THE COUNCIL
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116th Congress Federal Drug Pricing Legislation

Newly Included Legislative Updates

- July 22: Sen. Rand Paul (R-KY) introduced the Legalizing Drug Discounts for Seniors Act of 2020 (S. 4274), which eliminates the prohibition of certain discounts for drugs covered by Medicare Part D covered.

I. Single-Issue Legislation (116th Congress) (*all legislation has been introduced; no further action has been taken, unless noted)*

Drug Pricing Transparency
Prescription Drug Importation
Price Gouging
PBM Reforms and Transparency
Multi-Issue Legislation
Miscellaneous

Drug Pricing Transparency Legislation

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019 (S. 474) Sen. Ron Wyden (D-OR)	Requires manufacturers of certain drugs to publicly report/justify significant price increases and other attendant costs to HHS.	Imposes reporting obligations on manufacturers of FDA-approved, prescription, "applicable drugs"—as determined by HHS—that: • Have a wholesale acquisition cost of at least $10 per dose; and • Had an increase in the wholesale acquisition cost of the drug of at least 300% in the past 5 years or 100% over 1 year; or • Are in the top 50th percentile of net spending in Medicare or Medicaid in the past 5 years; and • Had an increased wholesale acquisition cost of at least 50% in the past 5 years or 15% over 1 year. Allows HHS to identify a drug with a price increase within a *de minimis* range of the percentages listed.	*HHS.* Requires HHS to notify the manufacturer within 60 days of its determination that a drug is considered an "applicable drug" (and therefore is subject to reporting requirements). *Manufacturers.* Requires manufacturers to submit a justification of the applicable drug's price increase within 180 days of HHS' notification that the drug qualified as an applicable drug. *Exceptions*. Does not require a manufacturer to submit a justification if a manufacturer reduces the wholesale acquisition cost of the drug so that it no longer qualifies as an applicable drug for at least a 6-month period.	Requires manufacturers' reports to include all relevant information/supporting documentation necessary to justify the increase, which may include: • The factors that contributed to the increase; • An explanation of how each factor contributed to the increase; • Total expenditures of the manufacturer (i.e., on the drug's materials and manufacturing, acquiring patents and licensing for each drug, etc.); • The percentage of the manufacturer's total expenditures for R&D that were derived from federal funds; • The manufacturer's total R&D expenditures; • The total revenue and net profit generated from the applicable drug for each calendar year since its approval; • Total marketing and advertising costs; and • Additional information specific to the manufacturer of the applicable drug (e.g., total revenue/net profit of the manufacturer for the period of the increase, metrics used to determine executive compensation, any additional information related to the drug pricing decisions of the manufacturer, etc.).	Subjects a manufacturer of an applicable drug that fails to submit a report for the drug to a penalty of $10,000 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 $100,000 for each piece of false information in the report.	*Publication of Manufacturer Data.* Requires HHS to post the justification and an easily-understandable summary of the justification publicly on the CMS website within 30 days of receiving the justification.

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Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019 (H.R. 2069) Rep. Steven Horsford (D-NV) *May 21 – A hearing was held on the legislation.*	Requires manufacturers to publicly disclose/justify "SPIKE" increases in drug prices.	***Beginning in 2021***, requires manufacturers to justify (via report and summary) if there is a triggered "SPIKE" increase in a covered outpatient drug for which: • There is a 10% (or $10,000) increase in the wholesale acquisition cost of the drug over the course of a calendar year within the last five years (i.e., a so-called "look back" period); • There is a 25% (or $25,000) increase in the wholesale acquisition cost of the drug over three years; or • The estimated cost or spending per individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment. *Exclusions*. Does not apply to "low cost" drugs with a wholesale acquisition cost of less than $10 per unit or less than $100 in average estimated expenditures per individual per year.	*HHS.* Requires HHS to notify the manufacturer within 60 days of its determination that there is a triggering SPIKE increase with respect to a drug. *Manufacturers.* Requires manufacturers to submit a justification and associated summary of the triggered SPIKE increase within 90 days of HHS' notification. *Exceptions.* Does not require a justification for a triggered "SPIKE" increase if a justification has already been made by the manufacturer within the applicable look-back period.	Requires manufacturers' reports to include all relevant information/supporting documentation necessary to justify the increase, which must include: • The factors that contributed to the increase; and • An explanation of how each factor contributed to the increase. Requires reports to further include—as applicable—the following information/supporting documentation: • Total expenditures of the manufacturer (i.e., on the drug's materials and manufacturing, acquiring patents and licensing for each drug, etc.); • The percentage of the manufacturer's total expenditures for R&D that were derived from federal funds; • The manufacturer's total R&D expenditures; • The total revenue and net profit generated from the applicable drug for each calendar year since its approval; • Total marketing and advertising costs; • Additional information specific to the manufacturer of the applicable drug (e.g., total revenue/net profit of the manufacturer for the period of the increase, metrics used to determine executive compensation, additional expenditure information, any additional information related to the drug pricing decisions of the manufacturer, etc.); and • Any other relevant information/supporting documentation necessary to justify the triggering SPIKE increase or as specified by HHS. Requires such justifications to be certified by the manufacturer's CEO, CFO, or other individual who has delegated authority to sign for/reports directly to the CEO or CFO.	*Manufacturers.* If a manufacturer fails to submit a required justification, subjects them to a penalty of $10,000 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 $100,000 for each piece of false information in the report.	*Publication of Manufacturer Data.* Requires HHS to post the easily-understandable summary of the justification publicly on the CMS website within 30 days of receiving the justification. Contains other provisions governing: • Public posting by HHS of other metrics that could increase the number of drugs for which a triggered SPIKE increase would occur, among other things.

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Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act (H.R. 2113) Rep. Richard Neal (D-MA) House Summary *April 9 – Approved unanimously by the Ways and Means Committee, as amended.*	Requires manufacturers to publicly disclose/justify "SPIKE" increases in drug prices, among other things.	***Similar to the House version of the SPIKE Act of 2019.*** ***Beginning in 2021***, requires manufacturers to justify (via report and summary) if there is a triggered "SPIKE" increase in a covered outpatient drug for which: • There is at least a 10% (or $10,000) cumulative increase in the wholesale acquisition cost of the drug over the course of a calendar year within the last five years (i.e., a so-called "look back" period); • There is at least a 25% (or $25,000) cumulative increase in the wholesale acquisition cost of the drug over three years; or • The estimated cost or spending per individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment.	***Similar to the House version of the SPIKE Act of 2019.*** *HHS.* Requires HHS to notify the manufacturer within 60 days of its determination that there is a triggering SPIKE increase with respect to a drug. *Manufacturers.* Requires manufacturers to submit a justification and associated summary of the triggered SPIKE increase within 90 days of HHS' notification. *Exceptions.* Does not require a justification for a triggered "SPIKE" increase if: • A justification has already been made by the manufacturer within the applicable look-back period; or • A drug increases by an amount greater than the dollar threshold but the amount is not higher than the drug price if adjusted/indexed for inflation.	***Similar to the House version of the SPIKE Act of 2019.*** Requires manufacturers' reports to include all relevant information/supporting documentation necessary to justify the increase, which must include: • The factors that contributed to the increase; and • An explanation of how each factor contributed to the increase. Requires reports to further include—as applicable—the following information/supporting documentation: • Total expenditures of the manufacturer (i.e., on the drug's materials and manufacturing, acquiring patents and licensing for each drug, etc.); • The percentage of the manufacturer's total expenditures for R&D that were derived from federal funds; • The manufacturer's total R&D expenditures; • The total revenue and net profit generated from the applicable drug for each calendar year since its approval; • Total marketing and advertising costs; • Additional information specific to the manufacturer of the applicable drug (e.g., total revenue/net profit of the manufacturer for the period of the increase, metrics used to determine executive compensation, additional expenditure information, any additional information related to the drug pricing decisions of the manufacturer, etc.); and • Any other relevant information/supporting documentation necessary to justify the triggering SPIKE increase or as specified by HHS.	***Similar to the House version of the SPIKE Act of 2019.*** *Manufacturers.* If a manufacturer fails to submit a required justification, subjects them to a penalty of $10,000 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 $100,000 for each piece of false information in the report.	*Publication of Manufacturer Data.* Requires HHS to post the easily-understandable summary of the justification publicly on the CMS website within 30 days of receiving the justification. ***Similar to the House version of the SPIKE Act of 2019.*** *Rebates.* ***Beginning in 2020***, 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.*** Contains other provisions governing: • Public posting by HHS of other metrics that could increase the number of drugs for which a triggered SPIKE increase would occur, among other things. ***Similar to the House version of the SPIKE Act of 2019.*** • Reporting by manufacturers

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		Exclusions. Does not apply to "low cost" drugs with a wholesale acquisition cost of less than $10 per unit or less than $100 in average estimated expenditures per individual per year.		Requires such justifications to be certified by the manufacturer's CEO, CFO, or other individual who has delegated authority to sign for/reports directly to the CEO or CFO.		of certain drugs, devices, biologics, or medical supplies on the total aggregate value/quantity of samples provided to certain health care providers annually, among other things. ***Similar to the Sunshine for Samples Act of 2019***. • An HHS report to Congress on inpatient hospital drug trends, shortages, and costs, among other things. • Reporting by certain manufacturers and HHS on drug pricing under Medicare Part B (and associated penalties for failure to report). ***Similar to the Reporting Accurate Drug Prices Act of 2019***.
Drug Pricing Transparency Act (H. R. 2087) Rep. Lloyd Doggett (D-TX) *May 21 – A hearing was held on the legislation.*	Requires manufacturers of certain drugs *without* a Medicare rebate agreement to report drug pricing information to HHS.	***Beginning in 2020***, requires manufacturers of certain drugs covered by Medicare Part B and for others (e.g., drugs for end stage renal disease patients) *without* a Medicare rebate agreement to report drug pricing information to HHS.	*Manufacturers*. Requires all manufacturers of certain drugs under the Medicare program that do not have a rebate agreement in effect to report drug pricing information to HHS. *HHS*. Requires HHS to submit a report to Congress regarding the accuracy of average sales price	*Manufacturers*. Requires manufacturers of certain drugs without a Medicare rebate agreement to report the following information: • Average sales price and the total number of units; • Wholesale acquisition cost; • Information on those sales that were made at a nominal price or the total number of units of such drug/biological sold by the manufacturer in such quarter, and; • Total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug.	*Manufacturers*. Subjects wholesalers, manufacturers, or direct sellers who refuse to comply with HHS' request for information to a $100,000 civil monetary penalty.	*Verification*. Authorizes HHS to survey wholesalers and manufacturers that directly distribute a manufacturer's drugs to verify prices and average sales prices (including wholesale acquisition cost).

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			information submitted by manufacturers.		If a manufacturer fails to submit the requested information, subjects them to a penalty of $25,000 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 $100,000 for each piece of false information in the report.	
Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019 (S.1391/H.R. 2296) Sen. Tammy Baldwin (D-WI)/Rep. Jan	Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS prior to increasing the price of such	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	*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	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 list price;	Subjects a manufacturer of a qualifying drug that fails to submit a required report to a penalty of $100,000 for each day that the report fails to be submitted.	*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 30 days after the report has been received.

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Schakowsky (D-IL) *July 17 – House version was approved by the House Energy and Commerce Committee, as amended, by voice vote.* *July 11 – House version was approved by the House Energy and Commerce Subcommittee on Health, as amended, by voice vote.* *May 21 – A hearing was held on the house version.*	drugs.	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.	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; and • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted.	• 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.		
Prescription Drug Price Reporting Act (S. 1664/H.R. 5239) Sen. Rick Scott	Requires drug manufacturers annually report to HHS certain drug pricing information.	All prescription drugs marketed in the U.S.	*Manufacturers.* Requires manufacturers of all drugs marketed in the U.S. to annually report to HHS. Requires manufacturers of newly marketed drugs to report the drug code to HHS	*Manufacturers.* Requires the annual report to include: • Each applicable National Drug Code (or J-Code), brand name, generic/chemical name and therapeutic class, as applicable; • Current and annual average wholesale acquisition cost per 30-day supply or typical course of treatment; • Average net price per 30-day supply or typical course of treatment;		*Preemption.* Prohibits states from establishing or continuing to give effect to any law requiring the manufacturer to report or make public prescription drug pricing information.

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(R-FL)/Rep. David Joyce (R-OH)			within 60 days and provide the annual reporting information within the 30 days of the first annual reporting date. Requires manufacturers to report any increase or decrease in the wholesale acquisition cost of a prescription drug no later than 30 days prior to the date in which price changes take effect. *HHS.* Requires HHS to establish a publicly available website to post the required annual reporting information no later than 30 days after the information is submitted; and to post the required price change information no later than 5 business days after the information is submitted.	• Total rebates and other payments to health insurance plans or PBMs per 30-day supply or typical course of treatment *Price Changes*. Requires the report on changes in price to include the above information and the financial and non-financial factors the manufacturer took into consideration when making the price change, including any improvements to the drug.		*Consumer Notification.* Permits consumers to subscribe to price change notifications for: • All drugs; • A particular drug; • A particular therapeutic class of drugs; and • A specified amount or limit to price changes.

