes the HHS Secretary to negotiate the prices of Medicare Part D drugs by eliminating the noninterference clause.	Requires HHS to negotiate reimbursement rates for drugs covered under the public health insurance option.

	Elijah E. Cummings Lower Drug Costs Now Act	Medicare Drug Price Negotiation Act	Empowering Medicare Seniors to Negotiate Drug Prices Act	CHOICE Act and Medicare-X Choice Act
	net spending under prescription drug plans and Medicare Advantage prescription drug (MA-PD) plans • is among the 125 drugs with the highest net spending in the United States, or • is insulin. The bill requires the HHS Secretary to select drugs that would result in the greatest projected savings to the federal government or individuals during that plan year: • among the 250 highest-cost drugs, at least 25 drugs in 2024 and at least 50 drugs in 2025 and subsequent years • insulin, and • all new-entrant negotiation-eligible drugs.	• the 40 Part D drugs with the highest beneficiary spending • the 20 Part D drugs with a unit cost increase at or above the 95th percentile of overall Part D cost increases • Part D drugs for which a single treatment regimen is priced above the annual out-of-pocket spending threshold, and • single-source drugs or biologics that also satisfy at least one of the criteria specified above. HHS also would establish a formulary for required use by MA and Part D plan sponsors, which would include at least two covered Part D drugs in each category and class of covered Part D drugs. The formulary would still include requirements for the inclusion of all drugs in the existing six protected classes under Part D (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants).		
Payment determination and selected countries	In general, the target price is the lowest average price compared to the average international market (AIM) price. For selected drugs without an AIM price, the target price is 80 percent of the average manufacturer price. More importantly, the bill sets an upper limit on the maximum fair price negotiated at 120 percent of the AIM price. If an AIM price is unavailable, then the upper limit would be 85 percent of the average manufacturer price. AIM is based on prices in Australia, Canada, France, Germany, Japan, and the United Kingdom.	If negotiations fail, the bill would set prices at the lowest of the three following prices: • the average price of the drug as sold in Canada, France, Germany, Japan, and the United Kingdom • the contracted price with the Department of Veterans Affairs, or • the Medicaid best price.	N/A	Payment rates would be determined either: • through the HHS and manufacturer negotiations, or • by reference to payment rates under the original Medicare fee-for-service program, or through modified rates to accommodate payment for drugs not covered under the original Medicare fee-for-service program.

	Elijah E. Cummings Lower Drug Costs Now Act	Medicare Drug Price Negotiation Act	Empowering Medicare Seniors to Negotiate Drug Prices Act	CHOICE Act and Medicare-X Choice Act
Participation and penalties	Manufacturers that fail to offer the maximum face price to fair-price-eligible individuals, or a hospital, physician, or other provider would be subject to a civil monetary penalty equal to 10 times the amount equal to the difference between the price offered and the maximum fair price.	As mentioned, if negotiations fail, HHS will set prices based on the lowest of the three criteria listed in the previous cell.	N/A	This would apply to all prescription drugs covered under the public health insurance option. The penalty for failed negotiations is by having reimbursement set by default at the Medicare fee-for-service rate or some modified amount, presumably for drugs otherwise covered under Part D.
Applicability	Negotiation prices would apply to traditional Medicare beneficiaries, individuals enrolled in a Part D plan or MA-PD plan, and individual enrolled in commercial plans. Commercial plans may opt out of using negotiated prices.	The negotiation requirements apply to Medicare Part D prices (as administered by Medicare Advantage and Part D plan sponsors).	N/A	The negotiation requirements would apply to all drugs to be covered under the public health insurance plan.

II. Medicare Part D Redesign

	Elijah E. Cummings Lower Drug Costs Now Act	Lower Costs, More Cures Act	Prescription Drug Pricing Reduction Act
Annual out-of-pocket (OOP) cap	Limits out-of-pocket spending to $2,000 beginning in 2024, increased by the percentage increase in CPI-U for the 12-month period ending with June of the previous year.	Limits out-of-pocket spending to $3,100 beginning in 2022, indexed to the growth in Part D spending.	Limits out-of-pocket spending to $3,100 beginning in 2022, indexed to the growth in Part D spending.
Spreading out cost sharing	Requires the HHS Secretary to establish a process to provide certain enrollees of prescription drug plans and MA-PD plans the option to make coinsurance payments in periodic installments over the remainder of the plan year beginning in 2024.	Requires HHS to establish a process through rulemaking to establish a maximum monthly cap on cost-sharing payments for enrollees of prescription drug plans and MA-PD plans beginning in 2022 and to offer the option to make monthly out-of-pocket payments over the year beginning in 2024. Establishes a monthly $50 postdeductible cap on insulin and medical supplies associated with the injection of insulin, beginning in 2022, indexed to the growth in Part D spending.	Requires HHS to establish a process through rulemaking to establish a maximum monthly cap on cost-sharing payments for enrollees of prescription drug plans and MA-PD plans beginning in 2022 and to offer the option to make monthly out-of-pocket payments over the year beginning in 2022.

