THE COUNCIL
The Council of Insurance Agents & Brokers

Steptoe

Updated June 14, 2022

117th Congress Federal Drug Pricing Legislation

INTRODUCTION

Below you will find brief summaries of active federal legislation focused on prescription drug pricing and transparency. All legislation has been introduced, with no further action taken unless otherwise noted. The document is divided into the following sections:

- **Single-issue Legislation –** Covers proposals that singularly focus on one of the following drug pricing issue areas: price transparency, importation, price gauging, and PBM reforms
- **Multi-issue Legislation** – Covers proposals that focus on various drug pricing issue areas, including as part of broader health reform efforts
- **Miscellaneous** – Covers proposals that focus on drug pricing topics not directly covered by the four previously listed issue areas

QUICK LINKS

NEWLY INCLUDED UPDATES

- March 8: Rep. Cathy McMorris Rodgers (R-WA) introduced the "Accelerating Access for Patients Act of 2022" (H.R.6996) which would allow for accelerated approval of a product or drug for a serious or life-threatening condition.
- March 17: Rep. Mike Gallagher (R-WI) introduced the "Protecting our Pharmaceutical Supply Chain from China Act of 2022" (H.R.7121) which would ban the use of federal funds to purchase drugs that were manufactured in China.
- March 18: Rep. Alexandra Mooney (R-WV) introduced the "Make Medicine in America Again Act of 2022" (H.R.7166) which would amend the Internal Revenue Code of 1986 to provide for extended expensing of pharmaceutical manufacturing property in the United States.
- April 5: Rep. Brad Wenstrup (R-OH) introduced the "American Made Medicine Act of 2022" (H.R.7410)

- April 5: Sen. Tina Smith (D-MN) introduced the "American Made Pharmaceuticals Act of 2022" (H.R.7400)
- April 7: Rep. Carolyn Maloney (D-NY) introduced H.R.7473
- April 6: Sen. Raphael Warnock (D-GA) introduced "Capping Drug Costs for Seniors Act of 2022" (S.4011)

I. SINGLE-ISSUE LEGISLATION

Drug Pricing Transparency

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
The Reduced Costs and Continued Cures Act of 2021 (H.R. 5260) Rep. Scott Peters (D-CA)	Caps out-of-pocket costs on Medicare Part D prescription drugs for beneficiaries, allows Medicare to negotiate cost of non-exclusive Part B drugs and establishes reporting requirements for PBMs and manufacturers on drug costs and price concessions, among other things.	"Negotiation-eligible drugs" are single source drugs or biologicals for which: • The period of regulatory data protections or exclusivity has expired; • The period of any patents issued up to 1 year after FDA approval has expired. Manufacturers must submit justifications for any "applicable drug" as determined by the Secretary that: • Have a specified increase in wholesale acquisition cost; or • Is in top 50th percentile of net Medicare or Medicaid spending during any 12-month period and had a specified increase in wholesale acquisition cost; or • Had a launch price that exceeded out of pocket	*Manufacturers*. Requires manufacturers to explain year-over-year drug pricing increase. *PBMs and Issuers*. Requires additional reporting for issuers and PBMs offering group health insurance coverage. *HHS*. Requires HHS to notify manufacturers of each "negotiation-eligible drug" within 180 days of enactment and each "applicable drug" within 60 days of determination; also requires HHS publish specified drug discounts and other PBM provisions by 2025. *PDP and MA-PDs*. Requires prescription drug plans and MA-PD plans to report price concessions to pharmacies; also, must report to HHS potential fraud, waste, and abuse of Medicare Part D benefits.	**Beginning in 2025,** requires manufacturers to submit a justification summary to HHS for any significant year-over-year price increases (e.g., specified increases in wholesale acquisition costs), or any high launch prices for any "applicable drug", including: • Which factors have contributed to the increase in wholesale acquisition cost; and • The total expenditures of the manufacturers, including those spent on research and development. *PBMs and Issuers*. Requires PBMs and issuers to report the following information to plan sponsors at least every 6 months: • All manufacturer discounts, coupons, copayment assistance provided with respect to enrollees in the coverage; • A list of each drug dispensed during the reporting period (including number of enrollees and prescriptions filled for each drug, wholesale acquisition cost of each drug, out-of-pocket amounts spent by enrollees on the drug, and for drugs exceeding $10,000 in spending by the plan, a list of alternatives available and rationale for formulary placement); • Each therapeutic category or class of drugs dispensed (including spend per class, description of formulary tiers and utilization mechanisms employed for the class); • Total gross spending on drugs by the plan pre-rebates and other discounts;	If a manufacturer or PBM fails to submit the requested information, subjects them to a penalty of $10,000 per day for each day that the report is not submitted. Subjects manufactures to a civil monetary penalty of up to $10,000 for each day the reporting violation continues; and to a civil monetary penalty for knowingly reporting false information of up to $100,000 for each false item.	*Medicare Part D*. ***Beginning in 2022***, caps out-of-pocket costs for Medicare Part D at the following: • $1200 for individuals 300% or less of the Federal Poverty Level; • $1800 for individuals 300-400% of the Federal Poverty Level; and • $3100 for individuals above 400% of the Federal Poverty Level. Allows seniors with fixed incomes to pay out-of-pocket expenses with monthly installments. *Medicare Part B*. Allows HHS to negotiate drug prices with manufacturers for Part B products that no longer have exclusivity and for which there is no market competition. *Rebate*. Establishes a mandatory rebate for manufacturers of a single source or biological drug covered by Medicare Part B for

