

2019 Federal Drug Pricing Legislation

Newly Included Legislative and Procedural Updates

Legislative Updates

- September 19: Rep. Frank Pallone (D-NJ) introduced the Lower Drug Costs Now Act of 2019 ([H.R. 3, Speaker Pelosi's Drug Plan](#)), which establishes a drug price negotiation program, limits price hikes for Medicare Part B and D program drugs, and caps out-of-pocket costs for Medicare Part D enrollees, among other things.

I. Single-Issue Legislation (116th Congress - 2019) (*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
<p><i>Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019 (S. 474)</i></p> <p>Sen. Ron Wyden (D-OR)</p>	<p>Requires manufacturers of certain drugs to publicly report/justify significant price increases and other attendant costs to HHS.</p>	<p>Imposes reporting obligations on manufacturers of FDA-approved, prescription, “applicable drugs”—as determined by HHS—that:</p> <ul style="list-style-type: none"> • Have a wholesale acquisition cost of at least \$10 per dose; <u>and</u> • 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; <u>or</u> • Are in the top 50th percentile of net spending in Medicare or Medicaid in the past 5 years; <u>and</u> • Had an increased wholesale acquisition cost of at least 50% in the past 5 years or 15% over 1 year. <p>Allows HHS to identify a drug with a price increase within a <i>de minimis</i> range of the percentages listed.</p>	<p><i>HHS.</i> Requires HHS to notify the manufacturer within <u>60 days</u> of its determination that a drug is considered an “applicable drug” (and therefore is subject to reporting requirements).</p> <p><i>Manufacturers.</i> Requires manufacturers to submit a justification of the applicable drug’s price increase within <u>180 days</u> of HHS’ notification that the drug qualified as an applicable drug.</p> <p><i>Exceptions.</i> Does <u>not</u> 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.</p>	<p>Requires manufacturers’ reports to include all relevant information/supporting documentation necessary to justify the increase, which may include:</p> <ul style="list-style-type: none"> • 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.). 	<p>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.</p> <p>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.</p>	<p><i>Publication of Manufacturer Data.</i> Requires HHS to post the justification and an easily-understandable summary of the justification publicly on the CMS website within <u>30 days</u> of receiving the justification.</p>
<p><i>Stopping the Pharmaceutical Industry from</i></p>	<p>Requires manufacturers to publicly</p>	<p><i>Beginning in 2021</i>, requires manufacturers to justify (via report and summary) if there is</p>	<p><i>HHS.</i> Requires HHS to notify the manufacturer within <u>60 days</u> of its</p>	<p>Requires manufacturers’ reports to include all relevant information/supporting</p>	<p><i>Manufacturers.</i> If a manufacturer fails to submit a</p>	<p><i>Publication of Manufacturer Data.</i> Requires HHS to post the</p>

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<p><i>Keeping Drugs Expensive (SPIKE) Act of 2019 (H.R. 2069)</i></p> <p>Rep. Steven Horsford (D-NV)</p> <p><i>May 21 – A hearing was held on the legislation.</i></p>	<p>disclose/justify “SPIKE” increases in drug prices.</p>	<p>a triggered “SPIKE” increase in a covered outpatient drug for which:</p> <ul style="list-style-type: none"> • 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. <p><i>Exclusions.</i> Does <u>not</u> 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.</p>	<p>determination that there is a triggering SPIKE increase with respect to a drug.</p> <p><i>Manufacturers.</i> Requires manufacturers to submit a justification and associated summary of the triggered SPIKE increase within <u>90 days</u> of HHS’ notification.</p> <p><i>Exceptions.</i> Does <u>not</u> require a justification for a triggered “SPIKE” increase if a justification has already been made by the manufacturer within the applicable look-back period.</p>	<p>documentation necessary to justify the increase, which <u>must</u> include:</p> <ul style="list-style-type: none"> • The factors that contributed to the increase; and • An explanation of how each factor contributed to the increase. <p>Requires reports to further include—as applicable—the following information/supporting documentation:</p> <ul style="list-style-type: none"> • 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. 	<p>required justification, subjects them to a penalty of \$10,000 per day for each day that the report is not submitted.</p> <p>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.</p>	<p>easily-understandable summary of the justification publicly on the CMS website within <u>30 days</u> of receiving the justification.</p> <p>Contains other provisions governing:</p> <ul style="list-style-type: none"> • 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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				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.		
<p><i>Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act (H.R. 2113)</i></p> <p>Rep. Richard Neal (D-MA)</p> <p>House Summary</p> <p><i>April 9 – Approved unanimously by the Ways and Means Committee, as amended.</i></p>	<p>Requires manufacturers to publicly disclose/justify “SPIKE” increases in drug prices, among other things.</p>	<p><i>Similar to the House version of the SPIKE Act of 2019.</i></p> <p><i>Beginning in 2021</i>, requires manufacturers to justify (via report and summary) if there is a triggered “SPIKE” increase in a covered outpatient drug for which:</p> <ul style="list-style-type: none"> • 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. <p><i>Exclusions.</i> Does <u>not</u> apply to “low cost” drugs with a wholesale acquisition cost of less than \$10 per unit or less</p>	<p><i>Similar to the House version of the SPIKE Act of 2019.</i></p> <p><i>HHS.</i> Requires HHS to notify the manufacturer within <u>60 days</u> of its determination that there is a triggering SPIKE increase with respect to a drug.</p> <p><i>Manufacturers.</i> Requires manufacturers to submit a justification and associated summary of the triggered SPIKE increase within <u>90 days</u> of HHS’ notification.</p> <p><i>Exceptions.</i> Does <u>not</u> require a justification for a triggered “SPIKE” increase if:</p> <ul style="list-style-type: none"> • 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 <u>not</u> higher than the drug price if adjusted/indexed for inflation. 	<p><i>Similar to the House version of the SPIKE Act of 2019.</i></p> <p>Requires manufacturers’ reports to include all relevant information/supporting documentation necessary to justify the increase, which <u>must</u> include:</p> <ul style="list-style-type: none"> • The factors that contributed to the increase; and • An explanation of how each factor contributed to the increase. <p>Requires reports to further include—as applicable—the following information/supporting documentation:</p> <ul style="list-style-type: none"> • 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 	<p><i>Similar to the House version of the SPIKE Act of 2019.</i></p> <p><i>Manufacturers.</i> 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.</p> <p>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.</p>	<p><i>Publication of Manufacturer Data.</i> Requires HHS to post the easily-understandable summary of the justification publicly on the CMS website within <u>30 days</u> of receiving the justification.</p> <p><i>Similar to the House version of the SPIKE Act of 2019.</i></p> <p><i>Rebates. Beginning in 2020</i>, requires HHS to post the aggregate rebates, discounts, and other price concessions achieved by PBMs (e.g., generic dispensing rates) on the CMS website. <i>Similar to the Public Disclosure of Drug Discounts Act and the C-THRU Act of 2019.</i></p> <p>Contains other provisions governing:</p> <ul style="list-style-type: none"> • Public posting by HHS of other metrics that could increase the number of drugs for which a triggered

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		<p>than \$100 in average estimated expenditures per individual per year.</p>		<p>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</p> <ul style="list-style-type: none"> Any other relevant information/supporting documentation necessary to justify the triggering SPIKE increase or as specified by HHS. <p>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.</p>		<p>SPIKE increase would occur, among other things. <i>Similar to the House version of the SPIKE Act of 2019.</i></p> <ul style="list-style-type: none"> Reporting by manufacturers 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. <i>Similar to the Sunshine for Samples Act of 2019.</i> 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). <i>Similar to the Reporting Accurate Drug Prices Act of 2019.</i>

