

Drug Pricing Transparency Legislation

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	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 individual factors that have contributed to an increase in the drug’s wholesale acquisition cost; • An explanation of the role of each factor in contributing 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>

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. • An anesthetic drug inhaled during surgery. • A compounded drug. 	<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> • Filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner 	<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 temporarily suspend importation of a</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</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.

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			<p>licensed to practice in the U.S.</p> <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>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>drugs’ chemical authenticity.</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>Sen. Chuck Grassley (R-IA)/Rep. Chellie Pingree (D-ME)</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 dispense prescription drugs in Canada; • Are purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply; • Are filled using a valid prescription 	<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; • Certified by the Secretary that (1) the pharmacy is licensed to operate and dispense prescription drugs to individuals in Canada; and (2) 			<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 pharmacies, including the Internet Web site address of each such approved</p>

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		<p>issued by a physician licensed to practice in the U.S.; <u>and</u></p> <ul style="list-style-type: none"> • 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 therapeutic recombinant DNA-derived product, etc.). • A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding. • A photoreactive drug. 	<p>certain additional criteria are met.²</p>			<p>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.

Price Gouging Legislation

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
<p><i>Combating Unreasonable Rises and Excessively (CURE) High Drug Prices Act (S. 637)</i></p> <p>Sen. Richard Blumenthal (D-CT)</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.”³</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>	
<p><i>Prescription Drug Price Relief Act of 2018 (S. 102/H.R. 465)</i></p>	<p>Requires HHS to annually identify “excessively priced”</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</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; 		<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>	<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

³ 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.

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<p>Sen. Bernie Sanders (I-VT)/Rep. Ro Khanna (D-CA)</p> <p>Senate Summary</p>	<p>patented, brand name drugs⁴ 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>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>	<ul style="list-style-type: none"> • 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); • 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; 		<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>	<ul style="list-style-type: none"> • 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> <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>

⁴ 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.

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			<ul style="list-style-type: none"> 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>Anticompetitive Behavior.</i> Prohibits manufacturers from engaging in “anticompetitive behavior” (i.e., violating Section 5 of the FTC Act).</p>
<p><i>Stop Price Gouging Act</i> (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>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- 	<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> <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 	<p>Imposes an excise tax on each prescription drug deemed to have undergone an unnecessary price spike (i.e., a taxable prescription drug) sold by a manufacturer equal to the greater of:</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 to a</p>	<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 submission deadline <u>and</u> (2) the date on which the HHS OIG receives the late report. 	<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> <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</p>

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		<p>cause price increase exemption should apply; <u>or</u></p> <ul style="list-style-type: none"> 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"> 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>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.⁵</p>		<p>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 Transparency Legislation

Legislation	Overview	Transparency Measures	Miscellaneous
<p><i>Prescription Drug Price Transparency Act</i> (H.R. 1035)</p> <p>Rep. Doug Collins (R-GA)</p>	<p>Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement.</p>	<p><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:</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;” 	

⁵ 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
		<ul style="list-style-type: none"> • 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><i>Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019</i> (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 2018. 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> <p>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>

Miscellaneous Legislation

Legislation	Issue Area	Overview
<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) allow judges to award payments to generics to deter anticompetitive behavior by brand name drug companies, among other things.</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>
<p><i>Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act (S. 366/H.R. 1188)</i></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 (S. 64)</i></p> <p>Sen. Amy Klobuchar (D-MN)</p>	<p><i>Market Competition</i></p>	<p>Prohibits drug and biologics manufacturers 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>

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<p><u>H.R. 107</u></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 2019.</p>
<p><i>Right Rebate Act of 2019</i> (<u>S. 205/H.R. 937</u>)</p> <p>Sen. Ron Wyden (D-OR)/Rep. Kurt Schrader (D-OR)</p> <p>See <u>Senate Summary</u></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>Keeping Health Insurance Affordable Act of 2019</i> (<u>S. 3</u>)</p> <p>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> (<u>H.R. 1264</u>)</p> <p>Rep. Lloyd Doggett (D-TX)</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>Empowering Medicare Seniors to Negotiate Drug Prices Act</i> (<u>S. 62</u>)</p> <p>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> (<u>S. 99/H.R. 448</u>)</p> <p>Sen. Bernie Sanders (D-VT)/Rep. Elijah Cummings (D-MD)</p> <p>See <u>Senate Summary</u></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>

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<p><i>Medicare Negotiation and Competitive Licensing Act of 2019</i> (S. 377/H.R. 1046)</p> <p>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>Rep. Peter Welch (D-VT)</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>
<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>	<p><i>Medicare Part D</i></p>	<p>Eliminates the prescription drug cost-sharing requirement for seniors eligible under Medicare Part D.</p>