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
		threshold for Part D drugs	*GAO*. Requires GAO to submit a report to Congress on spending and the average sales price for applicable drugs under part B.	• Total amount the issuer or PBM expects to receive in rebates, fees, and other remuneration from manufacturers or other third parties; total net spending on drugs by the plan; and • Amounts paid directly or indirectly to brokers, consultants, or advisors, etc., who referred the plan to the PBM. *PBMs*. Amends PBM transparency requirements to include types of rebates, discounts, or price concessions that are bona fide service fees (e.g., distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)). *PDP and MA-PDs*. Requires sponsors offering a prescription drug plan or Medicare Advantage plan to report to the pharmacy any pharmacy price concession or incentive payment that occurs with respect to a pharmacy after payment for covered part D drugs at the point-of-sale.		prices that increase faster than inflation. *GAO*. Requires GAO study the impact of copayment coupons and other patient assistance programs for drug pricing under the Medicare and Medicaid programs. Incorporates other transparency requirements, including: • Requires the FTC to conduct a study/provide recommendation to Congress on the role of PBMs and assess potential anticompetitive practices in the drug supply chain; and • Codifies HHS final rule requiring drug manufacturers to disclose drug prices within direct-to-consumer advertisements.
Lower Costs, More Cures Act (H.R. 19) Rep. Cathy McMorris Rodgers (R-WA)	Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS	In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course	*Manufacturers*. Requires manufacturers of qualifying drugs to submit a report to HHS for each price increase that will result in an increase in the wholesale acquisition cost of a drug that is equal to: • 10% or more over a 12-month period; or	Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug*. Requires the report to include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer;	If a manufacturer fails to submit the requested information, subjects them to a penalty of $75,000 per day for each day that the report is not submitted.	*Publication of Manufacturer Data*. Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers the day the price increase of a qualifying drug is scheduled to go into effect.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
House Summary	prior to increasing the price of such drugs, among other things.	of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS); • Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and • Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	• 25% or more over a 36-month period. Requires such reports to be submitted to HHS at least 30 days before the planned effective date of the price increase. *HHS*. Requires HHS to submit an annual report to Congress that • Summarizes the information reported by the manufacturer; • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted; • Details the costs and expenditures incurred by HHS in carrying out manufacturer reporting requirements; and • Explains how HHS is improving consumer and provider information about drug value and price transparency.	• The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current wholesale acquisition cost; • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; and • The total marketing and advertising costs. *Manufacturers*. Requires the report to include: • The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period"); • All stock-based performance metrics used to determine executive compensation during the applicable period; • Any additional information the manufacturer chooses to provide related to its drug pricing decisions (e.g., expenditures on drug R&D, clinical trials of drugs that failed to receive FDA-approval, etc.); and • Any other information requested by HHS. Requires manufacturers of qualifying drugs to also submit reports to HHS if the estimated cost or spending per individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment.	Subjects a manufacturer who knowingly provides false information to a penalty of up to $75,000 for each piece of false information in the report.	*Rebates*. ***Beginning in 2021***, requires HHS to post the aggregate rebates, discounts, and other price concessions achieved by PBMs (e.g., generic dispensing rates) on the CMS website. Requires manufacturers of certain single-dose containers or single-use package drugs under Medicare Part B— excluding new drugs and drugs that require filtration— to provide refunds with respect to discarded amounts of such drugs. Incorporates other transparency requirements, including: • Requires the FTC to conduct a study/provide recommendation to Congress on the role of PBMs and assess potential anticompetitive practices in the drug supply chain; and • Allows certain individuals and entities (e.g., oversight agencies, researchers, private and public healthcare payers, etc.) to request prescription drug marketing sample information from HHS.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) Rep. Frank Pallone (D-NJ)	Establishes the Fair Price Negotiation Program ("Program"), limits price hikes for Medicare Part B and D covered drugs, and caps out-of-pocket costs for Medicare Part D enrollees, among other things	All prescription drugs marketed in the U.S. In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS); • Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and • Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	*Manufacturers*. Requires manufacturers to report to HHS drug price information for the Program. Requires manufacturers to submit to HHS certain drug pricing information for drugs furnished or dispensed to beneficiaries or participants of group health plans and health insurance offered in the group market. *HHS*. Requires HHS to submit an annual report to Congress that • Summarizes the information reported by the manufacturer; and • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. Requires HHS identify and publish a list of 250 negotiation-eligible drugs (e.g., insulin, Medicare Part D drugs, and the top 125 drugs with greatest net spending in the U.S. during the most recent plan year).	*Manufacturers*. Requires manufacturers of qualifying drugs to submit reports to HHS within 30 days of a price increase that will result in an increase in the wholesale acquisition cost that is equal to: • 10% or more over a 12-month period; or • 25% or more over a 36-month period. Requires manufacturers of qualifying drugs to also submit reports to HHS: • If the estimated price of the qualifying drug or spending per user of such drug is at least $26,000 beginning on or after January 1, 2024; or • There was an increase in the price of the qualifying drug that resulted in an increase in the wholesale acquisition cost that is equal to: – 10% or more within a 12-month period that begins and ends during the 5-year period preceding January 1, 2023; or – 25% or more within a 36-month period that begins and ends during the 5-year period preceding 2023 Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug*. Requires the report to include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer; • The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current wholesale acquisition cost;	*Manufacturers*. Subjects a manufacturer of a qualifying drug that fails to submit a required report to a penalty of $75,000 for each day that the report fails to be submitted; and no more than $100,00 for each item of knowingly submitted false information. If a manufacturers charges more than the maximum fair price, subjects manufacturers to a civil monetary penalty. If a manufacturer refuses to enter into negotiations after being selected by HHS, or if the manufacturer leaves the negotiation before	*Publication of Manufacturer Data*. Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers no later than the day the price increase of a qualifying drug is scheduled to go into effect; and requires HHS to post a list of each manufacturer reported qualifying drug price increase. *Manufacturers*. Establishes a mandatory rebate for manufacturers of all Medicare Part B and Part D drugs for prices that increase more than by inflation (e.g., requires manufacturer pay the price above inflation in a rebate to the Treasury Department). *Medicare Part D*. ***Beginning in 2024***, caps out-of-pocket costs at $2,000 for Medicare Part D enrollees and incorporates other provisions aimed at modernizing Medicare Part D, including: • Establishing a manufacturer discount program; and • Phasing out the coverage gap discount program to include three phases: deductible, initial coverage, and catastrophic.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
			Requires HHS negotiate drug pricing, for a minimum of 25 drugs, with manufacturers to establish a maximum fair price (e.g., not more than 120% of average international market price (including price averages of Australia, Canada, France, Japan, and U.K.). Requires HHS annually publish a list of the maximum fair prices for each negotiated drug. *DOL*. Imposes annual reporting obligations on DOL with respect to prescription drug prices of drugs furnished to beneficiaries of group health plans.	• The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; • The total marketing and advertising costs; • All stock-based performance metrics used by the manufacturer to determine executive compensation; and • Any other information requested by HHS. *Manufacturers*. Requires manufacturers in the negotiation to report to HHS the following information, among other things: • Research and developments costs; • Distribution of sales data and projected future revenue; • Unit costs of production and distribution; • Patent data on existing and pending exclusivity; and • Clinical trial data.	a maximum fair price is agreed to, subjects the manufacturer to an escalating excise tax levied on their drug sales during the period of noncompliance.	*DOL*. Requires DOL to report to Congress on rulemaking opportunities to develop: • An agreement process with manufacturers under which manufacturers would provide for inflation rebates being furnished to participants and beneficiaries of group health plans or with coverage offered in the group market); and • Potential models for enforcement mechanisms for such agreement process. In addition to reporting requirements, if the prices of negotiated drugs increase at a percentage higher than the CPI, requires DOL (if feasible) to promulgate regulations to establish an inflation rebate agreement process with manufacturers. Incorporates other provisions, including, among other things: • Appropriates $3 billion to establish and carry out the Fair Price Negotiation Program;