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<p>Drug Pricing Transparency Act (H. R. 2087)</p> <p>Rep. Lloyd Doggett (D-TX)</p> <p><i>May 21 – A hearing was held on the legislation.</i></p>	<p>Requires manufacturers of certain drugs <i>without</i> a Medicare rebate agreement to report drug pricing information to HHS.</p>	<p>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) <i>without</i> a Medicare rebate agreement to report drug pricing information to HHS.</p>	<p>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.</p> <p>HHS. Requires HHS to submit a report to Congress regarding the accuracy of average sales price information submitted by manufacturers.</p>	<p>Manufacturers. Requires manufacturers of certain drugs without a Medicare rebate agreement to report the following information:</p> <ul style="list-style-type: none"> • 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. 	<p>Manufacturers. Subjects wholesalers, manufacturers, or direct sellers who refuse to comply with HHS’ request for information to a \$100,000 civil monetary penalty.</p> <p>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.</p> <p>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.</p>	<p>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).</p>
<p>Fair Accountability and Innovative Research (FAIR) Drug</p>	<p>Requires manufacturers of certain drugs to submit</p>	<p>In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved “qualifying drugs” that:</p>	<p>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</p>	<p>Requires manufacturers’ reports to, at a minimum, include specific information on both the qualifying drug <u>and</u> the manufacturer.</p>	<p>Subjects a manufacturer of a qualifying drug that fails to submit a required report to a</p>	<p>Publication of Manufacturer Data. Requires HHS to post, in a user-friendly manner, publicly on its website,</p>

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<p>Pricing Act of 2019 (S.1391/H.R. 2296)</p> <p>Sen. Tammy Baldwin (D-WI)/Rep. Jan Schakowsky (D-IL)</p> <p><i>July 17 – House version was approved by the House Energy and Commerce Committee, as amended, by voice vote.</i></p> <p><i>July 11 – House version was approved by the House Energy and Commerce Subcommittee on Health, as amended, by voice vote.</i></p> <p><i>May 21 – A hearing was held on the house version.</i></p>	<p>justifications of price increases and other attendant costs to HHS prior to increasing the price of such drugs.</p>	<ul style="list-style-type: none"> • 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) <u>or</u> 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; <u>and</u> • Earn at least \$1 of their total sales from individuals enrolled in Medicare or Medicaid programs. 	<p>acquisition cost of a drug that is equal to:</p> <ul style="list-style-type: none"> • 10% or more over a 12-month period; or • 25% or more over a 36-month period. <p>Requires such reports to be submitted to HHS at least <u>30 days</u> before the planned effective date of the price increase.</p> <p><i>HHS.</i> Requires HHS to submit an annual report to Congress that</p> <ul style="list-style-type: none"> • Summarizes the information reported by the manufacturer; <u>and</u> • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. 	<p><i>Qualifying Drug.</i> Requires the report to include:</p> <ul style="list-style-type: none"> • 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; and • The total marketing and advertising costs. <p><i>Manufacturers.</i> Requires the report to include:</p> <ul style="list-style-type: none"> • 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 	<p>penalty of \$100,000 for each day that the report fails to be submitted.</p>	<p>the report submitted by manufacturers no later than <u>30 days</u> after the report has been received.</p>

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				of drugs that failed to receive FDA-approval, etc.); and <ul style="list-style-type: none"> Any other information requested by HHS. 		
<p>Prescription Drug Price Reporting Act (S. 1664) Sen. Rick Scott (R-FL)</p>	<p>Requires drug manufacturers annually report to HHS certain drug pricing information.</p>	<p>All prescription drugs marketed in the U.S.</p>	<p><i>Manufacturers.</i> Requires manufacturers of all drugs marketed in the U.S. to annually report to HHS.</p> <p>Requires manufacturers of newly marketed drugs to report the drug code to HHS within 60 days and provide the annual reporting information within the 30 days of the first annual reporting date.</p> <p>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.</p> <p><i>HHS.</i> 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.</p>	<p><i>Manufacturers.</i> Requires the annual report to include:</p> <ul style="list-style-type: none"> 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; Total rebates and other payments to health insurance plans or PBMs per 30-day supply or typical course of treatment <p><i>Price Changes.</i> 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.</p>		<p><i>Preemption.</i> Prohibits states from establishing or continuing to give effect to any law requiring the manufacturer to report or make public prescription drug pricing information.</p> <p><i>Consumer Notification.</i> Permits consumers to subscribe to price change notifications for:</p> <ul style="list-style-type: none"> All drugs; A particular drug; A particular therapeutic class of drugs; and A specified amount or limit to price changes.

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<p>Lower Drug Costs Now Act of 2019 (H.R. 3)</p> <p>Rep. Frank Pallone (D-NJ)</p> <p>Speaker Pelosi's Drug Plan</p>	<p>Establishes the Fair Price Negotiation 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</p>	<p>All prescription drugs marketed in the U.S.</p>	<p><i>HHS.</i> 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).</p> <p>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.).</p> <p>Requires HHS annually publish a list of the maximum fair prices for each negotiated drug.</p>	<p><i>Manufacturers.</i> Requires manufacturers in the negotiation to report to HHS the following information, among other things:</p> <ul style="list-style-type: none"> • 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. 	<p><i>Manufacturers.</i> If a manufacturers charges more than the maximum fair price, subjects manufacturers to a civil monetary penalty.</p> <p>If a manufacturer refuses to enter into negotiations after being selected by HHS, or if the manufacturer leaves the negotiation before 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.</p>	<p><i>Manufacturers.</i> 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).</p> <p><i>Medicare Part D. Beginning in 2022,</i> caps out-of-pocket costs at \$2,000 for Medicare Part D enrollees and incorporates other provisions aimed at modernizing Medicare Part D, including:</p> <ul style="list-style-type: none"> • Establishing a manufacturer discount program; and • Phasing out the coverage gap discount program to include three phases: deductible, initial coverage, and catastrophic.

Prescription Drug Importation Legislation

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<p><i>Affordable and Safe Prescription Drug Importation Act</i> (S. 97/H.R. 447)</p> <p>Sen. Bernie Sanders (I-VT)/Rep. Elijah Cummings (D-MD)</p> <p>Senate Summary</p>	<p>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).</p>	<p>Allows the importation of drugs from Canada, provided they:</p> <ul style="list-style-type: none"> • 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); <u>and</u> • Is labeled in English (and in accordance with all other requirements promulgated by HHS). <p>Does <u>not</u> include:</p> <ul style="list-style-type: none"> • A controlled substance. 	<p><i>Certified Foreign Sellers.</i> 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.</p> <p><i>Individuals.</i> Allows individuals to import a qualifying prescription drug from Canada (or another country) if it is:</p> <ul style="list-style-type: none"> • 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 do not exceed a 90-day supply; <u>and</u> 	<p><i>Importers.</i> Requires importers to submit biannual reports to HHS on each qualifying prescription drug imported into the U.S. that contains:</p> <ul style="list-style-type: none"> • 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. <p><i>HHS.</i> Requires HHS to submit a report one year after the program’s</p>	<p><i>Unfair and Discriminatory Acts and Practices.</i> Prohibits a manufacturer from:</p> <ul style="list-style-type: none"> • 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. <p><i>Suspension of Importation.</i> Grants HHS the authority to suspend or</p>	<p><i>Preemption.</i> Does not supplant or preempt state or other federal laws.</p> <p><i>Publication of Certified Foreign Sellers.</i> Requires HHS to publish online a list of certified foreign sellers, including web addresses, physical addresses, and telephone numbers of such sellers.</p> <p><i>Drug Testing Laboratories.</i> Authorizes HHS to approve laboratories to conduct random testing of prescription drugs sold by certified foreign sellers and assess the drugs’ chemical authenticity.</p>