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Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) Rep. Frank Pallone (D-NJ) ***Speaker Pelosi's Drug Plan*** *October 22 – Approved, by a party line vote, as amended, by the House Ways and Means Committee.* *October 17 – Approved, as amended, by a vote of 30-2, by the House Energy and Commerce Committee.* *September 25 – A hearing was held on the legislation.*	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. ***Similar to 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); • 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	*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).	***Similar to the FAIR Drug Pricing Act of 2019*** *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, 2021; 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, 2021; or – 25% or more within a 36-month period that begins and ends during the 5-year period preceding 2021 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	*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 2022***, 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.

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December 12 – Approved by the House, as amended, by a vote of 230-192.		Medicare or Medicaid programs.	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 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; • 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; • Reduces cost-sharing liability for certain low-income beneficiaries; and

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						• 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. 3129/H.R. 19) Sen. Mike Crapo (R-ID)/Rep. Greg Walden (R-OR) House Summary Senate Summary	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); • Are not defined as a	***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 • The total marketing and advertising costs.	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 2020***, 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 Medicare Part B— excluding

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		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.	*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.		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***

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						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 Affordability and Access Act (S. 3166) Sen. Cory Booker (D-NJ)	Establishes the Bureau of Prescription Drug Affordability and Access ("Bureau"), which reviews prescription drug prices to ensure that the	All FDA-approved prescription drugs (whether approved before or after enactment).	*Manufacturers*. Requires all manufacturers report certain patent, expenditure, and pricing information to the Bureau within 180 days of enactment. Requires manufacturers of newly-approved drug applications to report certain pricing information to the	*Manufacturers*. Requires all manufacturers report the following information on their FDA-approved prescription drugs: • The name of the drug and a description of its approved indications; • The number of individuals the drug is clinically indicated for in the U.S. and globally; • A list of patents that use or are a form of the drug; • A list of granted exclusivities for the drug; • The date the drug was approved by FDA;	*Manufacturers*. If a manufacturer fails to lower the wholesale acquisition cost of a drug within 30 days of receiving notice, permits FDA to authorize certain manufacturers to	*"Appropriate" Pricing*. Grants the Bureau the authority to—at any time—review the wholesale acquisition cost of a prescription drug to determine if its price is appropriate depending on the size of the affected patient population, the therapeutic benefits of the prescription drug to patients, the impact of the price on access to the drug, etc.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
	wholesale acquisition cost of each drug is appropriate, among other things.		Bureau at least 45 days before selling the drug. If a manufacturer plans to increase the wholesale acquisition cost by more than the Consumer Price Index percentage increase that year, requires the manufacturer to report to the Bureau certain pricing information no later than 60 days before the price increase takes effect. *Bureau.* Requires the Bureau to annually report to Congress on: • The activities of the Bureau; • Recommendations for legislative and administrative action; • Copies of the reports submitted by drug manufacturers; and • Other items the Bureau deems appropriate.	• Total expenditures on domestic/foreign development, acquisition of drug components/packaging, and other acquisitions related to the drug (e.g., buying patents and licensing); • Total expenditures on the cost of manufacturing the drug, marketing/promoting the drug, patient assistance copay programs, etc.; • Gross revenue, net revenue, gross profit, and net profit with respect to the drug; • Total number of units sold in interstate commerce; • Pricing information with respect to the sale of the drug (e.g., the current wholesale acquisition cost, the net average price realized by PBMs after any rebates, the list price in each applicable reference country (i.e., Canada, the U.K., Germany, France, and Japan), etc.); • Any federal benefits and amounts received by the manufacturer for the drug (e.g., tax benefits, Federal grants, patent extensions, waivers of fees, etc.); • The percentage of research and development expenditures that were derived from federal funds; • Executive compensation for CEO, CFO, and the three other most compensated executive officers; and • Any other information as requested by the Bureau. Requires manufacturers of newly approved drugs report certain pricing information to the Bureau no later than 45 days before selling the drug, including most of the reporting information listed above and the planned/estimated: • Introductory wholesale acquisition cost; and • Certain pricing information with respect to the drug's sale (e.g., list price in applicable reference countries; net price, after accounting for discounts, rebates, or other financial considerations in each applicable reference country; and estimated annual profit revenue).	use such manufacturer's patent, clinical, trail data, or other government-granted exclusivity to sale such drug. If a manufacturer fails to comply with the interim appropriate price set by the Bureau, subjects manufacturers to a civil monetary penalty of no less than an amount equal to 150% of all revenues received by the manufacturer that are in excess of the expected revenues at the interim appropriate price.	If the Bureau determines that the wholesale acquisition cost of a prescription drug is not appropriate, requires the Bureau notify and direct the manufacturer to lower such cost. Incorporates various other provisions authorizing the Bureau to review and control drug pricing, including, among other things: • Authorizing the Bureau to increase its established revenue benchmark; • Requires the Bureau establish a process to distribute funds to patients that paid a wholesale acquisition cost that was deemed inappropriate by the Bureau; and • Requires the Bureau establish an interim appropriate price (e.g., lower than the median list price) and direct manufacturers to set a wholesale acquisition cost at a level that does not exceed the interim price.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
				If a manufacturer plans to increase the wholesale acquisition cost of a drug by more than the percentage of the Consumer Price Index that year, requires manufacturers report the certain information to the Bureau no later than 60 days before the price increase takes effect, including: • All reporting information listed above; • The date and amount of the planned increase in the wholesale acquisition cost; • A justification of the planned increase in wholesale acquisition cost; and • Any other information as requested by the Bureau. If a manufacturer anticipates the global revenue of a prescription drug surpassing a certain revenue benchmark (i.e., $5 billion globally), requires the manufacturer to report the above pricing information to the Bureau. *Bureau.* Requires the Bureau annually report the following information to Congress: • The total estimated prescription drug savings achieved by the Bureau since the most recent report; • The disaggregated savings achieved since the most recent report by each therapeutic class of prescription drug; • A summary of the required reporting information submitted by manufacturers; • An analysis of the impact of the Bureau's work on patient affordability and access to prescription drugs; • Recommendations for legislation and administrative action; and • A copy of each report submitted by drug manufacturers.		

Prescription Drug Importation Legislation

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
Affordable and Safe Prescription Drug Importation Act (S. 97/H.R. 447) Sen. Bernie Sanders (I-VT)/Rep. Elijah Cummings (D-MD) Senate Summary	Requires HHS to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from "certified foreign sellers" (possibly later expanded to include sellers in OECD member countries).	Allows the importation of drugs from Canada, provided they: • Are approved for use in patients and marketed in Canada; • Are manufactured in an FDA-registered facility; • Have the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; or is biosimilar (identical in makeup to a licensed drug) and has the same method of administration, and strength as the licensed drug; • Is labeled in accordance with the laws of Canada (or another country from which importation is permitted); and • Is labeled in English (and in accordance with all other requirements promulgated by HHS). Does not include:	*Certified Foreign Sellers*. Requires importers (or individuals who import prescription drugs into the U.S.) to purchase qualifying prescription drugs from a "certified foreign seller" who (1) is certified by HHS,[1] (2) has paid the registration fee, and (3) sells only qualifying prescription drugs. *Individuals*. Allows individuals to import a qualifying prescription drug from Canada (or another country) if it is: • Dispensed (including through an online pharmacy) by a certified foreign seller that is a licensed foreign pharmacy; • Purchased for personal use by the individual (i.e., not for resale) in quantities that	*Importers.* Requires importers to submit biannual reports to HHS on each qualifying prescription drug imported into the U.S. that contains: • The facility identifier of the drug's registered manufacturer; • Transaction information (e.g., the name, strength, and dosage; the number of containers and container size; the lot number; the date of transaction and shipment, etc.) as required by HHS; and • The price paid by the importer for the drug. *HHS.* Requires HHS to	*Unfair and Discriminatory Acts and Practices*. Prohibits a manufacturer from: • Charging a higher price for a prescription drug sold to a certified foreign seller than the price that is charged to another person that does not import such a drug into the U.S. • Denying, restricting, or delaying supplies of a prescription drug to a certified foreign seller due to his or her status as a certified foreign seller. • Causing there to be a difference between a prescription drug for distribution in the U.S. and the drug for distribution in Canada. • Engaging in other actions to restrict, prohibit, or delay the importation of a prescription drug. *Suspension of Importation.* Grants	*Preemption.* Does not supplant or preempt state or other federal laws. *Publication of Certified Foreign Sellers.* Requires HHS to publish online a list of certified foreign sellers, including web addresses, physical addresses, and telephone numbers of such sellers. *Drug Testing Laboratories.* Authorizes HHS to approve laboratories to conduct random testing of prescription drugs sold by certified foreign sellers and

[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; (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, and have implemented policies to monitor compliance; (6) conduct ongoing and comprehensive quality assurance programs, including blind testing; (7) agree that laboratories approved by HHS will be used to test product samples/determine samples' chemical authenticity; (8) agree to notify HHS, 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 HHS.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
		• A controlled substance. • An anesthetic drug inhaled during surgery. • A compounded drug.	do not exceed a 90-day supply; and • Filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in the U.S. *Restrictions.* Currently limited to drugs being imported from Canada, but authorizes HHS (after reviewing the cost savings and increased access) to expand the program to include any country that: • Is an OECD member; • Has standards for the approval and sale of prescription drugs that are comparable to U.S. standards; and • Meets certain other criteria (e.g., authorizes approval of a drug only if a drug is deemed safe and effective by government experts, etc.).	submit a report one year after the program's effectuation (and every two years thereafter) on the importation of drugs into the U.S. *GAO.* Requires the GAO to compile a report containing an analysis of the bill's implementation, including a review of drug safety, expenses, and cost-savings (e.g., cost-savings to consumers, and trans-shipment and importation tracing processes, resulting from such implementation).	HHS the authority 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 in violation of the bill until an investigation is completed and it is determined that the drug, seller, or importer does not endanger the public health. *Penalties*. Imposes penalties on online pharmacies selling adulterated or counterfeit products with the intent to defraud, or mislead, with reckless disregard for safety of the public, or knowingly dispensing drugs without a valid prescription. Such pharmacies will face a penalty of not more than 10 years imprisonment or a fine of not more than $250,000.	assess the drugs' chemical authenticity. *Supply Chain Security.* (Generally) requires certified foreign sellers to purchase drugs from registered manufacturers or entities, unless HHS has entered into an MOU with Canada (or the permitted country).
Safe and Affordable Drugs from Canada Act of 2019	Requires HHS to promulgate regulations allowing individuals to import certain drugs	Authorizes HHS to promulgate regulations allowing the importation of drugs from Canada, provided they: • Are purchased from an approved Canadian pharmacy;	Authorizes the importation of drugs from Canada only if it is from an approved Canadian pharmacy and dispensed by a licensed pharmacist. To qualify,			*Publication of Approved Canadian Pharmacies*. In conjunction with the regulations, requires

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
(S. 61/H.R. 478) Sen. Chuck Grassley (R-IA)/Rep. Chellie Pingree (D-ME)	from approved Canadian pharmacies.	• Are dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada; • Are purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; • Are filled using a valid prescription issued by a physician licensed to practice in the U.S.; and • Have the same active ingredient(s), route of administration, dosage form, and strength as prescription drugs approved by the FDA. Does not include: • A controlled substance. • A biological product. • An infused drug (including a peritoneal dialysis solution). • An intravenously injected drug. • A drug inhaled during surgery. • A parenteral drug. • A drug manufactured through one or more biotechnology processes (e.g., a therapeutic DNA plasmid product, a therapeutic synthetic peptide product of not more than 40 amino acids, a monoclonal	the pharmacy must be: • Located in Canada; • Certified by the Secretary that (1) the pharmacy is licensed to operate and dispense prescription drugs to individuals in Canada; and (2) certain additional criteria are met.[2]			HHS to publish on its website a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs.