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
						• Reduces cost-sharing liability for certain low-income beneficiaries; and • Requires HHS promulgate regulations requiring each direct-to-consumer TV advertisement for a prescription drug include non-misleading information and list prices.
Lower Costs, More Cures Act (S. 2164) Sen. Mike Crapo (R-ID)	Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS prior to increasing the price of such drugs, among other things.	***Mirrors the FAIR Drug Pricing Act of 2019*** In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS);	***Mirrors the FAIR Drug Pricing Act of 2019*** *Manufacturers*. Requires manufacturers of qualifying drugs to submit a report to HHS for each price increase that will result in an increase in the wholesale acquisition cost of a drug that is equal to: • 10% or more over a 12-month period; or • 25% or more over a 36-month period. Requires such reports to be submitted to HHS at least 30 days before the planned effective date of the price increase. *HHS*. Requires HHS to submit an annual report to Congress that	***Mirrors the FAIR Drug Pricing Act of 2019*** Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug*. Requires the report to include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer; • The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current wholesale acquisition cost; • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; and	If a manufacturer fails to submit the requested information, subjects them to a penalty of $75,000 per day for each day that the report is not submitted. Subjects a manufacturer who knowingly provides false information to a penalty of up to $75,000 for each piece of false information in the report.	*Publication of Manufacturer Data*. Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers the day the price increase of a qualifying drug is scheduled to go into effect. *Rebates*. ***Beginning in 2022***, requires HHS to post the aggregate rebates, discounts, and other price concessions achieved by PBMs (e.g., generic dispensing rates) on the CMS website. ***Similar to the Public Disclosure of Drug Discounts Act and the C-THRU Act of 2019*** Requires manufacturers of certain single-dose containers or single-use package drugs under