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
		<ul style="list-style-type: none"> An anesthetic drug inhaled during surgery. A compounded drug. 	<ul style="list-style-type: none"> 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. <p><i>Restrictions.</i> Currently limited to drugs being imported from Canada, <u>but</u> authorizes HHS (after reviewing the cost savings and increased access) to expand the program to include any country that:</p> <ul style="list-style-type: none"> Is an OECD member; Has standards for the approval and sale of prescription drugs that are comparable to U.S. standards; <u>and</u> Meets certain other criteria (e.g., authorizes approval of a drug only if a drug is deemed safe and effective by government experts, etc.). 	<p>effectuation (and every two years thereafter) on the importation of drugs into the U.S.</p> <p><i>GAO.</i> 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).</p>	<p>temporarily suspend importation of a product (or suspend all products from a certified foreign seller or importer) if there is an importation involving</p> <ul style="list-style-type: none"> Counterfeit drugs, Drugs that have been recalled/withdrawn, or Drugs otherwise in violation of the bill <p>until an investigation is completed and it is determined that the drug, seller, or importer does not endanger the public health.</p> <p><i>Penalties.</i> 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.</p>	<p><i>Supply Chain Security.</i> (Generally) requires certified foreign sellers to purchase drugs from registered manufacturers or entities, <u>unless</u> HHS has entered into an MOU with Canada (or the permitted country).</p>
<p><i>Safe and Affordable Drugs from Canada Act of 2019</i> (S. 61/H.R. 478)</p>	<p>Requires HHS to promulgate regulations allowing individuals to import certain drugs from approved Canadian pharmacies.</p>	<p>Authorizes HHS to promulgate regulations allowing the importation of drugs from Canada, provided they:</p> <ul style="list-style-type: none"> Are purchased from an approved Canadian pharmacy; Are dispensed by a pharmacist licensed to practice pharmacy and 	<p>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:</p> <ul style="list-style-type: none"> Located in Canada; 			<p><i>Publication of Approved Canadian Pharmacies.</i> In conjunction with the regulations, requires HHS to publish on its website a list of approved Canadian</p>

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
<p>Sen. Chuck Grassley (R-IA)/Rep. Chellie Pingree (D-ME)</p>		<p>dispense prescription drugs in Canada;</p> <ul style="list-style-type: none"> • 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.; <u>and</u> • Have the same active ingredient(s), route of administration, dosage form, and strength as prescription drugs approved by the FDA. <p>Does <u>not</u> include:</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 			<p>pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may purchase prescription drugs.</p>

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
		therapeutic recombinant DNA-derived product, etc.). <ul style="list-style-type: none"> A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding. A photoreactive drug. 				
<p>Short on Competition Act (S. 844)</p> <p>Sen. Amy Klobuchar (D-MN)</p>	<p>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).</p> <p>Gives the FDA explicit authority to allow temporary importation from certain countries when HHS determines there is a drug shortage.</p>	<p>In the event of a drug shortage, authorizes the importation of certain drugs if they:</p> <ul style="list-style-type: none"> Are prescription drug products (i.e., subject to section 503(b) of the FDCA); 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; <u>and</u> Will be subject to certain notification and reporting requirements. 	<p>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).</p>	<p><i>Manufacturers.</i> Requires manufacturers to certify to HHS that they intend to seek approval of the drug.</p> <p><i>Importers.</i> Requires importers to file with HHS information:</p> <ul style="list-style-type: none"> 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; <p><i>HHS.</i> Requires HHS to include information on the number of drugs authorized for temporary</p>	<p><i>Denial of Importation.</i> Authorizes HHS to deny importation of an otherwise qualified drug if it is determined that:</p> <ul style="list-style-type: none"> 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. 	<p><i>Marginally-Competitive Markets.</i> If a marginally-competitive market exists with respect to an applicable drug (i.e., <u>not</u> a radio pharmaceutical drug product), authorizes HHS to:</p> <ul style="list-style-type: none"> Treat the marginally-competitive market³ as creating a drug shortage; Expedite the review of applications and inspections with respect to the drug; and Authorize the importation of the drug.

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
				importation in its annual report to Congress.		

Price Gouging Legislation

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
<p><i>Combating Unreasonable Rises and Excessively (CURE) High Drug Prices Act</i> (S. 637/H.R. 4158)</p> <p>Sen. Richard Blumenthal (D-CT)/Rep. Chellie Pingree (D-ME)</p> <p>Senate Summary</p>	<p>Requires prescription drug manufacturers to justify a price increase in “qualifying drugs” (i.e., prescription drugs covered by federal health care programs) that HHS deems to constitute “price gouging.”⁴</p>	<p><i>HHS.</i> Requires HHS to notify manufacturers—and request a statement of justification—if it determines that certain price increases within the last <u>2 years</u> constitute “price gouging.”</p> <p>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.</p> <p><i>Manufacturers.</i> If a notification is received by a manufacturer, requires the manufacturer to provide a statement of justification for the price increase within <u>45 days</u> of receiving the notification.</p>	<p><i>Manufacturers.</i> Provides that the required statement of justification for a price increase may include:</p> <ul style="list-style-type: none"> • Itemizing the components of the cost of producing the qualifying drug; • Identifying the circumstances and timing of: <ul style="list-style-type: none"> - An increase in materials/manufacturing costs that caused the price increase within 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. 		<p><i>HHS.</i> Authorizes HHS to require a manufacturer found to have engaged in price gouging to:</p> <ul style="list-style-type: none"> • Reimburse consumers and third-party payors; • Return to the original price 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. <p><i>DOJ.</i> Authorizes the Attorney General to bring an action in a district court for relief in certain circumstances.</p>	

⁴ 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.

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
<p>Prescription Drug Price Relief Act of 2018 (S. 102/ H.R. 465)</p> <p>Sen. Bernie Sanders (I-VT)/Rep. Ro Khanna (D-CA)</p> <p>Senate Summary</p>	<p>Requires HHS to annually identify “excessively priced” patented, brand name drugs⁵ that are being sold at prices higher than the median price in so-called “reference countries” (i.e., Canada, the U.K., Germany, France, and Japan).</p> <p>Authorizes HHS to approve cheaper generic versions of those drugs, if manufacturers refuse to lower the price of drugs to the median price.</p>	<p><i>Manufacturers.</i> Requires manufacturers to submit annual reports (January 15) on pricing information for each brand name drug (and as compared to prices in reference countries).</p> <p><i>HHS.</i> Requires HHS to annually report to Congress on its excessive drug price review for the preceding calendar year.</p> <p>Requires such reports to be made publicly available on the FDA website in a manner that is easy to find and understand.</p>	<p><i>Manufacturers.</i> Requires manufacturers to submit annual reports containing the following information on brand name drugs:</p> <ul style="list-style-type: none"> • 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; • 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. <p><i>HHS.</i> Requires HHS’ annual report to contain summary data regarding:</p> <ul style="list-style-type: none"> • 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); 		<p><i>Manufacturers.</i> Subjects manufacturers that fail to submit their annual reports to a civil penalty that is equal to the product of:</p> <ul style="list-style-type: none"> • An amount determined by HHS that is (1) not less than 0.5% of the gross revenues from sales of the drug for the calendar year; <u>and</u> (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; <u>and</u> • The number of days in the period between (1) the annual submission deadline <u>and</u> (2) the date on which HHS receives the late report. <p><i>Civil Action.</i> Authorizes HHS to bring civil actions against manufacturers of excessively priced drugs in certain circumstances.</p>	<p><i>Generic Drugs.</i> If HHS identifies an excessively priced drug, HHS will:</p> <ul style="list-style-type: none"> • Waive/void any government-granted exclusivities to the drug’s manufacturer with respect to that drug; and • 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. <p>Requires HHS to prioritize review of such generic drug applications (i.e., must be acted upon within 8 months of submission).</p> <p>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.</p>