2 To be certified as an approved Canadian pharmacy, the pharmacy must: (1) have been in existence for at least 5 years and have a purpose other than to participate in the drug importation program; (2) operate in accordance with pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada; (3) have processes to certify that the physical premises, data reporting procedures, and licenses are in compliance with all applicable laws and regulations, and have implemented policies designed to monitor ongoing compliance; (4) conduct ongoing and comprehensive quality assurance programs and implement such quality assurance measures; (5) agree that laboratories approved by the FDA will be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;(6) have established a process for resolving grievances; (7) not resell products from online pharmacies located outside Canada to customers in the U.S.; and (8) meet any other criteria established by FDA.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
		antibody product for in vivo use, a therapeutic recombinant DNA-derived product, etc.). • A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding. • A photoreactive drug.				
Short on Competition Act (S. 844) Sen. Amy Klobuchar (D-MN)	Allows HHS to grant expedited reviews/inspections and temporary importation when there are fewer than 5 competitors on drugs that have been on the market for at least 10 years (i.e., a marginally-competitive market exists). Gives the FDA explicit authority to allow temporary importation from certain countries when HHS determines there is a drug shortage.	In the event of a drug shortage, authorizes the importation of certain drugs if they: • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA); • Are lawfully marketed in an eligible country (i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, an EU member state, or a country in the European Economic Area); • Contain the same active ingredient as the drug for which there is a shortage; and • Will be subject to certain notification and reporting requirements.	Authorizes importation of a drug in the event of a shortage for up to 3 years, or when the drug shortage no longer applies (whichever occurs first).	*Manufacturers.* Requires manufacturers to certify to HHS that they intend to seek approval of the drug. *Importers.* Requires importers to file with HHS information: • Attesting that the requirements for a qualifying drug have been met. • Identifying the drug, the importer proposes to import and the manufacturer from which the importer proposes to import such drugs. • Requests authority to import the drug; *HHS.* Requires HHS to include information on the	*Denial of Importation.* Authorizes HHS to deny importation of an otherwise qualified drug if it is determined that: • The drug is not safe and effective. • The drug is used in conjunction with a device for which there is no reasonable assurance of safety and effectiveness. • The authorization to market the drug in one or more of the permissible countries has been rescinded or withdrawn because of concerns relating to the safety or effectiveness of the drug.	*Marginally-Competitive Markets.* If a marginally-competitive market exists with respect to an applicable drug (i.e., not a radio pharmaceutical drug product), authorizes HHS to: • Treat the marginally-competitive market[3] as creating a drug shortage; • Expedite the review of applications and inspections with respect to the drug; and • Authorize the importation of the

[3] A marginally-competitive market will be deemed to exist with respect to a drug if: (1) for at least 2 consecutive months prior to the determination, fewer than 5 drugs approved or that reference the applicable drug were commercially available in the U.S.; (2) the applicable drug was approved at least 10 years before the determination; and (3) each patent which claims an active ingredient of the applicable drug has expired.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
				number of drugs authorized for temporary importation in its annual report to Congress.		drug.
Lowering Prescription Drug Prices for America's Seniors and Families Act (S. 3384) Sen. Martha McSally (R-AZ)	Requires HHS to promulgate regulations allowing individuals to import certain drugs from approved Canadian pharmacies, among other things.	***Mirrors the Safe and Affordable Drugs from Canada Act of 2019*** Authorizes HHS to promulgate regulations allowing the importation of drugs from Canada, provided they: • Are purchased from an approved Canadian pharmacy; • Are dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada; • Are purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; • Are filled using a valid prescription issued by a physician licensed to practice in the U.S.; and • Have the same active ingredient(s), route of administration, dosage form, and strength as prescription drugs approved by the FDA.	***Mirrors the Safe and Affordable Drugs from Canada Act of 2019*** Authorizes the importation of drugs from Canada only if it is from an approved Canadian pharmacy and dispensed by a licensed pharmacist. To qualify, the pharmacy must be: • Located in Canada; • Certified by the Secretary that (1) the pharmacy is licensed to operate and dispense prescription drugs to individuals in Canada; and (2) certain additional criteria are met.[4]			*Publication of Approved Canadian Pharmacies*. In conjunction with the regulations, requires HHS to publish on its website a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs. *Medicare Part D*. Incorporates various other provisions aimed at lowering drug costs for individuals covered by Medicare Part D, including

4 To be certified as an approved Canadian pharmacy, the pharmacy must: (1) have been in existence for at least 5 years and have a purpose other than to participate in the drug importation program; (2) operate in accordance with pharmacy standards set forth by the provincial pharmacy rules and regulations enacted in Canada; (3) have processes to certify that the physical premises, data reporting procedures, and licenses are in compliance with all applicable laws and regulations, and have implemented policies designed to monitor ongoing compliance; (4) conduct ongoing and comprehensive quality assurance programs and implement such quality assurance measures; (5) agree that laboratories approved by the FDA will be used to conduct product testing to determine the safety and efficacy of sample pharmaceutical products;(6) have established a process for resolving grievances; (7) not resell products from online pharmacies located outside Canada to customers in the U.S.; and (8) meet any other criteria established by FDA.

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
		Does not include: • A controlled substance. • A biological product. • An infused drug (including a peritoneal dialysis solution). • An intravenously injected drug. • A drug inhaled during surgery. • A parenteral drug. • A drug manufactured through one or more biotechnology processes (e.g., a therapeutic DNA plasmid product, a therapeutic synthetic peptide product of not more than 40 amino acids, a monoclonal antibody product for in vivo use, a therapeutic recombinant DNA-derived product, etc.). • A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding. • A photoreactive drug.				provisions that: • ***Mirror the Preserve Access to Affordable Generics and Biosimilars Act***; • ***Mirror the Capping Drug Costs for Seniors Act***; • Require PDP sponsors and MA organizations to include real-time benefit information for beneficiaries; and • Establish a manufacturer discount program.

Price Gouging Legislation

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
Combatting Unreasonable Rises and Excessively (CURE) High Drug Prices Act (S. 637/H.R.	Requires prescription drug manufacturers to justify a price increase in "qualifying drugs" (i.e.,	*HHS.* Requires HHS to notify manufacturers—and request a statement of justification—if it determines that certain price increases within the last 2 years constitute "price gouging."	*Manufacturers.* Provides that the required statement of justification for a price increase may include: • Itemizing the components of the cost of producing the qualifying drug; • Identifying the circumstances and timing of: - An increase in materials/manufacturing costs that caused the price increase within		*HHS.* Authorizes HHS to require a manufacturer found to have engaged in price gouging to: • Reimburse consumers and third-party payors; • Return to the original price	

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
4158) Sen. Richard Blumenthal (D-CT)/Rep. Chellie Pingree (D-ME) Senate Summary	prescription drugs covered by federal health care programs) that HHS deems to constitute "price gouging."[5]	If HHS determines—after a review of the statement of justification—that the manufacturer has engaged in price gouging, requires HHS to notify the manufacturer of the determination. *Manufacturers.* If a notification is received by a manufacturer, requires the manufacturer to provide a statement of justification for the price increase within 45 days of receiving the notification.	the 5-year period preceding the date of the price increase; - Any expenditures made by the manufacturer to expand access to the qualifying drug and explaining any improvement in public health associated with those expenditures; • Providing sales and price information for other qualifying drugs with similar therapeutic effects; and • Providing any other information that the manufacturer deems relevant.		for up to one year; or • If the price gouging is done knowingly, pay a civil penalty of up to 3 times the excessive amount the manufacturer received as a result of the price increase. *DOJ*. Authorizes the Attorney General to bring an action in a district court for relief in certain circumstances.	
Prescription Drug Price Relief Act of 2019 (S. 102/ H.R. 465) Sen. Bernie Sanders (I-VT)/Rep. Ro	Requires HHS to annually identify "excessively priced" patented, brand name drugs[6] that are being sold at prices higher than the median	*Manufacturers*. Requires manufacturers to submit annual reports (January 15) on pricing information for each brand name drug (and as compared to prices in reference countries). *HHS*. Requires HHS to	*Manufacturers*. Requires manufacturers to submit annual reports containing the following information on brand name drugs: • The average manufacturer price of the drug in the U.S. and in the reference countries; • The wholesale acquisition cost of the drug in the U.S. and in the reference countries; • Cumulative global revenues generated by the drug;		*Manufacturers.* Subjects manufacturers that fail to submit their annual reports to a civil penalty that is equal to the product of: • An amount determined by HHS that is (1) not less than 0.5% of the gross revenues from sales of the	*Generic Drugs.* If HHS identifies an excessively priced drug, HHS will: • Waive/void any government-granted exclusivities to the drug's manufacturer with respect to that drug; and

[5] In general, the bill defines "price gouging" as a price increase that (1) is in substantial excess of what could be reasonably justified; and (2) because of insufficient competition, consumers cannot reasonably avoid. Price gouging, however, will be presumed if the average manufacturer price has increased (1) 10% or more over the preceding year; (2) 20% or more over the preceding 3 years; or (3) 30% or more over the preceding 5 years.

[6] In general, HHS will find an excessive price when the domestic average manufacturing price for any brand name drug exceeds the median price charged for such drug in the 5 reference countries. In assessing the extent to which the price is excessive (or if there is insufficient data to determine the median price of the drug in other countries, the drug is otherwise deemed unaffordable, or an individual petitions for such a determination), HHS will consider the following factors: (1) the size of the affected patient population; (2) the value of the drug to patients (i.e., whether the price impacts access to the drug); (3) federal government subsidies and investments related to the drug; (4) the costs associated with developing the drug; (5) whether the drug provided significant improvement in health outcomes when it was approved; (6) the cumulative global revenues generated by the drug; (7) whether the domestic average manufacturer price of the drug increased during any annual quarter by more than CPI-U; and (8) any other factors HHS deems appropriate.

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
Khanna (D-CA) Senate Summary	price in so-called "reference countries" (i.e., Canada, the U.K., Germany, France, and Japan). Authorizes HHS to approve cheaper generic versions of those drugs, if manufacturers refuse to lower the price of drugs to the median price.	annually report to Congress on its excessive drug price review for the preceding calendar year. Requires such reports to be made publicly available on the FDA website in a manner that is easy to find and understand.	• Annual net sales revenue generated by the drug in the U.S. and in the reference countries; • Total expenditures on domestic and foreign drug R&D 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; • The estimated size of the affected patient population; • Additional information the manufacturer chooses to provide related to drug pricing decisions; and • Additional information required by HHS. *HHS*. Requires HHS' annual report to contain summary data regarding: • The total number of drugs that were reviewed; • The total number of drugs found to be excessively priced (and the name/manufacturer of such drugs); • The total number of drugs found to be excessively priced (listed by manufacturer); • The extent to which the prices of the drugs were higher than reasonable, on average; • The total number of drugs for which an open, non-exclusive license has been granted; • The total number of generic drug applications received/approved that reference an excessively priced drug; • The median approval time for generic drug applications in such circumstances; • The total number of petitions HHS received to make excessive price determinations; • A list of any manufacturers who failed to report information, as required; and		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 annual submission deadline and (2) the date on which HHS receives the late report. *Civil Action.* Authorizes HHS to bring civil actions against manufacturers of excessively priced drugs in certain circumstances.	• Grant open, non-exclusive licenses allowing generic drug manufacturers to make more affordable versions of the drug, to be sold at a price below the "excessive price" as determined by HHS. Requires HHS to prioritize review of such generic drug applications (i.e., must be acted upon within 8 months of submission). Requires an entity accepting a license to make a generic version of an excessively priced brand name drug to pay a "reasonable royalty"—as set by HHS—to the holder(s) of the original drug patent. *Publication in HHS Database.* Requires HHS to establish/maintain a comprehensive database of brand name drugs and their excessive price determinations. *Anticompetitive Behavior*. Prohibits manufacturers from engaging in "anticompetitive behavior"

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
			• Any other information HHS deems appropriate.			(i.e., violating Section 5 of the FTC Act).
Stop Price Gouging Act (S. 378/H.R. 1093) Sen. Sherrod Brown (D-OH)/Rep. Mark Pocan (D-WI)	Requires prescription drug manufacturers to report an increase in drug prices/justify such an increase. Imposes an excise tax on (or otherwise penalizes) manufacturers that are deemed by HHS to have engaged in unnecessary price spikes.	*Manufacturer*. Requires manufacturers of prescription drugs to submit a quarterly report (January 17, April 18, June 15, September 15) to the HHS OIG. *HHS OIG*. Requires the HHS OIG to annually (February 28/29): • Complete an assessment of the information submitted by manufacturers; and • Transmit to the IRS a report on its findings (along with its assessment). *Exemptions*. Allows HHS to exempt any prescription drug that was the subject of a price spike during the previous calendar year from the excise tax if the following requirements are met: • HHS determines that a for-cause price increase exemption should apply; or • The prescription drug that was subject to a	*Manufacturers*. Requires manufacturers to submit quarterly reports containing the following information: • The total number of units of each prescription, FDA-approved drug that were sold in the last quarter; • The average and median price per unit of each prescription drug sold in the last quarter, broken down by month; • The gross revenues from sales of each prescription drug in the last quarter; 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. *HHS OIG Assessment.* Requires the annual assessment performed by the HHS OIG to include: • Identification of each price spike relating to a prescription drug; • A determination of the price spike revenue; • A determination of the accuracy of the information submitted by the manufacturer regarding increased input costs; and • An assessment of the manufacturer's rationale for the price spike. *HHS OIG Report to the IRS.* Requires the annual HHS OIG report to the IRS to include: • The information received from manufacturers;	Imposes an excise tax on each prescription drug deemed to have undergone an unnecessary price spike (i.e., a taxable prescription drug) sold by a manufacturer equal to the greater of: • The annual price spike tax for the prescription drug; or • The cumulative price spike tax for the prescription drug. 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	Subjects manufacturers who fail to submit the required reports to the HHS OIG to a civil penalty that is 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 which the HHS OIG receives the late report.	*Exemption Reporting.* Directs the HHS Inspector General to submit a recommendation to HHS on each drug that is exempt from the imposition of the excise tax. *Publication of Data.* Requires the HHS OIG to make its report to the IRS available to the public on its website. *Notice Requirements.* Requires HHS to notify the manufacturer no later than 30 days after the completion of the HHS OIG's assessment regarding any drug that has been found to have been subject to a price spike. *Hearing Opportunity*. Allows a manufacturer to request a hearing (only once within a 5-year period) before HHS within 30 days of receiving notice of the price spike determination.