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
		• Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and • Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	• Summarizes the information reported by the manufacturer; • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted; • Details the costs and expenditures incurred by HHS in carrying out manufacturer reporting requirements; and • Explains how HHS is improving consumer and provider information about drug value and price transparency.	• The total marketing and advertising costs. *Manufacturers*. Requires the report to include: • The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period"); • All stock-based performance metrics used to determine executive compensation during the applicable period; • Any additional information the manufacturer chooses to provide related to its drug pricing decisions (e.g., expenditures on drug R&D, clinical trials of drugs that failed to receive FDA-approval, etc.); and • Any other information requested by HHS. Requires manufacturers of qualifying drugs to also submit reports to HHS if the estimated cost or spending per individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment.		Medicare Part B— excluding new drugs and drugs that require filtration— to provide refunds with respect to discarded amounts of such drugs. Incorporates other transparency requirements, including: • Requires the FTC to conduct a study/provide recommendation to Congress on the role of PBMs and assess potential anticompetitive practices in the drug supply chain; • Allows certain individuals and entities (e.g., oversight agencies, researchers, private and public healthcare payers, etc.) to request prescription drug marketing sample information from HHS; • Requires PDP sponsors to include real-time benefit information under the Medicare program; and • Codifies HHS final rule requiring drug manufacturers to disclose drug prices within direct-to-consumer advertisements. • ***Mirrors the Drug-price Transparency in Communications (DTC) Act***

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
						FDA Reform. Implements a series of FDA reforms, including provisions that: • ***Mirror the Biologic Patent Transparency Act***; • ***Mirror the Orange Book Transparency Act***; • ***Mirror the Ensuring Timely Access to Generics Act***; • ***Mirror the Protecting Access to Biosimilars Act***; • ***Mirror the Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019*** • ***Mirror the Ensuring Innovation Act***; and • Permits FDA to expedite approval for a biosimilar or generic drug.