⁵ 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
			<ul style="list-style-type: none"> 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 Any other information HHS deems appropriate. 			<p><i>Publication in HHS Database.</i> Requires HHS to establish/maintain a comprehensive database of brand name drugs and their excessive price determinations.</p> <p><i>Anticompetitive Behavior.</i> Prohibits manufacturers from engaging in “anticompetitive behavior” (i.e., violating Section 5 of the FTC Act).</p>
<p>Stop Price Gouging Act (S. 378/H.R. 1093)</p> <p>Sen. Sherrod Brown (D-OH)/Rep. Mark Pocan (D-WI)</p>	<p>Requires prescription drug manufacturers to report an increase in drug prices/justify such an increase.</p> <p>Imposes an excise tax on (or otherwise penalizes) manufacturers that are deemed by HHS to have engaged in unnecessary price spikes.</p>	<p><i>Manufacturer.</i> Requires manufacturers of prescription drugs to submit a quarterly report (January 17, April 18, June 15, September 15) to the HHS OIG.</p> <p><i>HHS OIG.</i> Requires the HHS OIG to annually (February 28/29):</p> <ul style="list-style-type: none"> Complete an assessment of the information submitted by manufacturers; and Transmit to the IRS a report on its findings (along with its assessment). 	<p><i>Manufacturers.</i> Requires manufacturers to submit quarterly reports containing the following information:</p> <ul style="list-style-type: none"> 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. <p><i>HHS OIG Assessment.</i> Requires the annual assessment performed by the HHS OIG to include:</p>	<p>Imposes an excise tax on each prescription drug deemed to have undergone an unnecessary price spike (i.e., a taxable prescription drug)</p> <p>equal to the greater of:</p> <ul style="list-style-type: none"> The annual price spike tax for the prescription drug; <u>or</u> The cumulative price spike tax for the prescription drug. 	<p>Subjects manufacturers who fail to submit the required reports to the HHS OIG to a civil penalty that is equal to the product of:</p> <ul style="list-style-type: none"> 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; <u>and</u> (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; <u>and</u> The number of days in the period between (1) the quarterly 	<p><i>Exemption Reporting.</i> Directs the HHS Inspector General to submit a recommendation to HHS on each drug that is exempt from the imposition of the excise tax.</p> <p><i>Publication of Data.</i> Requires the HHS OIG to make its report to the IRS available to the public on its website.</p> <p><i>Notice Requirements.</i> Requires HHS to notify the manufacturer no later than <u>30 days</u> after the completion of the HHS OIG’s assessment regarding any drug that has been found to have been subject to a price spike.</p>

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
		<p><i>Exemptions.</i> 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:</p> <ul style="list-style-type: none"> HHS determines that a for-cause price increase exemption should apply; <u>or</u> The prescription drug that was subject to a price spike has an average manufacturer price of not greater than \$10 for a 30-day supply; <u>and</u> The drug is marketed by at least three other drug companies and used by the companies as a reference drug. 	<ul style="list-style-type: none"> 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. <p><i>HHS OIG Report to the IRS.</i> Requires the annual HHS OIG report to the IRS to include:</p> <ul style="list-style-type: none"> The information received from manufacturers; The price spike identified; The price spike revenue determinations; and Other determinations and assessments completed by the HHS OIG. 	<p>Subjects manufacturers to a graduated excise tax that depends on the size of the price increase, if it is determined that the manufacturer increased the price of the drug beyond medical inflation over a one year period or cumulatively.⁶</p>	<p>submission deadline <u>and</u> (2) the date on which the HHS OIG receives the late report.</p>	<p><i>Hearing Opportunity.</i> Allows a manufacturer to request a hearing (only once within a 5 year period) before HHS within <u>30 days</u> of receiving notice of the price spike determination.</p> <p><i>Study on Monopoly of Medical Products.</i> Requires GAO to conduct a study examining how drug manufacturers establish initial launch prices and suggest best practices for monitoring new drug prices.</p>

PBM Reforms and Transparency Legislation

Legislation	Overview	Transparency Measures	Miscellaneous
<i>Prescription Drug Price</i>	Requires PBMs to adhere to certain standards when	<i>PBMs.</i> 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:	

⁶ 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.

Legislation	Overview	Transparency Measures	Miscellaneous
<p>Transparency Act (H.R. 1035)</p> <p>Rep. Doug Collins (R-GA)</p>	<p>entering into contracts and ensure the transparency of their drug pricing standards for reimbursement.</p>	<ul style="list-style-type: none"> 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. <p>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:</p> <ul style="list-style-type: none"> 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. 	
<p>Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019 (S. 476)</p> <p>Sen. Ron Wyden (D-OR)</p> <p>Senate Summary</p>	<p>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.</p>	<p>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:</p> <ul style="list-style-type: none"> The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiations 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. 	<p><i>Rebating Limits.</i> 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.</p> <p>Requires HHS to establish the minimum percent to ensure that patients receive the maximum benefits of rebates, discounts, or price concessions while taking into account the costs of negotiating such rebates, discounts, and price concessions.</p> <p><i>Medicare Part D.</i> 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.</p>

Legislation	Overview	Transparency Measures	Miscellaneous
			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.
<p>S. 657</p> <p>Sen. Mike Braun (R-IN)</p>	<p>Prohibits PBMs from receiving rebates unless certain transparency requirements are met.</p>	<p>Prohibits PBMs from receiving rebates/reductions in price from drug manufacturers unless:</p> <ul style="list-style-type: none"> • 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). 	
<p><i>Fair Care Act of 2019</i> (H.R. 1332) (<i>excerpts</i>)</p> <p>Rep. Bruce Westerman (R-AR)</p> <p>House Summary</p>	<p>Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement, among other things.</p>	<p><i>PBMs.</i> 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:</p> <ul style="list-style-type: none"> • 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 <u>in writing or via secure electronic means</u> 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. <p>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:</p> <ul style="list-style-type: none"> • 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; 	<p>Incorporates other provisions to promote market competition, including:</p> <ul style="list-style-type: none"> • Targeting delay tactics related to sample-sharing and shared safety protocols that prevent entry of generic drugs into the market (<i>largely mirrors the CREATES Act</i>). • 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 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 (<i>mirrors the Improving Transparency and Accuracy in Medicare Part D Spending Act</i>). • 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 (<i>mirrors H.R. 107</i>).

Legislation	Overview	Transparency Measures	Miscellaneous
		<ul style="list-style-type: none"> • 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 (<i>largely mirrors the prior version of the Prescription Drug Price Transparency Act</i>). 	<ul style="list-style-type: none"> • 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.
<p>Public Disclosure of Drug Discounts Act (H.R. 2115)</p> <p>Rep. Abigail Spanberger (D-VA)</p> <p><i>May 21 – A hearing was held on the legislation.</i></p>	<p>Requires HHS to make publicly available on its website certain rebate information with respect to generic drugs.</p>	<p>Beginning in 2020, requires HHS to make certain information on generic dispensing rates publicly available on its website, including:</p> <ul style="list-style-type: none"> • 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). 	
<p>Phair Relief Act (S. 2247)</p> <p>Sen. John Kennedy (R-LA)</p>	<p>Requires PBMs to publicly disclose drug discounts and places a five-year freeze on PBMs direct or indirect remuneration (DIR) fees.</p>	<p>Beginning in 2020, requires HHS to make certain PBM rebate information publicly available on its website, including:</p> <ul style="list-style-type: none"> • 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). 	<p>Pass Through. 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.</p> <p>Quality Measures. Requires HHS establish or approve standard quality measures for pharmacy price concessions and incentive payments for Medicare Part D prescription drugs.</p>

Legislation	Overview	Transparency Measures	Miscellaneous
		<p>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)).</p> <p><i>DIR Payments.</i> 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.</p> <p><i>PDP Sponsors.</i> Requires PDP sponsors to promptly provide to HHS certain claim reimbursement information for drugs covered under Medicare Part D, including:</p> <ul style="list-style-type: none"> • 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. 	<p><i>Audit.</i> 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.</p>
<p><i>Competition Prescription Act of 2019</i> <i>(H.R. 3947)</i></p> <p>Rep. Mark Meadows (R-NC)</p>	<p>Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement, among other things.</p>	<p><i>PBMs.</i> 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 (<i>mirrors the Fair Care Act of 2019</i>):</p> <ul style="list-style-type: none"> • 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 <u>in writing or via secure electronic means</u> 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. <p>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:</p> <ul style="list-style-type: none"> • 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; 	<p>Incorporates other provisions to promote market competition, including:</p> <ul style="list-style-type: none"> • Targeting delay tactics related to sample-sharing and shared safety protocols that prevent entry of generic drugs into the market (<i>mirrors the CREATES Act</i>). • Establishing a program to expedite the development of/provide priority review for “generic complex drug products” (<i>mirrors the Fair Care Act of 2019</i>). • 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 (<i>mirrors the Improving Transparency and Accuracy in Medicare Part D Spending Act</i>).