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
		price spike has an average manufacturer price of not greater than $10 for a 30-day supply; and • The drug is marketed by at least three other drug companies and used by the companies as a reference drug.	• The price spike identified; • The price spike revenue determinations; and • Other determinations and assessments completed by the HHS OIG.	period or cumulatively.[7]		*Study on Monopoly of Medical Products*. Requires GAO to conduct a study examining how drug manufacturers establish initial launch prices and suggest best practices for monitoring new drug prices.
Life-Sustaining Prescription Drug Price Relief Act of 2019 (H.R. 5039) Rep. Dan Lipinski (D-IL) ***Similar to the Prescription Drug Price Relief Act of 2019***	Requires HHS to annually review prices of life-sustaining prescription drugs and identify drug prices that are "excessive."[8]	*Manufacturers*. Requires manufacturers to submit annual reports (January 15) on pricing information for each prescription drug (and as compared to prices in reference countries). *HHS*. Requires HHS to annually report to Congress on its excessive drug price review for the preceding calendar year. Requires such reports to be	*Manufacturers*. Requires manufacturers to submit annual reports containing the following information for all prescription drugs: • The average manufacturer price of the drug in the U.S. and in the reference countries, for the entire year, and broken down for each quarter of the year; • The wholesale acquisition cost of the drug in the U.S. and in the reference countries, for the entire year, and broken down for each quarter of the year; • Cumulative global revenues generated by the drug; • Annual net sales revenue generated by the drug		*Manufacturers*. If a manufacturer fails to submit the required drug pricing information to HHS in a timely manner or knowingly provides false information, subjects manufacturers to a civil monetary penalty that equals to an amount between 0.5% and 1% of the gross revenues from sales for the previous calendar year. *Medicare Part D Negotiations*. If a manufacturer fails to enter	*Petitions*. Permits any person to petition HHS to identify an excessive drug price; requires HHS make such petitions and rationale for such identification publicly available. *Medicare Part D Negotiation*. If HHS identifies an excessive price for a drug covered by Medicare Part D and furnished to an enrollee of a PDP or MA-PD plan,

[7] Prior to enforcement of 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.

[8] In general, HHS will find an excessive price when the domestic average manufacturing price exceeds 110% of the average price charged for such drug in so-called "reference countries" (i.e., Canada, the U.K., Germany, France, and Japan). In assessing the extent to which the price is excessive (or if there is insufficient data to determine the average price of the drug in other countries), HHS will consider the following factors: (1) the size of the affected patient population; (2) the risk adjusted value of federal subsidies and investments related to the drug; (3) the costs associated with developing the drug; (4) whether the drug provided significant improvement in health outcomes when it was approved; (5) the cumulative global revenues generated by the drug; (6) whether the domestic average manufacturer price of the drug increased during any annual quarter by more than CPI-U; (7) a petition for a price determination made by person; and (8) any other factors HHS deems appropriate.

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
		made publicly available on the FDA website in a manner that is easy to find and understand.	in the U.S. and in the reference countries, for the entire year, and broken down for each quarter of the year; • Itemized total expenditures on domestic and foreign drug R&D 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, for the entire year, and broken down for each quarter of the year, including grants; • The estimated size of the affected patient population; • Additional information the manufacturer chooses to provide related to drug pricing decisions; and • Additional information required by HHS. *HHS*. Requires HHS' annual report to contain summary data regarding: • The total number of drugs that were reviewed; • The total number of drugs found to be excessively priced (and the name/manufacturer of such drugs); • The total number of drugs found to be excessively priced (listed by manufacturer); • The extent to which the prices of the drugs were higher than reasonable, on average; • The total number of petitions HHS received to make excessive price determinations; • A list of any manufacturers who failed to report information, as required; and • Any other information HHS deems appropriate. Requires HHS to create an excessive drug price database that, at a minimum, includes: • The name of the drug and manufacturer;		into a negotiation and agree to the total payment that HHS identifies for drugs under Medicare Part D, subjects manufacturers to a civil monetary penalty that equals to: • Two times the difference between (1) the total revenue of such drug from all sales in the U.S. (beginning 9 months after HHS' identifies the excessive price), and (2) the total revenue of such drug after such time period that would have been received <u>if the manufacturer charged the international reference price</u>; and • 50% of the revenue from U.S. sales of the drug in the first 90 days (beginning 9 months after HHS' identifies the excessive price), 75% of all revenue from such sales after such period, and 95% of all revenue from such sales in subsequent days <u>until an agreement is reached or an international reference price is reached</u>.	requires HHS negotiate the total payment (including any discounts, rebates, and other price concessions) that may be made with manufacturers, PDP sponsors, and MA organizations during a negotiated price period (as specified by HHS). Authorizes HHS to limit the negotiated price of drugs covered by Medicare Part D to below 110% of the average price charged for such drugs in the five reference countries (the so-called "international reference price").

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
			• Whether the drug was determined to have an excessive price; and • The number of petition HHS received to make an excessive price determination for the drug.			

PBM Reforms and Transparency Legislation

Legislation	Overview	Transparency Measures	Miscellaneous
Prescription Drug Price Transparency Act (H.R. 1035) Rep. Doug Collins (R-GA)	Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement.	*PBMs.* Prohibits PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor or with a Medicare Advantage ("MA") organization from doing either of the following: • Requiring the plan enrollee use any pharmacy providing pharmacy services in which the PBM has an ownership interest, or ownership interest in; and • Providing an incentive (including reduced copayment or coinsurance) to a plan enrollee to use any pharmacy providing pharmacy services in which the PBM has an ownership interest, if the incentive is applicable only to such pharmacies. Requires PBMs to do the following with respect to their drug pricing standards for reimbursement (e.g., their maximum allowable cost lists) for Medicare Part D and FEHBP: • Update the standard at least once every 7 days, beginning January 1 of each year, to accurately reflect the market price of acquiring the drug; • Disclose to applicable pharmacies and the respective contracting entities thereof the sources used for making any update to the standard immediately "without requirement of request;" • If the source for the standard is not publicly available, disclose to the applicable pharmacies and respective contracting entities thereof all updated, individual drug prices in advance of using such prices for reimbursement of claims; • Establish a process for applicable pharmacies to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price; and • Provide to applicable pharmacies and respective contracting entities all such pricing data in a spreadsheet and easily accessible format.	

Legislation	Overview	Transparency Measures	Miscellaneous
Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019 (S. 476) Sen. Ron Wyden (D-OR) Senate Summary	Requires public disclosure of the total amount of rebates provided by manufacturers to PBMs and the proportion of those rebates that are passed on to health plans.	Requires HHS to make publicly available on CMS' website certain information regarding a PBM's ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions, beginning in January 2020. Such information includes: • The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to the patient utilization under the plan; • The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor; • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount the PBM pays retail pharmacies (i.e., spread pricing); and • The total number of prescriptions that were dispensed.	*Rebating Limits.* Beginning in 2020, requires a PBM that manages prescription drug coverage under a contract with a PDP sponsor, MA organization, or qualified health benefits plan to pass through to the plan sponsor a minimum percent (established by HHS) of the aggregate amount of the rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan. Requires HHS to establish the minimum percent to ensure that patients receive the maximum benefits of rebates while considering the costs of negotiating such rebates. *Medicare Part D.* Prohibits a PDP sponsor or an MA organization under Medicare Part D from contracting with a PBM that is not in compliance with the rebating limits established by HHS and requires cost-sharing for Medicare Part D enrollees to be based off the negotiated price of the drug as agreed to by the drug manufacturer and the PBM.
S. 657 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).	
Fair Care Act of 2019 (H.R. 1332) (***excerpts***) Rep. Bruce Westerman (R-AR)	Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for	*PBMs.* Requires PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor, a Medicare Advantage ("MA") organization, or are part of an FEHBP contract to adhere to the following criteria when handling personally identifiable utilization and claims data, and other sensitive patient data: • Not transmit any personally identifiable utilization, PHI, or claims data with respect to a plan enrollee to a pharmacy owned by a PBM if the plan enrollee has not voluntarily elected in writing or via secure electronic means to fill that particular prescription at the PBM-owned pharmacy. • Not require that a plan enrollee use any pharmacy providing pharmacy services in which	Incorporates other provisions to promote market competition, including: • Targeting delay tactics related to sample-sharing and shared safety protocols that prevent entry of generic drugs into the market. ***Mirrors the CREATES Act.*** • Establishing a program to expedite the development of/provide priority review for "generic complex drug products." • Preempting state laws that prohibit a pharmacy from dispensing an FDA-approved biosimilar. • Limiting the exclusivity periods for drugs treating rare diseases and

Legislation	Overview	Transparency Measures	Miscellaneous
House Summary	reimbursement, among other things.	the PBM has an ownership interest. • Not provide an incentive to a plan enrollee to use any pharmacy providing pharmacy services in which the PBM has an ownership interest, if the incentive is applicable only to such pharmacies. Requires PBMs to do the following with respect to their drug pricing standards for reimbursement (e.g., their maximum allowable cost lists) for PDP sponsors, TRICARE, and FEHBP: • Update the standard at least once every 7 days, beginning January 1 of each year, to accurately reflect the market price of acquiring the drug; • Disclose to applicable pharmacies and the respective contracting entities thereof the sources used for making any update to the standard immediately "without requirement of request"; • If the source for the standard is not publicly available, disclose to the applicable pharmacies and respective contracting entities thereof all updated, individual drug prices in advance of using such prices for reimbursement of claims; • Establish a process for applicable pharmacies to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price; and • Provide to applicable pharmacies and respective contracting entities all such pricing data in a spreadsheet and easily accessible format.	conditions. • Allowing HHS to alter the reimbursement mechanism for drugs provided through the Medicare Part B program. • Prohibiting Medicare prescription drug plan sponsors from retroactively reducing payment on "clean claims" (i.e., those without defects like incomplete documentation) submitted by pharmacies. ***Mirrors the Improving Transparency and Accuracy in Medicare Part D Spending Act***. • Sunsetting the current maximum rebate amount (100%) for outpatient Medicaid drugs so that they apply only for rebate periods that begin between 2009 and 2025. ***Mirrors H.R. 107***. • Permitting HHS to establish a (1) mechanism prohibiting drug manufacturers from contributing financially to patient copays and (2) system of penalizing such behavior. • Enacting transparency provisions specific to the 340B program. • Requiring Congress to vote on all major actions (with an economic impact of $100 million+) proposed by FDA, among other things.
Public Disclosure of Drug Discounts Act (H.R. 2115) Rep. Abigail Spanberger (D-VA) *May 21 – A hearing was held on the legislation.* *October 28 –*	Requires HHS to make publicly available on its website certain rebate information with respect to generic drugs.	***Beginning in 2020***, requires HHS to make certain information on generic dispensing rates publicly available on its website, including: • The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed that is paid by the health benefits plan or PBM under the contract; • The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to the patient utilization under the plan; • The aggregate amount of the rebates, discounts, or price concessions passed through to the plan; and • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount the PBM pays retail pharmacies (i.e., spread pricing).	

Legislation	Overview	Transparency Measures	Miscellaneous
Approved by the House—as amended—by a vote of 403 to 0.			
Phair Relief Act (S. 2247) Sen. John Kennedy (R-LA)	Requires PBMs to publicly disclose drug discounts and places a five-year freeze on PBMs direct or indirect renumeration (DIR) fees.	***Beginning in 2020***, requires HHS to make certain PBM rebate information publicly available on its website, including: • The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to the patient utilization under the plan; • The aggregate amount of the rebates, discounts, or price concessions passed through to the plan; and • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount the PBM pays retail pharmacies (i.e., spread pricing). Amends PBM transparency requirements to include (instead of exclude) 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)). *DIR Payments*. Beginning in 2021, establishes a 5-year freeze on direct and indirect remuneration (DIR) fees under Medicare Part D; and prohibits increases in cost sharing amounts during such freeze. *PDP Sponsors*. Requires PDP sponsors to promptly provide to HHS certain claim reimbursement information for drugs covered under Medicare Part D, including: • The Network Reimbursement ID used to price the claim and other claim-level details (e.g., date of service and payment, ingredient cost reimbursed, etc.); • Any fees, pharmacy price concessions, discounts, incentives; and • Any other forms of remuneration to or from the pharmacy that affect payment and pricing.	*Pass-Through Pricing*. Beginning in 2022, requires PBMs that manage prescription drug coverage under a contract with a PDP sponsor, MA organization, or qualified health benefits plan, pass through to the plan sponsor a minimum percent (established by HHS) of the aggregate amount of rebates, discounts or price concessions that the PBM negotiates that are attributable to patient utilization under the plan. *Quality Measures*. Requires HHS establish or approve standard quality measures for pharmacy price concessions and incentive payments for Medicare Part D prescription drugs. *Audit*. Beginning in 2021, requires HHS conduct annual audits of PDP sponsors by reviewing a sample of claims between PDP sponsors (or other intermediaries) and pharmacies; requires HHS submit a report to Congress summarizing such auditing.
Competition Prescription Act of 2019 (H.R. 3947)	Requires PBMs to adhere to certain standards when entering into	*PBMs*. Requires PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor, a Medicare Advantage ("MA") organization, or are part of an FEHBP contract to adhere to the following criteria when handling personally identifiable utilization and claims data, and other sensitive patient data:	Incorporates other provisions to promote market competition, including: • Targeting delay tactics related to sample-sharing and shared safety protocols that prevent entry of generic drugs into the market. ***Mirrors the CREATES Act***.