Prescription Drug Importation

Legislation	*Overview*	*Provisions*	*Definitions*	*Reporting Requirements*
American Made Pharmaceuticals Act of 2022 (H.R.7400) Rep. Angie Craig (D-MN) **American Made Pharmaceuticals Act of 2022** (S.3991) Sen. Tina Smith (D-MN)	*Directs the Secretary of Health and Human Services to conduct a demonstration program to test providing preferential treatment under the Medicare, Medicaid, and CHIP programs for certain drugs and biologicals manufactured in the United States.*	*The Secretary will conduct a test under which U.S. manufactured drugs are given preference compared to drugs that are not U.S. manufactured drugs through the use of applicable tools.*	*Applicable drug: An approved or licensed drug, biological product, or critical drug.* *Applicable tools: The term "applicable tools" refers to actions such as:* • *Preferential treatment on a formulary* • *Providing lower cost-sharing* • *Waiving rebate under the Medicaid program* • *Establish a Medicare Star Rating under Part D.* • *Providing bonus payments to providers of services and suppliers.*	*The Secretary must submit and annual report to Congress on activities under the program, together with recommendation for legislation and administrative action.*
American Made Medicine Act of 2022 (H.R.7410) Rep. Brad Wenstrup (R-OH)	*Creates employer tax credits for domestic medical and drug manufacturing expenses and for advanced medical manufacturing equipment.*	*Creates several different tax credits:* *Domestic Medical and Drug Manufacturing Credit: 10.5% or less of taxable income or qualified medical and drug manufacturing income.* *Qualifying Advanced Medical Manufacturing Equipment Credit: The credit amount is contingent on when the equipment was placed in service:* • *30% when placed in service before January 1, 2029.* • *20% when placed in service during 2029.*	*"Qualified medical and drug manufacturing income" means an amount equal to the excess of:* • *The taxpayer's domestic medical and drug manufacturing gross receipts for the taxable year, over* • *the sum of the cost of goods sold that are allocable to such receipts and* • *other expenses, losses, or deductions which are properly allocable to such receipts.* *"Qualifying Advanced Medical Manufacturing Equipment Credit" is property:*	*The Secretary retains the right to issue additional rules requiring or restricting the allocation of items and wages, and may issue additional rules as the Secretary deems appropriate.*

		• *10% when placed in service during 2030.* • *0% when placed in service after December 31, 2030.:* *Medical Manufacturing EPA Compliance Credit: The credit amount is contingent on when the qualifying medical manufacturing EPA compliance property was placed in service.* • *30% when placed in service before January 1, 2029* • *20% when placed in service during 2029* • *10% when placed in service during 2030* • *0% when placed in service after December 31, 2030*	• *Which is machinery or equipment that is designed and used to manufacture a drug, device, or biological product.* • *Which has been identified by the Secretary as machinery or equipment that incorporates novel technology or existing technology in an innovative way, and can improve medical product quality, address shortages or medicines, and speed time-to-market.* • *Which is placed in the service in the United States by the taxpayer.* • *With respect to which depreciation is allowable.* *"Qualifying medical manufacturing EPA compliance equipment" is property:* • *Which is used by the taxpayer in the trade or business of manufacturing a drug, device, biological product, or active pharmaceutical ingredient.* • *Which is used to meet emissions limits under the Clean Air Act or wastewater*	
Make Medicine in America Again Act of 2022 (H.R.7166) Rep. Alexander Mooney (R-WV)	*Amends the Internal Revenue Code of 1986 to provide for extended expensing of pharmaceutical manufacturing property in the United States.*	*Provides a pharmaceutical manufacturing credit of 50% of qualified production activity expenditures.*	*"Qualified production activity expenditures" means:* • *Wages paid (including health plan expenses) or incurred to an employee of the taxpayer for services performed by an employee for a qualified pharmaceutical manufacturing business in the United States (but only if the*	

			employee's principal place of employment is in the United States) • *Amounts paid or incurred for any tangible personal property used by a qualified pharmaceutical manufacturing business in the United States (but only if the primary use of such property is in the United States)* • *Any direct or indirect costs paid or incurred in the operating of a qualified pharmaceutical manufacturing business in the United States*	
Protecting our Pharmaceutical Supply Chain from China Act of 2022 (H.R.7121) Rep. Mike Gallagher (R-WI)	*Bans the use of federal funds to purchase drugs that were manufactured in China.*	*The Secretary will compile and maintain a list of all drugs approved for use in the US and make note of any active ingredients in those drugs that were either manufactured outside of the US or are determined by the Secretary to be critical to the health and safety of consumers in the US. The list will also provide information about each step of the supply chain of every drug before its importation into the US.* *The Secretary will also maintain a list of drugs that are produced in or have ingredients produced in China.*		*Beginning January 1, 2023, pharmacies will only be able to purchase drugs where 60% or more of the active pharmaceutical ingredients are not manufactured in China. On January 1, 2024, pharmacies will only be able to purchase drugs where 100% or more of the active pharmaceutical ingredients are not manufactured in China.*