Legislation	Overview	Transparency Measures	Miscellaneous
		<ul style="list-style-type: none"> • 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 (<i>mirrors the prior version of the Prescription Drug Price Transparency Act</i>). 	<ul style="list-style-type: none"> • 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 (<i>mirrors H.R. 107</i>). • 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 (<i>mirrors the State-Based, Market-Oriented Prescription Drug Negotiations Act</i>). • 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. <p><i>FDA Reform.</i> 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 (<i>mirrors the Biologic Patent Transparency Act</i>).</p> <p><i>Medicare Part B.</i> Requires HHS assign a uniform Common Procedure System code to describe all biosimilar products that share a common reference product to simplify billing.</p>

Multi-Issue Legislation

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
<i>Medicare for America Act of</i>	<i>Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.</i>		Prohibits manufacturers from charging “excessive prices”—as defined by	<i>Drug Pricing Transparency.</i> Subjects manufacturers who fail to submit a report	<i>Publication of Manufacturer Data.</i> Requires HHS to post, in a user-friendly manner, publicly on its website, the report

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
<p>2019 (H.R. 2452)</p> <p>Rep. Rosa DeLauro (D-CT)</p> <p>House Summary</p> <p><i>Part of a larger package that includes a single-payer/public option proposal</i></p>	<p>Imposes reporting obligations on manufacturers of FDA-approved, prescription, “qualifying drugs”:</p> <ul style="list-style-type: none"> • 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 <u>and</u> 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; <u>and</u> • For which, during the previous calendar year, at least \$1 of their total sales was earned from individuals enrolled in Medicare or Medicaid programs. <p>Requires manufacturers of qualifying drugs to submit reports to HHS within <u>30 days</u> of a price increase that will result in an increase in the wholesale acquisition cost that is equal to:</p> <ul style="list-style-type: none"> • 10% or more over a 12-month period; or • 25% or more over a 36-month period. <p>Requires manufacturers’ reports to, at a minimum, include specific information on both the qualifying drug <u>and</u> the manufacturer.</p> <p><i>Qualifying Drug.</i> Requires the report to include:</p> <ul style="list-style-type: none"> • The percentage by which the manufacturer will raise the wholesale acquisition cost; 		<p>the Board⁷—for prescription drugs or medical devices.</p> <p>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.</p> <p>If the manufacturer fails to correct the violation by the end of such period, subjects the manufacturer to enforcement.</p>	<p>justifying a price increase for a qualifying drug to a civil penalty of \$100,000 for each day the violation continues.</p> <p><i>Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.</i></p> <p><i>Price Gouging.</i> If the Board finds the manufacturer of a prescription drug or medical device charged an “excessive price,” the following are considered available penalties:</p> <ul style="list-style-type: none"> • A reduced patent term; • Civil penalties; or • Imposition of a tax on excess prescription drug and medical device profits. <p><i>Reduced Patent Term.</i> If the manufacturer of a prescription drug or medical device <u>is also an owner of a patent for such drug or device</u>, authorizes the Board to:</p> <ul style="list-style-type: none"> • Reduce the term of any patent relating to the drug or device by not more than <u>5 years</u>; or 	<p>submitted by manufacturers no later than <u>30 days</u> after the report has been received.</p> <p><i>Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.</i></p> <p><i>Annual Report.</i> Requires HHS to submit an annual report to Congress that:</p> <ul style="list-style-type: none"> • Summarizes the drug pricing information reported by the manufacturer of a qualifying drug; <u>and</u> • Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. <p><i>Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019.</i></p> <p><i>Prescription Drug and Medical Device Price Review Board.</i> Establishes, within HHS, the Prescription Drug and Medical Device Price Review Board.</p> <p>Grants the Board the authority to:</p> <ul style="list-style-type: none"> • Obtain official data directly from any federal agency, provided it is necessary to carry out the Board’s duties; • Use the U.S. mail;

⁷ 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
	<ul style="list-style-type: none"> • 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. <p><i>Manufacturers.</i> Requires the report to include:</p> <ul style="list-style-type: none"> • 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. 			<ul style="list-style-type: none"> • If the term of each patent for the drug or device has expired, reduce the term by not more than 5 years of <u>another</u> patent owned by the patent owner. <p><i>Civil Penalties.</i> 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.</p> <p><i>Tax.</i> 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.</p>	<ul style="list-style-type: none"> • Receive/use administrative support services from the GSA; • Contract with/compensate government and private agencies to conduct research, surveys, etc.; • Undertake investigations; and • Issue subpoenas. <p>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.</p> <p><i>Direct-to-Consumer Drug Advertising.</i> 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.</p>

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
<p>Affordable Medications Act (S. 1801)</p> <p>Sen. Tina Smith (D-MN)</p> <p>Senate Summary</p>	<p><i>Similar to the Transparent Drug Pricing Act.</i></p> <p>Requires manufacturers of FDA-approved, prescription drugs to submit certain information in a single, annual report to HHS, including:</p> <ul style="list-style-type: none"> The total expenditures of the manufacturer on: <ul style="list-style-type: none"> Domestic and foreign drug R&D; Cost of goods sold (broken out by source and cost of each component and identifying specific costs that reflect internal transfers within the manufacturer’s company); Acquisition costs in total and per unit sold; and Marketing and advertising for the promotion of the drug; The gross revenue, net revenue, gross profit, and net profit to the manufacturer; The total number of units of the prescription drug that were sold in interstate commerce; Pricing information (e.g., wholesale acquisition cost, net average price realized by PBMs for drugs provided in the U.S., the net price of the drug charged to purchasers in each OECD country); 	<p><i>Similar to the Affordable and Safe Prescription Drug Importation Act.</i></p> <p>Allows wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed/certified foreign sellers,⁸ provided certain circumstances are met—after two years, authorizes importation from OECD countries that meet standards comparable to U.S. standards.</p> <p>Identifies such qualifying prescription drugs to include prescription drugs that:</p> <ul style="list-style-type: none"> 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 	<p><i>Similar to the Stop Price Gouging Act.</i></p> <p>Requires manufacturers to submit quarterly reports to the HHS OIG containing:</p> <ul style="list-style-type: none"> The total number of units of each prescription, FDA-approved drug sold; The gross revenues from sales of such drugs; and Any additional information related to anticipated or increased input costs, or public health considerations that the manufacturer may want the HHS OIG to consider in its assessment. <p>Requires the HHS OIG to annually complete an assessment of the reports received that:</p>	<p><i>Manufacturers.</i> 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.</p> <p>Subjects manufacturers that fail to submit the required quarter reports to a civil penalty equal to the product of:</p> <ul style="list-style-type: none"> 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; <u>and</u> (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; <u>and</u> The number of days in the period between (1) the quarterly submission deadline <u>and</u> (2) the date on which the HHS OIG receives the late report. <p><i>Prescription Drug Importation Prohibitions.</i> Classifies certain</p>	<p><i>Rebating.</i> Restores prescription drug rebates for seniors who are dually eligible for Medicare and Medicaid <u>and</u> extends these rebates to other Medicare patients in Medicare low-income subsidy plans.</p> <p>Excludes authorized generic drugs from calculations of average manufacturer price under the Medicaid drug rebate program.</p> <p><i>Prescription Drug Cost Sharing.</i> 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).</p> <p><i>Advertising.</i> Eliminates tax breaks for drug companies for expenses related to direct-to-consumer advertising.</p> <p>Incorporates other provisions, including:</p> <ul style="list-style-type: none"> 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.