Legislation	Overview	Transparency Measures	Miscellaneous
Rep. Mark Meadows (R-NC)	contracts and ensure the transparency of their drug pricing standards for reimbursement, among other things.	• Not transmit any personally identifiable utilization, PHI, or claims data with respect to a plan enrollee to a pharmacy owned by a PBM if the plan enrollee has not voluntarily elected in writing or via secure electronic means to fill that particular prescription at the PBM-owned pharmacy. • Not require that a plan enrollee use any pharmacy providing pharmacy services in which the PBM has an ownership interest. • Not provide an incentive to a plan enrollee to use any pharmacy providing pharmacy services in which the PBM has an ownership interest, if the incentive is applicable only to such pharmacies. ***Mirrors the Fair Care Act of 2019***. Requires PBMs to do the following with respect to their drug pricing standards for reimbursement (e.g., their maximum allowable cost lists) for PDP sponsors, TRICARE, and FEHBP: • Update the standard at least once every 7 days, beginning January 1 of each year, to accurately reflect the market price of acquiring the drug; • Disclose to applicable pharmacies and the respective contracting entities thereof the sources used for making any update to the standard immediately "without requirement of request"; • If the source for the standard is not publicly available, disclose to the applicable pharmacies and respective contracting entities thereof all updated, individual drug prices in advance of using such prices for reimbursement of claims; • Establish a process for applicable pharmacies to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price; and • Provide to applicable pharmacies and respective contracting entities all such pricing data in a spreadsheet and easily accessible format.	• Establishing a program to expedite the development of/provide priority review for "generic complex drug products." ***Mirrors the Fair Care Act of 2019***. • Preempting state laws that prohibit a pharmacy from dispensing an FDA-approved biosimilar. • Allowing FDA to expedite applications for approval of drugs authorized to be marketed in the European Union. • Allowing HHS to alter the reimbursement mechanism for drugs provided through the Medicare Part B program. • Prohibiting Medicare prescription drug plan sponsors from retroactively reducing payment on "clean claims" (i.e., those without defects like incomplete documentation) submitted by pharmacies. ***Mirrors the Improving Transparency and Accuracy in Medicare Part D Spending Act***. • Sunsetting the current maximum rebate amount (100%) for outpatient Medicaid drugs so that they apply only for rebate periods that begin between 2009 and 2025. ***Mirrors H.R. 107***. • Permitting HHS to establish a (1) mechanism prohibiting drug manufacturers from contributing financially to patient copays and (2) system of penalizing such behavior. • Allows insurers and drug manufacturers to negotiate wholesale acquisition prices by creating a safe harbor from antitrust liability for private health insurers, as long as the wholesale acquisition price is jointly negotiated by the insurer and manufacturer. ***Mirrors the State-Based, Market-Oriented Prescription Drug Negotiations Act***. • Establishing a Chief Pharmaceutical Negotiator appointment position in the office of the U.S. Trade Representative to conduct trade negotiations related to pharmaceutical products and services; requires the appointee annually report all enforcement and other relevant actions to Congress. *FDA Reform*. Codifies the publication of the FDA's "Purple Book" as a single, searchable list; requires additional information to be published in the Purple Book; and limits the enforceability of late-filed patents when a biosimilar application has already been filed with the FDA. ***Mirrors the Biologic Patent Transparency Act***. *Medicare Part B*. Requires HHS assign a uniform Common Procedure

Legislation	Overview	Transparency Measures	Miscellaneous
			System code to describe all biosimilar products that share a common reference product to simplify billing.
Lower Health Care Costs Act of 2019 (S. 1895) Sen. Lamar Alexander (R-TN) ***Part of a larger package that includes provisions related to surprise billing, transparency, etc.***	Requires PBMs and issuers to report certain information to plan sponsors, among other things.	*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; • 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. Requires additional reporting for issuers and PBMs that conduct transactions with wholly or partially-owned pharmacies.	*Spread Pricing.* Prohibits PBMs from engaging in spread pricing or charging more for a drug than the PBM paid to acquire the drug. *Rebating.* Requires PBMs to pass on 100% of any rebates or discounts to the plan sponsor; and requires PBMs, TPAs, and issuers providing prescription drug management services to remit 100% of rebates, fees, discounts, and all other remuneration received from manufacturers, distributors or other third parties that are related to drug utilization under a plan/coverage to the group health plan. *Penalties*. Subjects PBMs to a civil monetary penalty of not more than $10,000 for each day the reporting violation continues; and subjects PBMs that knowingly report false information to a civil monetary penalty of not more than $100,000 for each false item. *Gag Clauses*. Prohibits gag clauses between providers and health plans that prevent individuals from seeing costs/data; prohibits gag clauses between providers and insurance plans that prevent plan sponsors from accessing de-identified claims data. *Data Access*. Appropriates $20 million for 2020 and $15 million for 2021-2025 for HHS to contract with a nonprofit entity to establish and maintain a database on de-identified health care claims information. *Drug Pricing Transparency*. Requires all group health plans to annually report to HHS the following information, among other things: • 50 most frequently dispensed brand name drugs for claims paid by the issuer, and the total number of paid claims for each drug; • 50 most expensive prescription drugs by total annual plan spend, and the annual amount spent by the plan for each drug; • 50 prescription drugs with the greatest increase in plan expenditure over the previous plan year with changes in expended amounts for each drug; • Total amount spent by the plan, including, among other things:

Legislation	Overview	Transparency Measures	Miscellaneous
			prescription drug costs and prescription drug spending by the plan and by enrollees; • Any impact on premiums by rebates, fees, or other remuneration paid by drug manufacturers or service providers, including such amounts paid for each therapeutic class of drugs and amounts paid for the 25 drugs that yielded the highest amount of such remuneration from drug manufacturers; and • Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration paid by drug manufacturers or service providers. *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***; • Permit FDA to expedite approval for a biosimilar or generic drug; and • Authorize FDA to outdated drug labeling and require changes to the labeling of generic drugs.
PBM Transparency in Prescription Drug Costs Act (H.R. 5304) Rep. Kurt Schrader (D-OR)	Requires PBMs and issuers to report certain information to plan sponsors, among other things.	Requires health insurers offering group coverage and PBMs that service group health plans to report certain information to self-funded group plan sponsors (and at the request of other group plans) at least every six months, including: • Information collected from manufacturers on the total amount of copayment assistance dollars paid that were funded by the drug manufacturer with respect to the enrollees; • A list of each therapeutic category or class of drugs that were dispensed and specific information about the therapeutic class (e.g., the total gross spending by the plan; the number of enrollees who filled a prescription for a drug in that category or class; aa description of the formulary tiers and utilization mechanisms, etc.); • Total gross spending on prescription drugs before rebates and other manufacturer fees or remuneration; • Total amount received/expected to be received by the health plan or insurer in	Prohibits group health plans, insurers, and PBMs from entering into a contract with a manufacturer, distributor wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of the required information to plan sponsors. *Spread Pricing*. Requires a plan administrator of an applicable self-insured health plan or PBM of such plan to offer at least one contract that does not charge the plan or enrollee a price for a drug that exceeds the price paid to the dispensing pharmacy. *Pass-Through Pricing*. Prohibits a plan administrator of an applicable self-insured health plan, or PBM of such plan, from charging the plan or enrollee

Legislation	Overview	Transparency Measures	Miscellaneous
		manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party related to the utilization or spending of such drug; • Total net spending on prescription drugs by the health plan or insurer; and • Amounts paid directly/indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan or health insurers business to the PBM. Requires such insurers and PBMs to report a list of each covered drug dispensed, including, with respect to each drug: • The brand name, chemical entity, and National Drug Code; • The number of enrollees for whom the drug was filled during the plan year, total number of prescriptions filled for the drug (including original prescriptions and refills), and total number of dosage units of the drug dispensed across the plan year; • The wholesale acquisition cost; • The total out-of-pocket spending by enrollees on such drug, including enrollee spending through copayments, coinsurance, and deductibles; and • For any drug with gross spending of the group health plan or health insurer exceeding $10,000 during the reporting period: – A list of all other available drugs in the same therapeutic category or class; and – A justification of its preferred formulary placement of a particular drug or drugs in that therapeutic category/class. Requires group health insurers and PBMs that service group health plans and conduct transactions with a wholly or partially owned pharmacy to quarterly report information to the plan sponsor, including: • An explanation of benefit design parameters; • The percentage of total prescriptions dispensed by such pharmacies; and • A list of all drugs dispensed or charged by such pharmacy, including, for each drug: – The amount charged to the enrollee; – The median amount charged to the plan or coverage; – The range of the costs, including amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly/partially owned by the insurer or PBM; and – The lowest cost for such drug that is available at any pharmacy included in the network of the plan or coverage.	an amount for a prescription drug that exceeds the price paid to the dispensing pharmacy. *Rebating.* Requires PBMs and TPAs of group health plans or insurers to remit 100% of rebates, fees, alternative discounts, and all other remuneration received from a manufacturer, distributor or other TPA that are related to utilization of drugs under such plan or insurer to the health plan issuer. *Auditing.* Requires PBMs and TPAs of group health plans or insurers to allow such plan sponsors or designated third parties to audit their rebate contracts with manufacturers. *Penalties.* Subjects health insurers and PBMs that fail to provide the required reports or otherwise fail to comply with this Act to a civil monetary penalty of $10,000 for each day such violation continues; and subjects insurers and PBMs that knowingly report false information to a civil monetary penalty of no more than $100,000 for each false item.

Multi-Issue Legislation

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
Medicare for America Act of 2019 (H.R. 2452) Rep. Rosa DeLauro (D-CT) House Summary ***Part of a larger package that includes a single-payer/public option proposal***	***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.*** Imposes reporting obligations on manufacturers of FDA-approved, prescription, "qualifying drugs": • That have a wholesale acquisition cost of at least $100 or more per month supply or per course of treatment that lasts less than a month and is (1) prescribed by physicians or commonly administered by hospitals, (2) not designated as a drug for a rare disease or condition, and (3) not designated as a vaccine by HHS; and • For which, during the previous calendar year, at least $1 of their total sales was earned from individuals enrolled in Medicare or Medicaid programs. 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.		Prohibits manufacturers from charging "excessive prices"—as defined by the Board[9]—for prescription drugs or medical devices. Requires the Board to provide the manufacturer with notice (i.e., tell the manufacturer that they are charging an excessive price) and a period to correct the violation. If the manufacturer fails to correct the violation by the end of such period, subjects the manufacturer to enforcement.	*Drug Pricing Transparency.* Subjects manufacturers who fail to submit a report justifying a price increase for a qualifying drug to a civil penalty of $100,000 for each day the violation continues. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.*** *Price Gouging.* If the Board finds the manufacturer of a prescription drug or medical device charged an "excessive price," the following are considered available penalties: • A reduced patent term; • Civil penalties; or • Imposition of a tax on excess prescription drug and medical device profits. *Reduced Patent Term*. If the manufacturer of a prescription drug or medical device is also an	*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 30 days after the report has been received. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.*** *Annual Report.* Requires HHS to submit an annual report to Congress that: • Summarizes the drug pricing information reported by the manufacturer of a qualifying drug; and • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.*** *Prescription Drug and Medical Device Price Review Board.* Establishes, within HHS, the Prescription Drug and Medical Device Price Review Board. Grants the Board the authority to: • Obtain official data directly from any federal agency, provided it is necessary to carry out the Board's duties; • Use the U.S. mail; • Receive/use administrative support services from

[9] In developing a formula to determine what qualifies as an "excessive price," the Board must take into consideration (at a minimum) the following: (1) the average manufacturer price of other drugs/medical devices over the respective annual quarter(s); (2) the average manufacturer price of other drugs/medical devices in the same therapeutic class over the same quarter(s); (3) the average price at which the drug/medical device and other drugs/medical devices in the same therapeutic class have been sold by manufacturers in countries outside the U.S.; (4) the costs associated with producing and marketing the drug/medical device, the value of the drug/device to patients, the total federal investment in the development of the drug/device, the size of the patient population receiving the drug/device, and other factors determinative as to the true cost of production; and (5) whether the price of the drug/medical device increased during any annual quarter by greater than 2% of the CPI.