Price Gouging

Legislation	Overview	
None		

PBM Reforms and Transparency

Legislation	Overview	Transparency Measures	Miscellaneous
Drug Price Transparency Act of 2021 (S. 1523) Sen. Mike Braun (R-IN)	Prohibits PBMs from receiving rebates unless certain transparency requirements are met.	Prohibits PBMs from receiving rebates/reductions in price from drug manufacturers unless: • The rebates/reductions in price are reflected at the point-of-sale (e.g., the pharmacy counter); and • Any other rebates/reductions in price are flat fee-based service fees that the manufacturer pays to the PBM for services related to the provision of PBM services to a health plan/insurer (i.e., requires fees to be transparent to the health plan or health insurance issuer).	
Improving Transparency to Lower Drug Costs Act of 2021 (H.R 3682) Rep. Abigail Spanberger (D-VA)	Requires PBMs to report their aggregate rebates, discounts, and other price concessions for prescription drugs to a public website.	***Beginning in 2022***, requires HHS to make certain information on PBMs publicly available on its website, including: • Price concessions and the amount of such negotiated rebates, discounts, direct and indirect remuneration fees, administrative fees, and price concessions that are passed through to plan sponsors.	

II. MULTI-ISSUE LEGISLATION

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
Affordable Medications Act (S. 1801) Sen. Tina Smith (D-MN) Senate Summary	***Similar to the Transparent Drug Pricing Act.*** Requires manufacturers of FDA-approved, prescription drugs to submit certain information in a single, annual report to HHS, including: • The total expenditures of the manufacturer on: – Domestic and foreign drug R&D; – Cost of goods sold (broken out by source and cost of each component and identifying specific costs that reflect internal transfers within the manufacturer's company); – Acquisition costs in total and per unit sold; and – Marketing and advertising for the promotion of the drug; • The gross revenue, net revenue, gross profit, and net profit to the manufacturer; • The total number of units of the prescription drug that were sold in interstate commerce; • Pricing information (e.g., wholesale acquisition cost, net average price realized	***Similar to the Affordable and Safe Prescription Drug Importation Act.*** Allows wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed/certified foreign sellers,[1] provided certain circumstances are met—after two years, authorizes importation from OECD countries that meet standards comparable to U.S. standards. Identifies such qualifying prescription	***Similar to the Stop Price Gouging Act.*** Requires manufacturers to submit quarterly reports to the HHS OIG containing: • The total number of units of each prescription, FDA-approved drug sold; • The gross revenues from sales of such drugs; and • Any additional information related to anticipated or increased input costs, or public health considerations that the manufacturer may want the HHS OIG to consider in its assessment.	*Manufacturers*. Subjects any manufacturer that fails to submit complete reports to a civil penalty of up to $200,000 for each day on which the violation continues. Subjects manufacturers that fail to submit the required quarter reports to a civil penalty equal to the product of: • An amount determined by the HHS OIG that is (1) not less than 0.5% of the gross revenues from sales of the drug for the calendar year; and (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; and • The number of days in the period between (1) the quarterly submission deadline and (2) the date on	*Rebating*. 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 plans. Excludes authorized generic drugs from calculations of average manufacturer price under the Medicaid drug rebate program. *Prescription Drug Cost Sharing*. Caps prescription drug cost sharing at $250 per month for individuals and $500 per month for families enrolled in QHPs and employer-based plans (applies for plan years beginning in 2021 and beyond). *Advertising*. Eliminates tax breaks for drug companies for expenses related to direct-to-consumer advertising. Incorporates other provisions, including: • The operation of, impact of, and costs associated with patient assistance programs. • Negotiating fair prices for Medicare prescription drugs. • Ensuring that market exclusivity periods for biologics do not exceed 7 years.

[1] To qualify as a certified foreign seller (i.e., be eligible for certification), the seller must: (1) be a foreign wholesale distributor or licensed foreign pharmacy located in Canada (or other country from which importation is later permitted); (2) be engaged in the distribution or dispensing of prescription drugs imported or offered for importation into the U.S.; (3) have been in existence for at least 5 years and have a purpose other than participation in the drug importation program; (4) if selling to an individual, do so only after receiving a valid prescription; (5) have processes to certify that the physical premises, data reporting procedures, and licenses are in compliance with all applicable laws and regulations in Canada (or other country from which importation is later permitted), and have implemented policies to monitor compliance; (6) conduct ongoing and comprehensive quality assurance programs, including blind testing; (7) agree that laboratories approved by FDA will be used to test product samples/determine samples' chemical authenticity; (8) agree to notify FDA, importers, and individuals of product recalls in Canada (and refrain from exporting such recalled products); (9) have a process for resolving grievances and be held accountable for violations of established rules; (10) not sell products to customers in the U.S. that the seller could not otherwise legally sell in Canada; and (11) meet any other criteria established by the FDA.