⁸ 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
	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> – 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. <p>Requires HHS to collate the manufacturers’ reports and submit them to Congress, along with an analysis of the reports containing a summary of the data, consideration of certain factors (e.g., trends on R&D costs, federal benefits, etc.); and the relationship between those factors and prescription drug prices.</p> <p>Requires the reports and the HHS analysis to be publicly available on the HHS website.</p>	<p>good manufacturing practices regulations;</p> <ul style="list-style-type: none"> • Have the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; or is biosimilar to an approved biological product and has the same product of administration and strength as the approved biological product); and • Are labeled in accordance with the laws of Canada (or, ultimately, in another country from which importation is later permitted) <u>and</u> the requirements promulgated by HHS (including labeling in English). <p>Does <u>not</u> include:</p> <ul style="list-style-type: none"> • Controlled substances; • Anesthetic drugs inhaled during surgery; or • Compounded drugs. <p>Requires importers to submit biannual reports to HHS concerning any drug importation transactions.</p> <p>Requires HHS to report to Congress on the importation of drugs into the U.S.</p>	<ul style="list-style-type: none"> • 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. <p>Requires the HHS OIG to annually submit a report to the IRS (and later make it publicly available) that includes:</p> <ul style="list-style-type: none"> • 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 	<p>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.</p> <p>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.</p> <p>Imposes penalties of at most 10 years of imprisonment <u>or</u> a fine of at most \$250,000 on online pharmacies that either:</p> <ul style="list-style-type: none"> • Sell online with the intent to defraud, mislead, or with reckless disregard for public safety, an adulterated or counterfeit drug; <u>or</u> • Dispense a drug to an individual in the U.S. who does not possess a valid prescription. 	<ul style="list-style-type: none"> • 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
	<p>Offers an extension for the initial report from small businesses (i.e., those with fewer than 500 employees).</p> <p>Requires manufacturers to disclose to practitioners the wholesale acquisition cost for a 30-day supply of the drug <u>whenever</u> the manufacturer communicates with a practitioner about a drug, including through promotional, education, or marketing communications, meetings, paid events, etc.</p>	<p>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. <u>and</u> trans-shipment and importation tracing processes.</p>	<ul style="list-style-type: none"> The determinations and assessments made. <p>Requires the IRS to notify manufacturers regarding any drug that has been determined to have been subject to a price spike.</p> <p>Subjects manufacturers to a graduated excise tax that depends on the size of the price increase, if it is determined that the manufacturer increased the price of the drug beyond medical inflation over a one year period or cumulatively.⁹</p>		

⁹ 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	Transparency Measures	FDA Reform	PBM Reforms	Penalties
<p>Lower Health Care Costs Act of 2019 (S. 1895)</p> <p>Sen. Lamar Alexander (R-TN)</p>	<p><i>Gag Clauses.</i> 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 (e.g., data that could be shared under HIPAA business associate agreements).</p> <p><i>Transparency Organization.</i> 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, which would, among other things:</p> <ul style="list-style-type: none"> • Create an advisory committee to establish the entity’s research and reporting objectives; • Create reports for employers/employee organizations seeking to use the database; and • Authorize grants to states maintaining or creating similar transparency initiatives. <p><i>Group Health Plans.</i> Requires all group health plans to annually report to HHS the following information, among other things:</p> <ul style="list-style-type: none"> • 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: 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. <p><i>PBMs and Issuers.</i> Requires PBMs and issuers to report the following information to plan sponsors at least every 6 months:</p> <ul style="list-style-type: none"> • All manufacturer discounts, coupons, copayment assistance provided with respect to enrollees in the coverage; 	<p>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. <i>Mirrors the Biologic Patent Transparency Act</i></p> <p>Authorizes FDA to remove or add patents from the “Orange Book;” imposes transparency requirements related to patents. <i>Mirrors the Orange Book Transparency Act</i></p> <p>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; and permits FDA to establish a time period for petitions to be submitted/allows petitions outside that period to be denied. <i>Mirrors the Ensuring Timely Access to Generics Act</i></p> <p>Limits drug exclusivities for biological products, which codifies part of FDA’s 2018 guidelines for biosimilars, among other things. <i>Mirrors the Protecting Access to Biosimilars Act</i></p> <p>Amends the FDA’s market exclusivity rules by preventing generic drug manufacturers from “parking” applications and delaying the start of their exclusivity. <i>Mirrors the Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019</i></p> <p>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). <i>Mirrors the Ensuring Innovation Act</i></p> <p>Permits FDA to expedite approval for a biosimilar or generic drug.</p>	<p>Prohibits PBMs from engaging in spread pricing or charging more for a drug than the PBM paid to acquire the drug; and requires PBMs to pass on 100% of any rebates or discounts to the plan sponsor.</p> <p>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.</p>	<p><i>PBMs.</i> 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.</p>

Legislation	Transparency Measures	FDA Reform	PBM Reforms	Penalties
	<ul style="list-style-type: none"> • 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 spend 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 spend on drugs by the plan; and • Amounts paid directly or indirectly to brokers, consultants, or advisors, etc., who referred the plan to the PBM. <p>Requires additional reporting for issuers and PBMs that conduct transactions with wholly or partially-owned pharmacies.</p>	<p>Authorizes FDA to outdated drug labeling and require changes to the labeling of generic drugs.</p>		

Miscellaneous Legislation

Legislation	Issue Area	Overview
<p><i>National Public Health Act of 2019</i> (H.R. 2095) Rep. Mark DeSaulnier (D-CA)</p>	<p><i>Access</i></p>	<p>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.</p>
<p><i>Biologic Patent Transparency Act</i> (S. 659) Sen. Susan Collins (R-ME)</p>	<p><i>FDA Process Reform</i></p>	<p>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</p>

Legislation	Issue Area	Overview
Senate Summary		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.
<p><i>Efficiency and Transparency in Petitions Act (S. 660)</i> Sen. Mike Braun (R-IN)</p>	<p><i>FDA Process Reform</i></p>	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.
<p><i>Purple Book Continuity Act of 2019 (H.R. 1520)</i> Rep. Anna Eshoo (D-CA)</p>	<p><i>FDA Process Reform</i></p>	<p>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.</p> <p><i>March 27 – Approved by the Energy and Commerce Subcommittee on Health—as amended—by voice vote.</i></p> <p><i>April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.</i></p> <p><i>May 8 – Approved by the House—as amended—by a vote of 229-192.</i></p>
<p><i>Orange Book Transparency Act (H.R. 1503)</i> Rep. Robin Kelly (D-IL)</p>	<p><i>FDA Process Reform</i></p>	<p>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.).</p> <p><i>March 27 – Approved by the Energy and Commerce Health Subcommittee by voice vote.</i></p> <p><i>April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.</i></p> <p><i>May 8 – Approved by the House—as amended—by a vote of 231-191.</i></p>
<p><i>Accelerated Drug Approval for Prescription Therapies (ADAPT) Act (S. 658)</i> Sen. Mike Braun (R-IN)</p>	<p><i>FDA Process Reform</i></p>	<p>Permits FDA to expedite applications for approval of certain drugs if there is evidence that:</p> <ul style="list-style-type: none"> • 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

Legislation	Issue Area	Overview
		<ul style="list-style-type: none"> 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 <p>Requires FDA to make a determination on a drug application no later than 180 days after submission.</p>
<p><i>Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act (S. 1209)</i></p> <p>Sen. Bill Cassidy (R-LA)</p>	<p><i>FDA Process Reform</i></p>	<p>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.</p>
<p><i>Ensuring Timely Access to Generics Act (S. 1169/H.R. 2455)</i></p> <p>Sen. Cory Gardner (R-CO)/Rep. John Joyce (R-PA)</p>	<p><i>FDA Process Reform</i></p>	<p>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.</p>
<p><i>Second Look at Drug Patents Act (S. 1617)</i></p> <p>Sen. Patty Murray (D-WA)</p>	<p><i>FDA Process Reform</i></p>	<p>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.</p>
<p><i>Affordable Insulin Approvals Now Act (S. 2103)</i></p> <p>Sen. Richard Durbin (D-IL)</p>	<p><i>FDA Process Reform</i></p>	<p>Requires FDA to continue reviewing generic insulin drug applications after FDA’s planned cut-off date (March 2020).</p>
<p><i>Advancing Education on Biosimilars Act of 2019 (S.1681)</i></p> <p>Sen. Mike Enzi (R-WY)</p>	<p><i>FDA Process</i></p>	<p>Requires FDA to establish a website to provide educational materials and other information regarding biological products for consumers and providers, including, among other things:</p> <ul style="list-style-type: none"> 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.