	Elijah E. Cummings Lower Drug Costs Now Act	Lower Costs, More Cures Act	Prescription Drug Pricing Reduction Act
Manufacturer discount	In the initial coverage phase, requires manufacturers to pay a 10 percent discount beginning in 2024 for brand-name drugs. In the catastrophic phase, requires manufacturers to pay a 30 percent discount beginning in 2024 for brand-name drugs.	Establishes a 10 percent manufacturer discount throughout the Part D benefit beginning in plan year 2022.	In the initial coverage phase, requires manufacturers to pay a 7 percent discount for brand-name drugs. In the catastrophic phase, requires manufacturers to pay a 14 percent discount beginning in 2022 for brand-name drugs.
Government reinsurance	Beginning in plan year 2024, government reinsurance in the Part D benefit is reduced from 80 percent to 20 percent in the catastrophic phase.	Beginning in plan year 2022, government reinsurance in the Part D benefit is reduced from 80 percent to 20 percent in the catastrophic phase.	Lowers federal reinsurance from 80 percent to 60 percent in 2022, 40 percent in 2023, and 20 percent in 2024 and subsequent years.
Insurer liability	Maintains beneficiary cost sharing at 25 percent (between the annual deductible and OOP cap). Therefore, for brand-name drugs, lowers insurer liability to 65 percent in the initial coverage phase, and increases insurer liability from 15 percent to 50 percent in the catastrophic phase.	Lowers beneficiary cost sharing from 25 percent to 15 percent. Therefore, for brand-name drugs, maintains insurer liability to 75 percent in the initial coverage phase, and increases insurer liability from 15 percent to 70 percent in the catastrophic phase.	Lowers beneficiary cost sharing from 25 percent to 20 percent beginning in 2022. For brand-name drugs, lowers insurer liability from 75 percent to 73 percent in the initial coverage phase. In the catastrophic phase, increases insurer liability from 15 percent to 26 percent in 2022, 46 percent in 2023, and 66 percent in 2024 and subsequent years.

III. Medicare Part B and Part D Inflation Rebates

	Elijah E. Cummings Lower Drug Costs Now Act	Prescription Drug Pricing Reduction Act
Inflation rebates	Requires manufacturers to pay a rebate to the Department of the Treasury for the amount that they raised the prices of Medicare Part B or Part D drugs above the rate of inflation since January 1, 2016, beginning in 2023. Directs the Secretary of Labor, with input from the HHS Secretary and Treasury Secretary, to submit a report on requiring inflation rebates for group health plans and group health insurance coverage. The Secretaries also are required to promulgate regulations by December 31, 2023, to implement such a model to require inflation rebates for those plans.	Requires manufacturers to pay a rebate to Medicare for the amount that their Medicare Part B or Part D drugs increased above the rate of inflation since July 1, 2019.

IV. International Mechanisms

	Prescription Drug Price Relief Act	Affordable and Safe Prescription Drug Importation Act
Reference countries	Canada, France, Germany, Japan, and the United Kingdom.	Initially, Canada, and two years after enactment the Secretary would have the authority to permit the importation of drugs from countries in the Organisation for Economic Co-operation and Development (OECD) that meet specified statutory or regulatory standards that are comparable to U.S. standards.
Applicable drugs	Any brand-name drug for which the domestic average manufacturing price (AMP) exceeds the median price charged in the five reference countries.	Drugs eligible for importation must be purchased from an FDA-certified foreign seller and have the same active ingredients, route of administration, and strength as drugs approved in the U.S. Certain biologics could only be imported by wholesales or pharmacies.
Mechanism	If the price of a drug is determined to be excessive, the HHS Secretary is authorized to: • waive or void any government-granted exclusivities • grant open, nonexclusive licenses allowing any person to make, use, offer to sell, or import the drug into the U.S. This allows generic drug manufacturers to make more affordable versions of the reference drugs. Any generic manufacturer accepting a license to make a generic version would be required to pay a reasonable royalty to the holder of the original drug patent.	The bill directs the HHS Secretary to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs from licensed Canadian sellers, within 180 days of enactment.

V. Generic Drug Promotion and Anticompetitive Behavior

	Lower Costs, More Cures Act	Prescription Drug Price Relief Act	Protecting Consumer Access to Generic Drugs Act
Mechanism	Prohibits drug and biologic manufacturers from compensating generic and biosimilar manufacturers to delay the entry of a generic or biosimilar into the market (i.e., pay-for-delay).	Authorizes HHS to waive or void any government-granted patent exclusivities for a drug if the Department determines that a drug's average manufacturing price exceeds the median price charged for such drug in five reference countries (Canada, France, Germany, Japan, and the United Kingdom). HHS would further be authorized to grant open, nonexclusive licenses allowing any entity to make, use, offer, or sell, or import into the U.S. generic versions of such drug.	Same as the Lower Costs, More Cures Act.
Enforcement	If a new drug application holder or biologics license application holder violates the prohibition on pay-for-delay, the legislation authorizes the Federal Trade Commission to commence civil action to recover a civil penalty against a manufacturer in violation. The amount	N/A	Same as the Lower Costs, More Cures Act.