	by PBMs for drugs provided in the U.S., the net price of the drug charged to purchasers in each OECD country); • Certain information related to the receipt of patient assistance programs offered by the manufacturer; • Information on the usage of patient assistance offered by the manufacturer; • Any federal health benefits received by the manufacturer (e.g., tax credits, patent applications that benefited from a federal grant); • The percentage of R&D expenditures on: – Activities conducted by the manufacturer; – Activities funded by federal entities; – Activities conducted by other entities such as academic institutions or other drug manufacturers; • Executive compensation for the CEO, CFO, and the 3 other most highly compensated executive officers; • Any additional information the manufacturer chooses to provide related to drug pricing decisions; and • Any other information required by HHS. Requires HHS to collate the manufacturers' reports and submit them to Congress, along with an analysis of the reports containing a summary of the data, consideration of certain factors (e.g., trends on R&D costs, federal benefits, etc.); and the relationship between those factors and prescription drug prices. Requires the reports and the HHS analysis to be publicly available on the HHS website.	drugs to include prescription drugs that: • Are approved for use in patients and marketed in Canada (or, ultimately, in another country from which importation is later permitted); • Are manufactured in a registered facility that is in compliance with the FDA's good manufacturing practices regulations; • Have the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; or is biosimilar to an approved biological product and has the same product of administration and strength as the approved biological product); and • Are labeled in accordance with the laws of Canada (or, ultimately, in another country from which importation is later	Requires the HHS OIG to annually complete an assessment of the reports received that: • Identifies each price spike related to a drug; • Determines the price spike percentage and price spike revenue; • Determines the accuracy of the information submitted by the manufacturer regarding increased input costs; and • Assesses the rationale of the manufacturer's price spike. Requires the HHS OIG to annually submit a report to the IRS (and later make it publicly available) that includes: • The information received from manufacturers; • The price spikes identified; • The price spike revenue determinations; • The average and median price of the	which the HHS OIG receives the late report. *Prescription Drug Importation Prohibitions.* Classifies certain acts by manufacturers (e.g., engaging in actions to restrict, prohibit, or delay the importation of a prescription drug) as unfair and discriminatory acts and practices. Authorizes HHS to suspend or temporarily suspend importation of a product (or suspend all products from a certified foreign seller or importer) if there is an importation involving counterfeit drugs, drugs that have been recalled/withdrawn, or drugs otherwise not permitted for importation. Imposes penalties of at most 10 years of imprisonment or a fine of at most $250,000 on online pharmacies that either: • Sell online with the intent to defraud, mislead, or with reckless disregard for public safety, an adulterated or counterfeit drug; or • Dispense a drug to an individual in the U.S. who does not possess a valid prescription.	• Establishing a "prize fund" for new and more effective treatments of bacterial infections. • Creating (and funding) the Center for Clinic Research within NIH to conduct all stages of clinical trials on drugs that may address an existing/emerging health need. • Rewarding innovative drug development by reducing certain exclusivity periods awarded by the FDA to brand name drugs. • Terminating market exclusivity periods on products found in violation of criminal or civil law. • Prohibiting and disincentivizing anticompetitive agreements between brand name and generic drug manufacturers to preserve access to affordable generics. • Promoting/sustaining competitive generic markets

	Offers an extension for the initial report from small businesses (i.e., those with fewer than 500 employees). Requires manufacturers to disclose to practitioners the wholesale acquisition cost for a 30-day supply of the drug whenever the manufacturer communicates with a practitioner about a drug, including through promotional, education, or marketing communications, meetings, paid events, etc.	permitted) and the requirements promulgated by HHS (including labeling in English). Does not include: • Controlled substances; • Anesthetic drugs inhaled during surgery; or • Compounded drugs. Requires importers to submit biannual reports to HHS concerning any drug importation transactions. Requires HHS to report to Congress on the importation of drugs into the U.S. Requires GAO to submit a report to Congress on the implementation of the drug importation program, including a review of drug safety, cost savings, and expenses to consumers in the U.S. and trans-shipment and importation tracing	drug for each month during the most recent calendar year; and • The determinations and assessments made. Requires the IRS to notify manufacturers regarding any drug that has been determined to have been subject to a price spike. Subjects manufacturers to a graduated excise tax that depends on the size of the price increase, if it is determined that the manufacturer increased the price of the drug beyond medical inflation over a one-year period or cumulatively.[2]		

[2] Prior to enforcing the tax, the HHS OIG and the FTC would work with manufacturers 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.

		processes.			