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	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 list price; • 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; and • Any other information requested by HHS. *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");			owner of a patent for such drug or device, authorizes the Board to: patent relating to the drug or 5 years; or nt for the drug or device has by not more than 5 years of y the patent owner. *Civil Penalties*. Authorizes the Board to impose a civil penalty on the manufacturer of not more than 10% of the manufacturer's gross sales of the drug or device during the period in which an excessive price is first charged and ending on the date on which the manufacturer ceases to charge an excessive price. *Tax*. Authorizes the imposition of a tax equal to the difference between the price at which such drug or device is sold and the reasonable price determined by the Board for such drug or device.	the GSA; • Contract with/compensate government and private agencies to conduct research, surveys, etc.; • Undertake investigations; and • Issue subpoenas. Requires the Board to annually submit to other federal agencies that dispense/make payments for the dispensing of prescription drugs, a report containing a list of each prescription drug and medical device for which an excessive price was charged during the preceding calendar year. *Direct-to-Consumer Drug Advertising.* Prohibits direct-to-consumer advertising of new prescription drugs during a 3-year period beginning on the date of the drug application approval, unless HHS approves a waiver.

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	• 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.				
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	***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,[10] provided certain circumstances are met—after two years,	***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	*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%	*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 2019 and beyond). *Advertising.* Eliminates tax breaks for drug companies for expenses related to direct-to-consumer advertising.

[10] 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.

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	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 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'	authorizes importation from OECD countries that meet standards comparable to U.S. standards. Identifies such qualifying prescription 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	increased input costs, or public health considerations that the manufacturer may want the HHS OIG to consider in its assessment. 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:	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 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	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. • 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

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	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. 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.	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 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.	• The information received from manufacturers; • The price spikes identified; • The price spike revenue determinations; • The average and median price of the 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	safety, an adulterated or counterfeit drug; or • Dispense a drug to an individual in the U.S. who does not possess a valid prescription.	

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
		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 processes.	over a one-year period or cumulatively.[11]		
Prescription Drug Pricing Reduction Act (PDPRA) of 2019/2020 (S. 2543/S. 4199) Sen. Chuck Grassley (R-IA) Committee Report Summary	*Manufacturers*. Requires manufacturers of Medicare Part B drugs, biologicals, and biosimilars that do not have an agreement under the Medicaid Drug Rebate Program (MDRP) to report average sales price amounts to HHS on a quarterly basis. ***Phasing in 2020 – 2024***, requires manufacturers to report to HHS information and documentation justifying applicable drug price increases and launch prices (e.g., manufacturer spending for materials, patents and licenses, research, etc.); and requires HHS make such information publicly available. Applies to prescription drugs with: • A list price of at least $10 per dose and price increase of at least 300% over 5 years or 100% over 1 year; • Net spending in the Medicare or Medicaid programs at the top 50th percentile;			*Manufacturers and PBMs*. If a manufacturer or PBM fails to comply with reporting requirements, subjects manufacturers and PBMs to $10,000 per day of violation and up to $100,000 per false item of information that is knowingly submitted. *Wholesalers and Manufacturers*. If a wholesaler or manufacturer refuses to provide requested information under the Medicaid program or provides false information, subjects wholesalers and manufacturers to a penalty of no more than $185,000.	*Coupons*. Requires manufacturers to include the value of coupons (e.g., financial support directly or indirectly to a patient to reduce or eliminate cost-sharing or other out-of-pocket costs) given to individuals with private insurance in calculating the average sales price of a drug, biological or biosimilar. *Audit.* Requires HHS conduct ongoing audits of drug price and product information reported by manufacturers under the MDRP; and authorizes HHS to survey wholesalers and manufacturers to verify manufacturer reported information. *Risk-Sharing Agreements*. Establishes a state option allowing states to pay for covered outpatient drugs through risk-sharing value-based agreements. Incorporates other provisions related to the Medicare and Medicaid programs, including, among other things: • Incorporates transparency measures for Medicare

[11] 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.

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	• A price increase of at least 50% over 5 years or 15% over 1 year; or • An initial launch price that makes the cost of a year supply or full course of treatment exceed total gross drug spending for the Medicare Part D annual out-of-pocket threshold. ***Mirrors the SPIKE Act of 2019*** *PBMs.* Requires PBMs contracting with state Medicaid programs to annually report to HHS certain information on Medicare Part D drugs, including: • The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to the patient utilization under the plan; • The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor; • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount the PBM pays retail pharmacies (i.e., spread pricing); • The total number of prescriptions that were dispensed; and • The aggregate amount of "bona fide service fees" (e.g., distribution service fees, inventory management fees, product stocking allowances, and administrative service fees) the PBM received from PDP sponsors, qualified health benefit plans, managed care entities, and manufacturers. ***Similar to the C-THRU Act of 2019***. *HHS.* Requires HHS make publicly available:				Part D and MA plans; • Requires pass-through pricing for covered outpatient drugs under Medicaid; • Requires payments for pharmacy management services to be limited to ingredient costs and professional dispensing fees under Medicaid; • Adjusts the payment rate for new drugs and biologicals under Medicare Part B; • Temporarily increases the payment rate for biosimilar biological products under Medicare Part B; • Establishes a mandatory rebate for manufacturers of all Medicare Part B and Part D covered 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); • Requires manufacturers provide rebates to HHS for single-dose vial drugs under Medicare Part B; • Establishes a maximum add-on amount that a provider can be paid for each drug under Medicare Part B; • Authorizes HHS to use wholesale acquisition cost or other reasonable drug price measures as a payment methodology for drugs under Medicare Part B; • Expands HHS online price transparency tool to allow beneficiaries to include comparable information for services that can be provided in a physician's office (i.e., instead of only outpatient ambulatory services); • Requires GAO study the impact of copayment coupons and other patient assistance programs for drug pricing under the Medicare and Medicaid programs; • Excludes certain generic drugs under MDRP from the calculation of average manufacturer price; and • Increases the average manufacturer price cap on

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	• Wholesale acquisition costs for outpatient drugs covered under the MDRP. • The aggregate price concession information currently reported by plans or PBMs under Medicare Part D; and • Discrepancies with direct and indirect remuneration data provided by Medicare Part D and Medicare Advantage plans.				Medicaid covered drugs from 100% to 125%.

Miscellaneous Legislation

Legislation	Issue Area	Overview
National Public Health Act of 2019 (H.R. 2095) Rep. Mark DeSaulnier (D-CA)	*Access*	Requires manufacturers of newly approved drugs that are determined to have a fiscal impact on public health (i.e., a drug or a drug collectively taken with a similar drug that amounts to $50 million or more per year) provide the drug to the public within 180 days of FDA approval; subjects manufacturers to a civil penalty up to $20,000 for each day the drug is in violation of the law.
Biologic Patent Transparency Act (S. 659/H.R. 4850) Sen. Susan Collins (R-ME)/Rep. Abigail Spanberger (D-VA) Senate Summary	*FDA Process Reform*	Codifies the publication of the FDA's "Purple Book" as a single, searchable list; requires additional information to be published in the Purple Book (e.g., patents that claim/relate to FDA-approved biological products, information related to biosimilarity and interchangeability, information related to exclusivities, and approved indications); and limits the enforceability of late-filed patents when a biosimilar application has already been filed with the FDA.
Efficiency and Transparency in Petitions Act (S. 660) Sen. Mike Braun (R-IN)	*FDA Process Reform*	Requires any petition on a pending generic drug submitted to the FDA within 1 year of when the petitioner/drug manufacturer discovers the issue that is the basis for the petition; authorizes HHS to amend this 1-year deadline for certain petitions.
Purple Book Continuity Act of 2019 (H.R. 1520)	*FDA Process Reform*	Requires HHS to (1) publish and make publicly available certain information on licensed biological products; and (2) revise the information, every 30 days, to include newly licensed biological products among other things.

Legislation	Issue Area	Overview
Rep. Anna Eshoo (D-CA)		*March 27 – Approved by the Energy and Commerce Subcommittee on Health—as amended—by voice vote.* *April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.* *May 8 – Approved by the House—as amended—by a vote of 229-192.*
Orange Book Transparency Act (H.R. 1503) Rep. Robin Kelly (D-IL)	*FDA Process Reform*	Authorizes FDA to remove or add patents from the "Orange Book" (i.e., list of FDA approved drug products, etc.); imposes transparency requirements related to patents (i.e., requires drug application holders to promptly submit a patent withdrawal or removal to FDA for patents found to be invalid, etc.). *March 27 – Approved by the Energy and Commerce Health Subcommittee by voice vote.* *April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.* *May 8 – Approved by the House—as amended—by a vote of 231-191.*
Accelerated Drug Approval for Prescription Therapies (ADAPT) Act (S. 658) Sen. Mike Braun (R-IN)	*FDA Process Reform*	Permits FDA to expedite applications for approval of certain drugs if there is evidence that: • The drug is authorized to be marketed in specific countries (e.g., European Union members, Israel, Australia, Canada, and Japan) • The drug is safe and clinically effective and a satisfactory history of clinical trials and data • The manufacturer is capable of manufacturing the drug safely and consistently, and can assure the safety of the supply chain outside the United States • All relevant United States patents or legal exclusivities are expired • The drug is not approved for marketing in the United States • HHS has not rescinded or withdrawn any such approval • There is a public health or unmet medical need for the drug in the United States Requires FDA to make a determination on a drug application no later than 180 days after submission.
Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 1209)	*FDA Process Reform*	Prohibits FDA from immediately approving new drug substance patents to facilitate generic market entry; requires the Orange Book to be updated to reflect when a patent has been invalidated by the U.S. Patent and Trademark Office, among other things.

Legislation	Issue Area	Overview
Sen. Bill Cassidy (R-LA)		
Ensuring Timely Access to Generics Act (S. 1169/H.R. 2455) Sen. Cory Gardner (R-CO)/Rep. John Joyce (R-PA)	*FDA Process Reform*	Permits FDA to reject citizen petitions if they believe that the primary purpose of the petition is to delay the approval of a drug application based on specific factors (e.g., appearance of a false date on a petition, submission of multiple petitions on issues that could have reasonably been known during earlier petitions, etc.); and permits FDA to establish a time period for petitions to be submitted/allows petitions outside that period to be denied.
Second Look at Drug Patents Act (S. 1617) Sen. Patty Murray (D-WA)	*FDA Process Reform*	Requires drug manufacturers submit all new patents to the U.S. Patent and Trademark Office within 30 days of FDA approval; and permits patents to be listed in the FDA's "Orange Book" (i.e., list of FDA approved drug products, etc.) on a provisional basis, unless the Patent Trial Appeal Board confirms the patent to be patentable or if the patent is not challenged within 300 days after the drug application is approved.
Affordable Insulin Approvals Now Act (S. 2103) Sen. Richard Durbin (D-IL)	*FDA Process Reform*	Requires FDA to continue reviewing generic insulin drug applications after FDA's planned cut-off date (March 2020).
Advancing Education on Biosimilars Act of 2019 (S.1681/H.R. 4400) Sen. Mike Enzi (R-WY)/Rep. Larry Bucshon (R-IN)	*FDA Process*	Requires FDA to establish a website to provide educational materials and other information regarding biological products for consumers and providers, including, among other things: • The FDA action package (e.g., documents related to the drug application approval such as the approval letter) for each biological product within 30 days of the drug application approval; • Review summary of each biological product within 48 hours of approval of the application; and • History and timing of manufacturing changes with respect to biological products.
Conditional Approval Act (S. 3133/H.R. 5497) Sen. Mike Braun (R-IN)/Rep. Bruce Westerman (R-AR)	*FDA Process*	Allows manufacturers to petition FDA for conditional approval of drugs that pass early clinical trials.
Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019 (H.R. 938)	*Market Competition*	Amends the FDA's market exclusivity rules by preventing generic drug manufacturers from "parking" applications (i.e., holding onto 180-day exclusivity in order to block other generic drugs from entering the market) and delaying the start of their exclusivity.

Legislation	Issue Area	Overview
Rep. Kurt Schrader (D-OR)		*March 27 – Approved by the Energy and Commerce Subcommittee on Health by voice vote.* *April 3 – Approved by the Energy and Commerce Committee by voice vote.*
Competitive Deals Resulting in Unleashed Generics and Savings (DRUGS) Act of 2019 (H.R. 1344) Rep. Lloyd Doggett (D-TX)	*Market Competition*	Eliminates tax benefits and deductions for prescription drug manufacturers of newly-approved, brand-name drugs that engage in pay-for-delay deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market).
Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (S. 340/H.R. 965) Sen. Patrick Leahy (D-VT)/Rep. David Cicilline (D-RI) Senate Summary	*Market Competition*	Aims to promote competition in the pharmaceutical drug market by (1) requiring brand name drug manufacturers to sell "sufficient quantities" at "commercially reasonable" prices to generic competitors who need samples for bioequivalency testing as part of the Abbreviated New Drug Applications; (2) creating a legal framework to provide generics with the ability to get injunctive relief faster from the courts; and (3) allowing judges to award payments to generics to deter anticompetitive behavior by brand name drug companies, among other things. *March 27 – H.R. 965 was approved by the Energy and Commerce Subcommittee on Health by voice vote.* *April 3 – H.R. 965 was approved by the Energy and Commerce Committee—as amended—by a vote of 51-0.* *April 30 – H.R. 965 was approved by the Judiciary Committee by voice vote.*
Fair Access for Safe and Timely (FAST) Generics Act of 2019 (H.R. 985) Rep. Peter Welch (D-VT)	*Market Competition*	Prohibits drug manufacturers from restricting access to reference products (i.e., products that are necessary to demonstrate a drug's sameness, biosimilarity or interchangeability) to develop drugs, generic drugs, or biosimilars, among other things.
Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act (S. 366/H.R. 1188) Sen. Richard Durbin (D-IL)/Rep. Jared Golden (D-ME)	*Market Competition*	Reduces a prescription drug's market exclusivity by 180 days if a drug manufacturer increases the wholesale acquisition cost of the drug by more than: (1) 10% over 1 year, (2) 18% over 2 years, or (3) 25% over 3 years; reduces the market exclusivity by an additional 30 days for every additional 5% increase; requires a drug manufacturer that increases the wholesale acquisition cost by such percentages to report the increase to HHS within 30 days; reduces a manufacturer's market exclusivity by 30 days each day that the manufacturer fails to report to HHS, among other things.