	Lower Costs, More Cures Act	Prescription Drug Price Relief Act	Protecting Consumer Access to Generic Drugs Act
	of any civil monetary penalty levied through a civil action can be no greater than the greater of: • for brand manufacturers, no more than three times the monetary value given to the generic manufacturer as part of the pay-for-delay agreement • for generic manufacturers, no more than three times the monetary value received by the brand manufacturer as part of the pay-for-delay agreement.		

VI. Manufacturer Reporting

	Elijah E. Cummings Lower Drug Costs Now Act	Lower Costs, More Cures Act	Prescription Drug Pricing Reduction Act	Prescription Drug Price Relief Act	FAIR Drug Pricing Act
Qualifying drugs	Drugs that have a wholesale acquisition cost (WAC) of at least $100 per month supply and have a price increase of 10 percent over a 12-month period or 25 percent over a 36-month period.	Drugs with a WAC of $100 or more for a month's supply or a typical course of treatment and is administered to treat a disease affecting 200,000 or more people.	Drugs with a WAC of at least $10 per dose and had a price increase of at least 300 percent over five years or 100 percent over one year; drugs in the top 50th percentile of net drug spending in Medicare or Medicaid and had a price increase of at least 50 percent over five years or 15 percent over one year; and new drugs with a launch price high enough that it exceeds the Medicare Part D out-of-pocket threshold.	All brand-name drugs produced by the manufacturer.	Same as the Elijah E. Cummings Lower Drug Costs Now Act.
Manufacturer reporting requirements	Manufacturers are required to notify HHS and submit a transparency and justification report 30 days before they increase the price of applicable drugs. The report must contain: • the percentage by which the manufacturers will raise the WAC on the	Manufacturers are required to report each increase in price that is equal to 10 percent or more in the previous 12 months, or 25 percent or more in past three years 30 days before the price increase takes effect. The report must contain: • the percentage by which the manufacturers will	For qualifying drugs, manufacturers would be required to report the following: • the percentage by which the manufacturers will raise the WAC on the planned effective date of such price increase	Manufacturers are required to submit an annual report to the HHS Secretary that includes the following: • the AMP of the drug in the U.S. and in Canada, France, Germany, Japan, and the United Kingdom for the entire year	Same as the Elijah E. Cummings Lower Drug Costs Now Act.

	Elijah E. Cummings Lower Drug Costs Now Act	Lower Costs, More Cures Act	Prescription Drug Pricing Reduction Act	Prescription Drug Price Relief Act	FAIR Drug Pricing Act
	planned effective date of such price increase • a justification for, and description of, each manufacturer's price increase that will occur during the 12-month period or 36-month period • the identity of the initial developer of the drug • a description of the history of the manufacturer's price increases for the drug since approval • current list price • total expenditures of the manufacturers on materials and manufacturing; and acquiring patents and licensing on such drug • percentage of the total expenditures of the manufacturers on research and development • total revenue and net profit generated from the drug for each calendar year since approval, and • total costs associated with marketing and advertising for the drug.	raise the WAC on the planned effective date of such price increase • a justification for, and description of, each manufacturer's price increase that will occur during the 12-month period or 36-month period • the identity of the initial developer of the drug • a description of the history of the manufacturer's price increases for the drug since approval • current list price • total expenditures of the manufacturers on materials and manufacturing; and acquiring patents and licensing on such drug • percentage of the total expenditures of the manufacturers on research and development • total revenue and net profit generated from the drug for each calendar year since approval, and • total costs associated with marketing and advertising for the drug.	• a justification for, and description of, each manufacturer's price increase • total expenditures of the manufacturers on materials and manufacturing; and acquiring patents and licensing on such drug • percentage of the total expenditures of the manufacturers on research and development • total revenue and net profit generated from the drug for each calendar year since approval, and • total costs associated with marketing and advertising for the drug.	• the WAC of the drug in the U.S. and in Canada, France, Germany, Japan, and the United Kingdom for the entire year • cumulative global revenues generated by the drug • annual net sales revenue generated by the drug in the U.S. and in Canada, France, Germany, Japan, and the United Kingdom • total itemized expenditures on domestic and foreign drug research and development related to the drug • total expenditures on domestic and foreign marketing and advertising related to the drug • investments in human clinical trials related to the drug, by each trial and each year • the estimated size of the affected patient population • additional information the manufacturer chooses to provide related to drug pricing decisions, such as information related to the methodology used to set the price of the drug, and	

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				• additional information the Secretary deems necessary. Any manufacturer that fails to report such information will face a civil monetary penalty equal to an amount which is not less than 0.5 percent of the gross revenue of sales and not greater than 1 percent of the gross revenue of sales.	