III. Miscellaneous

Legislation	Issue Area	Overview
No Bill Text H.R.7473() ***Rep. Carolyn Maloney (D-NY)***		*This bill would prohibit pharmaceutical manufacturers from interfering with therapeutically equivalent or interchangeable substitution decisions by health care providers to limit competition from a generic drug or biosimilar biological product, and for other purposes.*
Lowering Medicare Premiums and Prescription Drug Costs Act (H.R. 5099) Rep. Brad Schneider (D-IL)	*Medicare Part D*	Creates a Medicare Cost Assistance Program to help cover the cost of premiums for eligible individuals.
Seniors Prescription Drug Relief Act (S. 2327) Sen. Bill Cassidy (R-LA)	*Medicare Part D*	Limits out-of-pocket costs to $3,100 on Medicare Part D prescription drugs for beneficiaries and expands the current Medicare coverage gap discount program, among other things.
Capping Drug Costs for Seniors Act of 2022 (S.4011) *Sen. Raphael Warnock (D-GA)*	*Medicare Part D*	*Caps beneficiary liability under Medicare Part D at $2,000 beginning 2025 and increasing by a specified percentage thereafter; also reduces the reinsurance payment amount from 80% to 20% for applicable drugs*

Legislation	Issue Area	Overview
Drug Price Transparency in Medicaid Act of 2021 (H.R. 6101) Rep. Buddy Carter (R-GA)	*Limited PBM Transparency Requirements*	Requires contracts between states and PBMs, managed care entities, or other specified entities for coverage of outpatient drugs to require that payment for such drugs and related administrative services be based on a pass-through pricing model under which payments for the drug are limited to ingredient costs and professional dispensing fees and further requires: • PBMs and entities to pass through such fees and costs to the dispensing pharmacy or provider; • Payment for administrative services be limited to a reasonable administrative fee that covers the reasonable cost of providing such services; • The PBM or entity to make available to the state or HHS, upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred or received (e.g., ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoices fees, discounts, or other related adjustments); and • HHS to conduct a survey of retail community drug prices and report to Congress on specialty drug coverage and reimbursement. Prohibits the distribution of federal matching payments under Medicaid if such entity or PBM engages in spread pricing.
Capping Prescription Costs Act of 2021 (H.R. 6228/S. 3339) Rep. Kathy Manning (D-NC)/Sen. Raphael Warnock (D-GA)	*Limited Transparency Requirements*	Caps prescription drug cost sharing at $250 per month for individuals and $500 per month for families enrolled in Qualified Health Plans and employer-based plans (applies for plan years beginning in 2023 and beyond).
Drug-price Transparency in Communications (DTC) Act (S. 2304) Sen. Richard Durbin (D-IL)	*Limited Transparency Requirements*	Codifies the HHS final rule requiring drug manufacturers to disclose drug prices within direct-to-consumer advertisements.
Expanding Access to Low-Cost Generics Act of 2021 (S. 2910) Sen. Tina Smith (D-MN)	*Market Competition*	Allows certain generic drug manufacturers to share the 180-day market exclusivity period with manufacturers of the corresponding brand-name drug.
Increasing Access to Biosimilars Act of 2021 (S. 1427)	*Market Competition*	Directs HHS to establish a shared savings demonstration project to increase access to biosimilars in the Medicare program.

Legislation	Issue Area	Overview
Sen. John Cornyn (R-TX)		
Stop STALLING Act (S.1425) Sen. Amy Klobuchar (D-MN)	*Market Competition*	Authorizes the FTC to enforce civil penalties on those who submit "sham" drug petitions (i.e., baseless attempts to interfere with the business of a competitor using the FDA's petition process) for anticompetitive purposes.
Preserve Access to Affordable Generics and Biosimilars Act (S. 1428) Sen. Amy Klobuchar (D-MN)	*Market Competition*	Prohibits drug and biologics manufacturers from engaging in "pay-for-delay" deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market); "reverse-payment" settlement (i.e., agreements in which branded companies pay generic companies not to compete as part of a patent settlement); grants the FTC authority to initiate enforcement proceedings against parties engaging in such agreements, among other things.
Accelerating Access for Patients Act of 2022 *(H.R.6996)* *Rep. Cathy McMorris Rodgers (R-WA*	*Market Competition*	*This bill would allow for accelerated approval of a product or drug for a serious or life-threatening condition.*