Legislation	Issue Area	Overview
Preserve Access to Affordable Generics and Biosimilars Act (S. 64) 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.
Protecting Consumer Access to Generic Drugs Act of 2019 (H.R. 1499) Rep. Bobby Rush (D-IL)	*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); retroactively penalizes manufacturers that engage in such deals, among other things. *April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.*
Protecting Access to Biosimilars Act (S. 1140/H.R. 2011) Sen. Tina Smith (D-MN)/Rep. Diana DeGette (D-CO)	*Market Competition*	Limits drug exclusivities for biological products, which codifies part of FDA's 2018 guidelines for biosimilars, among other things.
State-Based, Market-Oriented Prescription Drug Negotiations Act (H.R. 2038) Rep. Mark Meadows (R-NC)	*Market Competition*	Allows insurers and drug manufacturers to negotiate wholesale acquisition prices by creating a safe harbor from antitrust liability for private health insurers, as long as the wholesale acquisition price is jointly negotiated by the insurer and manufacturer.
Stop STALLING Act (S. 1224/H.R. 2374) Sen. Amy Klobuchar (D-MN)/Rep. Hakeem Jeffries (D-NY)	*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. *April 30 – H.R. 2374 was approved by the House Judiciary Committee by voice vote.* *June 27 – S. 1224 was approved, as amended, by the Senate Judiciary Committee.*
Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2375) Rep. Jerry Nadler (D-NY)	*Market Competition*	Authorizes the FTC to enforce penalties on drug and biologics manufacturers that engage in "pay-for-delay" deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market), among other things. *April 30 – Approved by the Judiciary Committee by voice vote.*

Legislation	Issue Area	Overview
Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act (H.R. 2700) Rep. Michael Burgess (R-TX)	*Market Competition*	Aims to improve generic drug competition, among other things, by: • Requiring FDA to make determinations for new drug applications within 180 days of certain conditions being met (i.e., at least 30 months have passed since the application was submitted); • Prohibiting filers of new drug applications and biologics license applications from entering into agreements on patent infringement if (1) a subsequent filer receives anything of value, including a drug license; and (2) a subsequent filer agrees to limit or forego research, development, manufacturing, marketing, or sales; • Authorizing the FTC to enforce and commence civil action for violators of such agreements; • Allowing drug manufacturers to bring civil action against a drug license holder if they fail to provide sufficient quantities of a drug (i.e., enough to conduct testing for a new drug application or fulfill any regulatory requirements relating to the approval of such application).
Affordable Prescriptions for Patients Act of 2019 (S. 1416) Sen. John Cornyn (R-TX)	*Market Competition*	Codifies the definitions of "product hopping" (i.e., holding onto 180-day exclusivity in order to block other generic drugs from entering the market) and "patent thicketing" (i.e., filing numerous patents on one drug to extend drug exclusivity); and authorizes the FTC to bring antitrust suits against drug manufacturers that attempt such anti-competitive activities. *June 27 – Approved unanimously, as amended, by the Senate Judiciary Committee.*
Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act (H.R. 3379) Rep. Jan Schakowsky (D-IL)	*Market Competition*	Reduces market exclusivity for biological products from 12 years to 5 years.
Ensuring Innovation Act (S.1636) Sen. Pat Roberts (R-KS)	*Market Competition*	Codifies FDA's guidance on granting exclusivities for "active moiety" in New Chemical Entity drug products (i.e., to prevent granting exclusivities to products that do not represent innovation and delay generics from entering the market).
Preserving Access to Cost Effective Drugs (PACED) Act (S. 440) Sen. Tom Cotton (R-AR)	*Market Competition*	Permits the U.S. Patent and Trademark Office and the International Trade Commission to review patents regardless of sovereign immunity claims made as part of sham transactions (i.e., patent holders that pay Indian tribes to take "ownership" of their patents, allowing the tribe to claim sovereign immunity in a dispute). *June 27 – Approved, as amended, by the Senate Judiciary Committee.*

Legislation	Issue Area	Overview
Emergency Access to Insulin Act (S. 2004) Sen. Tina Smith (D-MN)	*Market Competition*	Reduces market exclusivity periods for insulin and other biologics from 12 years to 7 years, among other things.
Star Rating for Biosimilars Act (S. /H.R. 4629) Sen. Bill Cassidy (R-LA)/Rep. Paul Tonko (D-NY)	*Market Competition*	Requires HHS to add new measures based on access to biosimilar biological products to the 5-star rating system under Medicare Advantage to incentivize the use of generics.
Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019 (H.R. 3991) Rep. Hank Johnson (D-GA)	*Market Competition*	Extends current patent infringement laws to any patent that claims a biological product, a method of using a biological product, and a method or product used to manufacture a biological product; and limits the number of patents that may be used to bring action on infringement, among other things. *November 20 – Approved by the House Judiciary Committee, as amended, by voice vote.*
Affordable Prescriptions for Patients Through Promoting Competition Act of 2019 (H.R. 4398/H.R. 5133) Rep. David Cicilline (D-RI)	*Market Competition*	Prohibits manufacturers from "price hopping" (i.e., marketing new and exclusively sold drugs when the patent on an existing drug is set to expire); and subjects manufacturers to judicial review for such anticompetitive practices. *November 20 – H.R. 5133 was approved by the House Judiciary Committee by voice vote.*
Expanding Access to Low-Cost Generics Act of 2019 (S. 3092) 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.
H.R. 107 Rep. Michael Burgess (R-TX)	*Medicaid Rebate*	Sunsets the current maximum rebate amount (100%) for outpatient Medicaid drugs by so that they apply only for rebate periods that begin between 2009 and 2020.
Right Rebate Act of 2019 (S. 205/H.R. 937)	*Medicaid Rebate*	Aims to prevent the misclassification of drugs under the Medicaid drug rebate program by: • Providing HHS with the authority to reclassify drugs/correct misclassifications, impose civil monetary penalties on

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Sen. Ron Wyden (D-OR)/Rep. Kurt Schrader (D-OR) Senate Summary		manufacturers that misclassify drugs, and recover incorrect/underpaid rebate payments; and • Creating oversight mechanisms for the program (e.g., manufacturer reports to HHS, HHS reports to Congress, etc.), among other things.
Fair and Accurate Medicaid Pricing (AMP) Act of 2019 (S. 1785/H.R. 3276) Sen. Maggie Hassan (D-NH)/Rep. Joe Kennedy (D-MA)	*Medicaid Rebate*	Excludes authorized generic drugs from the calculation of the average manufacturer price; and excludes manufacturers from the definition of wholesaler under the Medicaid drug rebate program.
Sustaining Excellence in Medicaid Act of 2019 (H.R. 3253) Rep. Debbie Dingell (D-MI)	*Medicaid Rebate*	Expands the payment methodology in cases where average sales price during first quarter sales is unavailable, among other things. *June 18 – Approved by the House, as amended, by a vote of 371-46.* *July 25 – Approved by the Senate, as amended, by voice vote.* *August 6 – Signed by the President and became Public Law No; 116-39.*
Stop Drug Companies from Overcharging Seniors in Medicare Part B Act of 2019 (S. 2081) Sen. Gary Peters (D-MI)	*Medicare Rebate*	Requires manufacturers to provide rebates for certain drugs covered under Medicare Part B (e.g., drugs for which the growth in average sales price has exceeded inflation).
Recovering Excessive Funds for Unused and Needless Drugs Act of 2019 (REFUND) Act of 2019 (H.R. 4178) Rep. Eliot Engel (D-NY)	*Medicare Rebate*	Requires manufacturers provide rebates to HHS for single-dose vial drugs under Medicare Part B.
Pharmaceutical Rebates for Excessive Pricing Above Inflation Act (H.R. 4619) Rep. Jan Schakowsky (D-IL)	*Medicare Rebate*	Requires manufacturers to provide rebates for certain drugs covered under Medicare Part D (e.g., drugs for which the growth in average sales price has exceeded inflation).

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Freedom from Price Gouging Act (H.R. 4663) Rep. Katie Porter (D-CA)	*Medicare Rebate*	Establishes a mandatory rebate for manufacturers of a single source or biological drug covered by Medicare Part B for prices that increase faster than inflation.
Empowering States to Address Drug Costs Act (S. 2252) Sen. Chris Van Hollen (D-MD)	*Medicaid Rebate*	Permits states to use drug price information (e.g., average manufacturer price, best price, and rebate calculation data) disclosed under the Medicaid Drug Rebate Program to establish rate setting entities (e.g., drug affordability boards) or multi-payer purchasing pools.
Chronic Care Management Improvement Act (H.R. 3436) Rep. Susan DelBene (D-WA)	*Medicare Part B*	Removes patient cost-sharing responsibilities for chronic care management services under Medicare Part B.
Bolstering Innovative Options to Save Immediately on Medicines (BIOSIM) Act (H.R. 4455) Rep. Kurt Schrader (D-OR)	*Medicare Part B*	Temporarily increases the reimbursement amount for biosimilar drugs under Medicare Part B from 6% to 8% for a period of five years.
Keeping Health Insurance Affordable Act of 2019 (S. 3) Sen. Ben Cardin (D-MD)	*Medicare Part D & Medicare Rebate*	Requires drug manufacturers to provide rebates to Medicare in a specific amount (i.e., equal to total number of units for form and strength of drug, etc.) to HHS for covered Medicare Part D drugs; authorizes HHS to negotiate drug prices with manufacturers, among other things.
Payment Commission Data Act of 2019 **(**S. 801/H.R. 1264/H.R. 1781) Sen. Catherine Cortez Masto (D-NV), Rep. Lloyd Doggett (D-TX), and Rep. Buddy Carter (R-GA)	*Medicare Part D & Medicaid Rebate*	Provides the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission with access to certain drug payment information for outpatient Medicare Part D & Medicaid drugs, including certain rebate information, among other things. *April 3 – H.R. 1781 was approved by the Energy and Commerce Committee—as amended—by voice vote.* *October 28 – H.R. 1781 was approved by the House—as amended—by voice vote.*

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Empowering Medicare Seniors to Negotiate Drug Prices Act (S. 62) Sen. Amy Klobuchar (D-MN)	*Medicare Part D*	Allows HHS to negotiate Medicare Part D prescription drug prices with drug manufacturers, PDP sponsors, and pharmacies.
Medicare Drug Price Negotiation Act (S. 99/H.R. 448) Sen. Bernie Sanders (D-VT)/Rep. Elijah Cummings (D-MD) Senate Summary	*Medicare Part D*	Directs HHS to negotiate Medicare Part D prescription drug prices; establishes "fallback prices" for drugs if HHS is unsuccessful in negotiating an appropriate price with the manufacturer; allows HHS to establish one national drug formulary for use by all PDP sponsors, among other things. *September 25 – A hearing was held on the legislation.*
Medicare Negotiation and Competitive Licensing Act of 2019 (S. 377/H.R. 1046) Sen. Sherrod Brown (D-OH)/Rep. Lloyd Doggett (D-TX)	*Medicare Part D*	Aims to lower Medicare Part D drug prices by: • Requiring HHS to negotiate Medicare Part D prescription drug prices with drug manufacturers; and • If the drug manufacturers refuse to negotiate in good faith, authorizing HHS to issue any patent, clinical trial data, or other competitive license to another entity who agrees to manufacture a generic version of the drug. *September 25 – A hearing was held on the legislation.*
Medicare Prescription Drug Negotiation Act of 2019 (H.R. 275) Rep. Peter Welch (D-VT)	*Medicare Part D*	Directs HHS to negotiate drug prices (including discounts, rebates and other price concessions) with manufacturers for covered Medicare Part D drugs, while maintaining the same rule for formularies; requires HHS to submit a report to Congress on the prices negotiated. *September 25 – A hearing was held on the legislation.*
Reducing Existing Costs Associated with Pharmaceuticals for Seniors (RxCap) Act of 2019 (S. 475) Sen. Ron Wyden (D-OR)	*Medicare Part D*	Eliminates the prescription drug cost-sharing requirement for seniors eligible under Medicare Part D.
Improving Transparency and Accuracy in Medicare Part	*Medicare Part D*	Prohibits PDP sponsors and MA-PD organizations from retroactively reducing payments on clean claims (i.e., a Medicare claim