Legislation	Issue Area	Overview
<p><i>Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019 (H.R. 938)</i></p> <p>Rep. Kurt Schrader (D-OR)</p>	<p><i>Market Competition</i></p>	<p>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.</p> <p><i>March 27 – Approved by the Energy and Commerce Subcommittee on Health by voice vote.</i></p> <p><i>April 3 – Approved by the Energy and Commerce Committee by voice vote.</i></p>
<p><i>Competitive Deals Resulting in Unleashed Generics and Savings (DRUGS) Act of 2019 (H.R. 1344)</i></p> <p>Rep. Lloyd Doggett (D-TX)</p>	<p><i>Market Competition</i></p>	<p>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).</p>
<p><i>Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (S. 340/H.R. 965)</i></p> <p>Sen. Patrick Leahy (D-VT)/Rep. David Cicilline (D-RI)</p> <p>Senate Summary</p>	<p><i>Market Competition</i></p>	<p>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.</p> <p><i>March 27 – H.R. 965 was approved by the Energy and Commerce Subcommittee on Health by voice vote.</i></p> <p><i>April 3 – H.R. 965 was approved by the Energy and Commerce Committee—as amended—by a vote of 51-0.</i></p> <p><i>April 30 – H.R. 965 was approved by the Judiciary Committee by voice vote.</i></p>
<p><i>Fair Access for Safe and Timely (FAST) Generics Act of 2019 (H.R. 985)</i></p> <p>Rep. Peter Welch (D-VT)</p>	<p><i>Market Competition</i></p>	<p>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.</p>

Legislation	Issue Area	Overview
<p><i>Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act</i> (S. 366/H.R. 1188)</p> <p>Sen. Richard Durbin (D-IL)/Rep. Jared Golden (D-ME)</p>	<p><i>Market Competition</i></p>	<p>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.</p>
<p><i>Preserve Access to Affordable Generics and Biosimilars Act</i> (S. 64)</p> <p>Sen. Amy Klobuchar (D-MN)</p>	<p><i>Market Competition</i></p>	<p>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.</p>
<p><i>Protecting Consumer Access to Generic Drugs Act of 2019</i> (H.R. 1499)</p> <p>Rep. Bobby Rush (D-IL)</p>	<p><i>Market Competition</i></p>	<p>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.</p> <p><i>April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.</i></p>
<p><i>Protecting Access to Biosimilars Act</i> (S. 1140/H.R. 2011)</p> <p>Sen. Tina Smith (D-MN)/Rep. Diana DeGette (D-CO)</p>	<p><i>Market Competition</i></p>	<p>Limits drug exclusivities for biological products, which codifies part of FDA’s 2018 guidelines for biosimilars, among other things.</p>
<p><i>State-Based, Market-Oriented Prescription Drug Negotiations Act</i> (H.R. 2038)</p> <p>Rep. Mark Meadows (R-NC)</p>	<p><i>Market Competition</i></p>	<p>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.</p>
<p><i>Stop STALLING Act</i> (S. 1224/H.R. 2374)</p>	<p><i>Market Competition</i></p>	<p>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.</p> <p><i>April 30 – H.R. 2374 was approved by the House Judiciary Committee by voice vote.</i></p>

Legislation	Issue Area	Overview
Sen. Amy Klobuchar (D-MN)/Rep. Hakeem Jeffries (D-NY)		<i>June 27 – S. 1224 was approved, <u>as amended</u>, by the Senate Judiciary Committee.</i>
<i>Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2375)</i> Rep. Jerry Nadler (D-NY)	<i>Market Competition</i>	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. <i>April 30 – Approved by the Judiciary Committee by voice vote.</i>
<i>Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act (H.R. 2700)</i> Rep. Michael Burgess (R-TX)	<i>Market Competition</i>	Aims to improve generic drug competition, among other things, by: <ul style="list-style-type: none"> • 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).
<i>Affordable Prescriptions for Patients Act of 2019 (S. 1416)</i> Sen. John Cornyn (R-TX)	<i>Market Competition</i>	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. <i>June 27 – Approved unanimously, <u>as amended</u>, by the Senate Judiciary Committee.</i>
<i>Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act (H.R. 3379)</i> Rep. Jan Schakowsky (D-IL)	<i>Market Competition</i>	Reduces market exclusivity for biological products from 12 years to 5 years.
<i>Ensuring Innovation Act (S.1636)</i> Sen. Pat Roberts (R-KS)	<i>Market Competition</i>	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).

Legislation	Issue Area	Overview
<p><i>Preserving Access to Cost Effective Drugs (PACED) Act</i> (S. 440)</p> <p>Sen. Tom Cotton (R-AR)</p>	<p><i>Market Competition</i></p>	<p>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).</p> <p><i>June 27 – Approved, <u>as amended</u>, by the Senate Judiciary Committee.</i></p>
<p><i>Emergency Access to Insulin Act</i> (S. 2004)</p> <p>Sen. Tina Smith (D-MN)</p>	<p><i>Market Competition</i></p>	<p>Reduces market exclusivity periods for insulin and other biologics from 12 years to 7 years, among other things.</p>
<p><i>Star Rating for Biosimilars Act</i> (S.)</p> <p>Sen. Bill Cassidy (R-LA)</p>	<p><i>Market Competition</i></p>	<p>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.</p>
<p><i>Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act of 2019</i> (H.R. 3991)</p> <p>Rep. Hank Johnson (D-GA)</p>	<p><i>Market Competition</i></p>	<p>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.</p>
<p>H.R. 107</p> <p>Rep. Michael Burgess (R-TX)</p>	<p><i>Medicaid Rebate</i></p>	<p>Sunsetts 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.</p>
<p><i>Right Rebate Act of 2019</i> (S. 205/H.R. 937)</p> <p>Sen. Ron Wyden (D-OR)/Rep. Kurt Schrader (D-OR)</p> <p>Senate Summary</p>	<p><i>Medicaid Rebate</i></p>	<p>Aims to prevent the misclassification of drugs under the Medicaid drug rebate program by:</p> <ul style="list-style-type: none"> • Providing HHS with the authority to reclassify drugs/correct misclassifications, impose civil monetary penalties on 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.
<p><i>Fair and Accurate Medicaid Pricing (AMP) Act of 2019</i></p>	<p><i>Medicaid Rebate</i></p>	

Legislation	Issue Area	Overview
<p>(S. 1785/H.R. 3276) Sen. Maggie Hassan (D-NH)/Rep. Joe Kennedy (D-MA)</p>		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.
<p><i>Sustaining Excellence in Medicaid Act of 2019</i> (H.R. 3253) Rep. Debbie Dingell (D-MI)</p>	Medicaid Rebate	<p>Expands the payment methodology in cases where average sales price during first quarter sales is unavailable, among other things.</p> <p><i>June 18 – Approved by the House, as amended, by a vote of 371-46.</i></p> <p><i>July 25 – Approved by the Senate, <u>as amended</u>, by voice vote.</i></p> <p><i>August 6 – Signed by the President and became Public Law No; 116-39.</i></p>
<p><i>Stop Drug Companies from Overcharging Seniors in Medicare Part B Act of 2019</i> (S. 2081) Sen. Gary Peters (D-MI)</p>	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).
<p><i>Recovering Excessive Funds for Unused and Needless Drugs Act of 2019 (REFUND) Act of 2019</i> (H.R. 4178) Rep. Eliot Engel (D-NY)</p>	Medicare Rebate	Requires manufacturers provide rebates to HHS for single-dose vial drugs under Medicare Part B.
<p><i>Empowering States to Address Drug Costs Act</i> (S. 2252) Sen. Chris Van Hollen (D-MD)</p>	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.
<p><i>Chronic Care Management Improvement Act</i> (H.R. 3436) Rep. Susan DelBene (D-WA)</p>	Medicare Part B	Removes patient cost-sharing responsibilities for chronic care management services under Medicare Part B.