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D Spending Act (S. 988/H.R. 789/H.R. 803) Sen. Shelley Moore Capito (R-WV)/Rep. Peter Welch (D-VT)		that is free of defects such as incomplete documentation) submitted by pharmacies.
Creating Lower Cost Alternatives for Your Prescription Drugs (CLAY) Act (H.R. 2757) Rep. Joe Cunningham (D-SC)	*Medicare Part D*	Reduces generic drug cost-sharing to $1 or less and all other prescription drugs to $3 or less for low-income subsidy beneficiaries of Medicare Part D; eliminates all prescription drug cost-sharing for such beneficiaries beginning in 2021.
Medicare Prescription Drug Fraud Prevention Act of 2019 (S. 1505) Sen. John Cornyn (R-TX)	*Medicare Part D*	Requires prescription drug plans and MA-PD plans to report to HHS potential fraud, waste, and abuse of Medicare Part D benefits.
Improving Low-Income Access to Prescription Drugs Act of 2019 (H.R. 3029) Rep. Pete Olson (R-TX)	*Medicare Part D*	Permanently authorizes the Limited Income Newly Eligible Transition Program, which provides temporary prescription drug coverage for low-income beneficiaries who have not yet enrolled in a prescription drug plan or an MA-PD plan, or who has enrolled but the plan has not yet taken effect; permits HHS to waive certain eligibility requirements to carry out the program.
Streamlining Part D Appeals Process Act (S. 1861/H.R. 3924) Rep. Ben Cardin (D-MD)/Rep. Thomas Suozzi (D-NY)	*Medicare Part D*	Qualifies a pharmacy's refusal to fill a prescription as coverage determination for the Medicare Part D appeals process.
Fair Choices for Medicare Beneficiaries Act of 2019 (H.R. 3421) Rep. Jimmy Gomez (D-CA)	*Medicare Part D*	Appropriates $15 million for each fiscal year of 2020 – 2022 towards outreach and assistance for low-income programs for prescription drug plans under Medicare Part D and MA-PD plans.
Real-Time Beneficiary Drug Cost Bill/Ship Rx Act of 2019	*Medicare Part D*	Codifies a provision of HHS' proposed rule that requires prescription drug plan sponsors include real-time benefit information as

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(H.R.3415/H.R. 3408) Rep. Elissa Slotkin (D-MI)/Rep. Jodey Arrington (R-TX)		part of such sponsor's electronic prescription program under Medicare Part D, including: • A description of any alternative drugs that are included in the plan's formulary; • Applicable cost-sharing requirements for covered drugs and alternatives, including a description of any variance based on the pharmacy dispensing such drug or alternative; and • Applicable prior authorization or other utilization management requirements for any drug in the plan's formulary.
Improving Low Income Access to Prescription Drugs Act of 2019 (S. 1999) Sen. Bob Casey (D-PA)	*Medicare Part D*	Provides transitional and retroactive Medicare Part D prescription drug coverage for certain low-income beneficiaries.
Capping Drug Costs for Seniors Act (H.R. 4649) Rep. Steven Horsford (D-NV)	*Medicare Part D*	Limits out-of-pocket costs to $2,000 on Medicare Part D prescription drugs for beneficiaries and expands the current Medicare coverage gap discount program, among other things.
Medicare Prescription Drug Savings and Choice Act (S. 2650/H.R. 4769) Sen. Richard Durbin (D-IL)/Rep. Jan Schakowsky (D-IL)	*Medicare Part D*	Requires HHS offer a Medicare operated prescription drug plan; and requires HHS negotiate with manufacturers the prices of drugs covered by Medicare Part D under such plan, among other things.
Ensuring Access to Lower-Cost Medicines for Seniors Act (H.R. 4913) Rep. David McKinley (R-WV)	*Medicare Part D*	Requires Medicare PDP sponsors that use a formulary to include certain generic drugs and biosimilar biological products (e.g., a generic drug with a wholesale acquisition cost that is less than the FDA listed drug) on such formulary; prohibits such PDP sponsors from limiting access to generic drugs on the formulary; and requires such PDP sponsors to have at least one cost-sharing tier on their formulary for certain generic drugs, among other things.
Legalizing Drug Discounts for Seniors Act of 2020 (S. 4274) Sen. Rand Paul (R-KY)	*Medicare Part D*	Amends anti-kickback statutes to eliminate the prohibition of certain discounts for drugs covered by Medicare Part D.
Strengthening Average Sales Price Reporting Act of 2019	*Medicare Part D*	Requires manufacturers without rebate agreements to report to HHS the average sales price and wholesale acquisition cost of drugs

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(S. 2051) Sen. Bob Menendez (D-NJ)	*Limited Transparency Requirements*	covered under the Medicare Program; subjects a wholesaler, manufacturer, or direct seller to a civil monetary penalty not to exceed $100,000 if they refuse to provide the information.
Right Price for Medicare Act (S. __) Sen. Bill Cassidy (R-LA)	*Medicare Part D Limited Transparency Requirements*	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)).
Transparency for Pharmacists Act (S. __) Sen. Bill Cassidy (R-LA)	*Medicare Part D Limited Transparency Requirements*	Requires HHS to develop a standard set of quality metrics for contracts between pharmacies and plans offering Medicare Part D coverage, in consultation with relevant stakeholders (e.g., PDP sponsors of prescription drug plans, Medicare Advantage organizations offering MA-PD plans, PBMs, etc.).
We Protect American Investment in Drugs Act (S. 2387) Sen. Chris Van Hollen (D-MD)	*Pricing*	Establishes the Drug Affordability and Access Committee; requires the Committee make reasonable pricing determinations for prescription drugs and recommend them to drug manufacturers; requires manufacturers that are entering into a partial or exclusive licensing agreement to limit the annual price increase on such drug to the percentage of the medical care consumer price index for urban consumers; and requires such manufacturers submit certain drug pricing information (i.e., list price, retail price, annual expenditures, etc.) to the Committee on a "good faith timeline."
Closing Loopholes for Orphan Drugs Act (H.R. 4538) Rep. Peter Welch (D-VT)	*Pricing*	Limits the exclusion of "orphan drugs" under the 340B Drug Discount Program to only apply when a drug is transferred, prescribed, sold, or otherwise used for a rare condition or disease for which the drug is designated.
Prescription Drug Rebate Reform Act of 2019 (S. 1384/H.R. 3805) Sen. Mitt Romney (R-UT)/Rep. Mike Gallagher (R-WI)	*Pricing/Rebates*	Requires patient coinsurance obligations be based on the net price of the prescription drug, rather than list price, before or after a deductible is met.
End Price Gouging for Medications Act (S. 1987/H.R. 3523)	*Reference-Based Pricing*	Requires HHS to annually establish reference prices for all prescription drugs (both brand name and generic) by determining the median retail list price for the available drug for at least three of the "reference countries" in which the drug is available (i.e.,

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Sen. Jeff Merkley (D-OR)/Rep. Peter Welch (D-VT)		Australia, Canada, France, Germany, Italy, Japan, the Netherlands, Spain, Sweden, Switzerland, and the U.K.); applies such reference prices to covered inpatient/outpatient drugs under Medicare, Medicaid, CHIP, TRICARE, FEHBP, and other federal programs; and requires manufacturers to offer drugs at the reference-based price (i.e., prohibits manufacturers from having the total acquisition cost of the drug exceed the reference price for the drug) to insured and uninsured individuals alike, as a condition for receiving reimbursement under federal programs; and subjects noncompliant drug manufacturers to a civil penalty.
Pharmacy Benefit Managers Accountability Study Act of 2019 (S. 1532/H.R. 3223) Sen. Marsha Blackburn (R-TN)/Rep. Roger Marshall (R-KS)	*Limited PBM Transparency Requirements*	Requires GAO to provide a study with legislative recommendations to Congress, including, among other things: • The role of PBMs in the pharmaceutical supply chain; • State of competition among PBMs and market share of the 10 largest PBMs; • Use of rebates and fees, including, for each drug in the formularies of the 10 largest PBMs, the amount of the rebate passed on to patients and payers, the amount kept by PBMs, and the role of fees charged by the PBM; • Structuring formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives; • Average prior authorization approval time for the 10 largest PBMs; and • Factors affecting the use of step therapy for the 10 largest PBMs.
Drug Price Transparency in Medicaid Act of 2019 (H.R. 5281) 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; • 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.
Prescription Drug Pricing Dashboard Act (S. 709) Sen. Bob Casey (D-PA)	*Limited Transparency Requirements*	Requires HHS to establish, annually update, and make publicly available an internet website-based dashboard on the price and utilization of prescription drugs purchased by federal programs, among other things.

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Transparent Drug Pricing Act (S. 977) Sen. Rick Scott (R-FL)	*Limited Transparency Requirements*	Requires pharmacists disclose to customers at the point of sale a customer's out-of-pocket cost with respect to such drug and the cost of the drug without using the health plan; requires insurers credit the full amount of out-of-pocket costs for prescription drugs towards deductibles; requires insurers publish a list of copayment amounts 60 days before each annual enrollment period; prohibits insurers from changing copayment amounts until the next plan year; requires insurers provide a mechanism enabling enrollees to determine their projected total out-of-pockets costs for each prescription drug covered; and prohibits the retail list price of an FDA-approved drug from exceeding the lowest retain price for the same drug in Canada, France, the United Kingdom, Japan, or Germany (this requirement would sunset after 5 years).
Sunshine for Samples Act of 2019 (H.R. 2064) Rep. Judy Chu (D-CA)	*Limited Transparency Requirements*	Requires manufacturers of certain drugs, devices, biologics, or medical supplies to annually report the total aggregate value/quantity of samples provided to certain health care providers; requires the report information be publicly available on a website that can be easily understood, searched, and downloaded, among other things. *May 21 – A hearing was held on the legislation.*
Prescription Pricing for the People Act of 2019 (S. 1227/H.R. 2376) Sen. Chuck Grassley (R-IA)/Rep. Doug Collins (R-GA)	*Limited Transparency Requirements*	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. *April 30 – H.R. 2376 was approved by the House Judiciary Committee by voice vote.* *May 21 – H.R. 2376 was considered in a hearing by the House Energy and Commerce Subcommittee on Health.* *June 27 – S. 1227 was approved, as amended, by the Senate Judiciary Committee.*
Drug-price Transparency in Communications (DTC) Act (S. 1437) 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.
Health Care Price Check Act of 2019 (S. 1497) Sen. Ron Wyden (D-OR)	*Limited Transparency Requirements*	Requires group and individual health plan insurers that have a contract with another entity that offers prescription drug management services to establish a toll-free telephone number for enrollees to directly receive information regarding the out-of-pocket costs for a covered prescription drug, including the variations in out-of-pocket-costs by: • Pharmacy options (e.g., preferred pharmacy, mail order, and other pharmacies in a designated geographic area); and

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		• Generics or other therapeutically equivalent alternatives.
H.R. 3327 Rep. Francis Rooney (R-FL)	*Limited Transparency Requirements*	Requires direct-to-consumer television advertisements for prescription drugs and biological products to disclose list prices for a 30-day supply or typical course of treatment, unless the current list price is less than $35 per month; and requires HHS maintain a public list of such prescription drugs that are required to disclose their list prices.
Responsibility in Drug Advertising Act of 2019 (S. 3180/H.R. 4106) Sen. Angus King (I-ME)/Rep. Rosa DeLauro (D-CT)	*Limited Transparency Requirements*	Prohibits direct-to-consumer prescription drug advertising within the first three years of a drug application being approved, unless a waiver is issued by FDA for such drug application; and allows FDA to prohibit any direct-to-consumer drug advertising for drugs that it determines has significant adverse health effects.
Affordable Pricing for Taxpayer-Funded Prescription Drugs Act of 2019 (H.R. 4640) Rep. Peter DeFazio (D-OR)	*Limited Transparency Requirements*	Requires federal agencies and non-profit entities conducting research and development or providing a patent for a drug, biologic, or other health care technology, to sign a reasonable pricing agreement with HHS prior to conducting such activity.
Patients' Right to Know Their Medication Act of 2019 (H.R. 5198) Rep. Jared Golden (D-ME)	*Limited Transparency Requirements*	Requires manufacturers provide hard copies of certain prescription drug information to consumers.
Transparency in Prescription Drug Advertising Act (H.R. 5894) Rep. Sharice Davids (D-KS)	*Limited Transparency Requirements*	Requires HHS to issue guidance requiring the list prices of drugs to be included in all drug advertising media (e.g., advertisements on television, newspaper, internet, etc.).
Affordable Drug Manufacturing Act of 2019 (S. 3162/H.R. 5501) Sen. Elizabeth Warren (D-MA)/Rep. Jan Schakowsky (D-IL)	*Public Prescription Drug Manufacturing*	Establishes the Office of Drug Manufacturing within HHS to, among other things: • Manufacture certain generic prescription drugs (i.e., "applicable drugs" that are not currently manufactured or for which the patent has expired; those that have expired exclusivity periods; those not marketed in the U.S., etc.) and drugs the federal government has licensed; • Sell publicly-manufactured drugs at a "fair price;"

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		• Manufacture/sell "active pharmaceutical ingredients; and • Sell rights to "applicable drugs" to manufacturers under certain circumstances.