Legislation	Issue Area	Overview
<p><i>Keeping Health Insurance Affordable Act of 2019</i> (S. 3) Sen. Ben Cardin (D-MD)</p>	<p><i>Medicare Part D & Medicare Rebate</i></p>	<p>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.</p>
<p><i>Payment Commission Data Act of 2019</i> (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)</p>	<p><i>Medicare Part D & Medicaid Rebate</i></p>	<p>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.</p> <p><i>April 3 – H.R. 1781 was approved by the Energy and Commerce Committee—as amended—by voice vote.</i></p>
<p><i>Empowering Medicare Seniors to Negotiate Drug Prices Act</i> (S. 62) Sen. Amy Klobuchar (D-MN)</p>	<p><i>Medicare Part D</i></p>	<p>Allows HHS to negotiate Medicare Part D prescription drug prices with drug manufacturers, PDP sponsors, and pharmacies.</p>
<p><i>Medicare Drug Price Negotiation Act</i> (S. 99/H.R. 448) Sen. Bernie Sanders (D-VT)/Rep. Elijah Cummings (D-MD) <i>See Senate Summary</i></p>	<p><i>Medicare Part D</i></p>	<p>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.</p>
<p><i>Medicare Negotiation and Competitive Licensing Act of 2019</i> (S. 377/H.R. 1046) Sen. Sherrod Brown (D-OH)/Rep. Lloyd Doggett (D-TX)</p>	<p><i>Medicare Part D</i></p>	<p>Aims to lower Medicare Part D drug prices by:</p> <ul style="list-style-type: none"> • 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.
<p><i>Medicare Prescription Drug Negotiation Act of 2019</i> (H.R. 275)</p>	<p><i>Medicare Part D</i></p>	<p>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.</p>

Legislation	Issue Area	Overview
Rep. Peter Welch (D-VT)		
<p><i>Reducing Existing Costs Associated with Pharmaceuticals for Seniors (RxCap) Act of 2019</i> (S. 475)</p> <p>Sen. Ron Wyden (D-OR)</p>	Medicare Part D	Eliminates the prescription drug cost-sharing requirement for seniors eligible under Medicare Part D.
<p><i>Improving Transparency and Accuracy in Medicare Part D Spending Act</i> (S. 988/H.R. 789/H.R. 803)</p> <p>Sen. Shelley Moore Capito (R-WV)/Rep. Peter Welch (D-VT)</p>	Medicare Part D	Prohibits PDP sponsors and MA-PD organizations from retroactively reducing payments on clean claims (i.e., a Medicare claim that is free of defects such as incomplete documentation) submitted by pharmacies.
<p><i>Creating Lower Cost Alternatives for Your Prescription Drugs (CLAY) Act</i> (H.R. 2757)</p> <p>Rep. Joe Cunningham (D-SC)</p>	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.
<p><i>Medicare Prescription Drug Fraud Prevention Act of 2019</i> (S. 1505)</p> <p>Sen. John Cornyn (R-TX)</p>	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.
<p><i>Improving Low-Income Access to Prescription Drugs Act of 2019</i> (H.R. 3029)</p> <p>Rep. Pete Olson (R-TX)</p>	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.
<p><i>Streamlining Part D Appeals Process Act</i> (S. 1861/H.R. 3924)</p> <p>Rep. Ben Cardin (D-MD)/Rep. Thomas Suozzi (D-NY)</p>	Medicare Part D	Qualifies a pharmacy's refusal to fill a prescription as coverage determination for the Medicare Part D appeals process.

Legislation	Issue Area	Overview
<p><i>Fair Choices for Medicare Beneficiaries Act of 2019</i> (H.R. 3421) Rep. Jimmy Gomez (D-CA)</p>	<p><i>Medicare Part D</i></p>	<p>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.</p>
<p><i>Real-Time Beneficiary Drug Cost Bill/Ship Rx Act of 2019</i> (H.R.3415/H.R. 3408) Rep. Elissa Slotkin (D-MI)/Rep. Jodey Arrington (R-TX)</p>	<p><i>Medicare Part D</i></p>	<p>Codifies a provision of HHS’ proposed rule that requires prescription drug plan sponsors include real-time benefit information as part of such sponsor’s electronic prescription program under Medicare Part D, including:</p> <ul style="list-style-type: none"> • 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.
<p><i>Improving Low Income Access to Prescription Drugs Act of 2019</i> (S. 1999) Sen. Bob Casey (D-PA)</p>	<p><i>Medicare Part D</i></p>	<p>Provides transitional and retroactive Medicare Part D prescription drug coverage for certain low-income beneficiaries.</p>
<p><i>Strengthening Average Sales Price Reporting Act of 2019</i> (S. 2051) Sen. Bob Menendez (D-NJ)</p>	<p><i>Medicare Part D Limited Transparency Requirements</i></p>	<p>Requires manufacturers without rebate agreements to report to HHS the average sales price and wholesale acquisition cost of drugs 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.</p>
<p><i>Right Price for Medicare Act</i> (S.), Sen. Bill Cassidy (R-LA)</p>	<p><i>Medicare Part D Limited Transparency Requirements</i></p>	<p>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)).</p>

Legislation	Issue Area	Overview
<p><i>Transparency for Pharmacists Act</i> (S.) Sen. Bill Cassidy (R-LA)</p>	<p><i>Medicare Part D Limited Transparency Requirements</i></p>	<p>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.).</p>
<p><i>We Protect American Investment in Drugs Act</i> (S. 2387) Sen. Chris Van Hollen (D-MD)</p>	<p><i>Pricing</i></p>	<p>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.”</p>
<p><i>Prescription Drug Rebate Reform Act of 2019</i> (S. 1384/H.R. 3805) Sen. Mitt Romney (R-UT)/Rep. Mike Gallagher (R-WI)</p>	<p><i>Pricing/Rebates</i></p>	<p>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.</p>
<p><i>End Price Gouging for Medications Act</i> (S. 1987/H.R. 3523) Sen. Jeff Merkley (D-OR)/Rep. Peter Welch (D-VT)</p>	<p><i>Reference-Based Pricing</i></p>	<p>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., 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.</p>
<p><i>Pharmacy Benefit Managers Accountability Study Act of 2019</i> (S. 1532/H.R. 3223) Sen. Marsha Blackburn (R-TN)/Rep. Roger Marshall (R-KS)</p>	<p><i>Limited PBM Transparency Requirements</i></p>	<p>Requires GAO to provide a study with legislative recommendations to Congress, including, among other things:</p> <ul style="list-style-type: none"> • 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

Legislation	Issue Area	Overview
		<ul style="list-style-type: none"> Factors affecting the use of step therapy for the 10 largest PBMs.
<p><i>Prescription Drug Pricing Dashboard Act (S. 709)</i> Sen. Bob Casey (D-PA)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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.</p>
<p><i>Transparent Drug Pricing Act (S. 977)</i> Sen. Rick Scott (R-FL)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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 retail price for the same drug in Canada, France, the United Kingdom, Japan, or Germany (this requirement would sunset after 5 years).</p>
<p><i>Sunshine for Samples Act of 2019 (H.R. 2064)</i> Rep. Judy Chu (D-CA)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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.</p> <p><i>May 21 – A hearing was held on the legislation.</i></p>
<p><i>Prescription Pricing for the People Act of 2019 (S. 1227/H.R. 2376)</i> Sen. Chuck Grassley (R-IA)/Rep. Doug Collins (R-GA)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>Requires the FTC to conduct a study/provide recommendations to Congress on the role of PBMs and assess potential anticompetitive practices in the drug supply chain.</p> <p><i>April 30 – H.R. 2376 was approved by the House Judiciary Committee by voice vote.</i></p> <p><i>May 21 – H.R. 2376 was considered in a hearing by the House Energy and Commerce Subcommittee on Health.</i></p> <p><i>June 27 – S. 1227 was approved, <u>as amended</u>, by the Senate Judiciary Committee.</i></p>
<p><i>Drug-price Transparency in Communications (DTC) Act (S. 1437)</i></p>	<p><i>Limited Transparency Requirements</i></p>	<p>Codifies the HHS final rule requiring drug manufacturers to disclose drug prices within direct-to-consumer advertisements.</p>

Legislation	Issue Area	Overview
Sen. Richard Durbin (D-IL)		
<p><i>Health Care Price Check Act of 2019</i> (S. 1497)</p> <p>Sen. Ron Wyden (D-OR)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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:</p> <ul style="list-style-type: none"> • Pharmacy options (e.g., preferred pharmacy, mail order, and other pharmacies in a designated geographic area); and • Generics or other therapeutically equivalent alternatives.
<p>H.R. 3327</p> <p>Rep. Francis Rooney (R-FL)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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.</p>
<p><i>Responsibility in Drug Advertising Act of 2019</i> (H.R. 4106)</p> <p>Rep. Rosa DeLauro (D-CT)</p>	<p><i>Limited Transparency Requirements</i></p>	<p>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.</p>