Current Federal Drug Pricing Legislation

* *Note*: Bills listed in ***red*** have been enacted and signed into law.

Drug Pricing Transparency Legislation

Legislation	Overview	Characteristics of a Qualifying/Applicable Drug	Reporting Requirements	Report Content	Penalties	Miscellaneous
Fair Accountability and Innovative Research Drug Pricing Act of 2017 (S. 1131/ H.R. 2439) Sen. Tammy Baldwin (D-WI)/Rep. Jan Schakowsky (D-IL) *See* Senate Summary	Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS prior to increasing the price of such drugs.	In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that: • Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS); • Are not defined as a drug for a rare disease or condition; • Have not been designated by HHS as a vaccine; and	*Manufacturers.* Requires manufacturers of qualifying drugs to submit a report to HHS for each price increase that will result in an increase in the wholesale acquisition cost of a drug that is equal to: • 10% or more over a 12-month period; or • 25% or more over a 36-month period. Such reports must be submitted to HHS at least 30 days before the planned effective date of the price increase. *HHS.* Requires HHS to submit an annual report to Congress that • Summarizes the information reported by the manufacturer; and • Includes copies of the reports/supporting detailed	Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer. *Qualifying Drug.* On the qualifying drug, the report must include: • The percentage by which the manufacturer will raise the wholesale acquisition cost; • A justification for/description of each manufacturer's planned price increase; • The identity of the drug's initial developer; • The history of the manufacturer's price increases since the drug's initial FDA approval; • The drug's current list price; • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing; • The percentage of expenditures on R&D from federal funds; • The total of the manufacturer's expenditures on R&D; • The total revenue and net profit generated from the qualifying drug for each calendar year since the drug's approval or the manufacturer acquired approval; and • The total marketing and advertising costs. *Manufacturers.* On the manufacturer, the report must include: • The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period");	Subjects a manufacturer of a qualifying drug that fails to submit a required report to a penalty of $100,000 for each day that the report fails to be submitted.	*Publication of Manufacturer Data.* Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers no later than 30 days after the report has been received.

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		• Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs.	economic analysis that are otherwise submitted.	• 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.		
Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2017 (S. 1348) Sen. Ron Wyden (D-OR) *See* Senate Summary	Requires manufacturers of certain drugs to publicly report/justify significant price increases and other attendant costs to HHS.	Imposes reporting obligations on manufacturers of FDA-approved, prescription, "applicable drugs"—as determined by HHS—that: • Have a wholesale acquisition cost of at least $10 per dose; and • Had an increase in the wholesale acquisition cost of the drug of at least 300% in the past 5 years or 100% over 1 year; or • Are in the top 50th percentile of net spending in Medicare or Medicaid in the past 5 years; and • Had an increased wholesale acquisition cost of at least 50% in the past 5 years or 15% over 1 year. Allows HHS to identify a drug with a price increase within a *de minimis* range of the percentages listed.	*HHS.* Requires HHS to notify the manufacturer within 60 days of its determination that a drug is considered an "applicable drug" (and therefore is subject to reporting requirements). *Manufacturers.* Requires manufacturers to submit a justification of the applicable drug's price increase within 180 days of HHS' notification that the drug qualified as an applicable drug. *Exceptions*. Does not require a manufacturer to submit a justification if a manufacturer reduces the wholesale acquisition cost of the drug so that it no longer qualifies as an applicable drug for at least a 6-month period.	Requires manufacturers' reports to include all relevant information/supporting documentation necessary to justify the increase, which may include: • The 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.).	Subjects a manufacturer of an applicable drug that fails to submit a report for the drug to a penalty of $10,000 per day for each day that the report is not submitted. Subjects a manufacturer who knowingly provides false information to a penalty of up to $100,000 for each piece of false information in the report.	*Publication of Manufacturer Data.* Requires HHS to post the justification and an easily-understandable summary of the justification publicly on the CMS website within 30 days of receiving the justification.

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Transparent Drug Pricing Act of 2017 (H.R. 4116) Rep. Lloyd Doggett (D-TX)	Requires manufacturers of FDA-approved drugs to submit annual reports to HHS on the drug's pricing information and other related costs.	Imposes reporting obligations on manufacturers with respect to each FDA-approved, prescription drug manufactured/marketed by the manufacturer.	*Manufacturers.* Subjects manufacturers to mandatory and voluntary reporting. Requires manufacturers to submit an initial report one year after enactment;[1] and annual reports thereafter. Offers manufacturers the opportunity to also submit voluntary, supplemental reports. *HHS.* Requires HHS to collate and submit manufacturers' reports to Congress with an analysis, which includes: • A summary of data from the annual reports; • Consideration of factors (e.g., trends on R&D costs, federal benefits, etc.); and • The relationship between the factors considered and prescription drug prices. *Extensions for Small Businesses.* Offers manufacturers that have fewer than 500 employees an extension in submitting the	*Mandatory, Annual Reports.* Requires manufacturers' annual reports to specify the following information: • The manufacturer's total expenditures (e.g., on domestic and foreign R&D; the acquisition of drug components and packaging; other acquisitions related to drugs; marketing, advertising, and educating for the promotion of a drug); • The gross revenue, net revenue, gross profit, and net profit of the manufacturer with respect to the drugs; • The total number of units of each type of drug that were sold in interstate commerce; • Pricing information with respect to the sale of drugs (e.g., wholesale acquisition cost; net average price realized by PBMs for drugs provided to individuals in the U.S.); the net price of each drug charged to purchasers in OECD countries); • Any federal benefits received by the manufacturer with respect to a drug; • The percentage of R&D expenditures that were derived from federal funds; • Executive compensation for the CEO, CFO, and the 3 other most highly compensated executive officers; and • Any other information as required by HHS. *Voluntary, Supplemental Reports*. Allows manufacturers to supplement a report with any additional information the manufacturer chooses to provide related to drug pricing decisions, including: • Total expenditures on drug research, drug development, and clinical trials on drugs that failed to become FDA-approved; and • A list of drugs and drug prices of other manufacturers for purposes of comparison with the manufacturer's own drugs and drug prices.	Subjects a manufacturer that fails to submit a complete report to a civil penalty of up to $200,000 for each day on which the complete report is not submitted.	*Publication of Manufacturer Data.* Requires HHS to make manufacturers' annual reports and HHS' reports and analysis publicly available, in a searchable format, on its website. *Audit by Third Party.* Directs HHS to select a percentage of annual reports submitted by manufacturers to be audited by an accredited third-party auditor. *Reports of Noncompliance*. Directs HHS to report to the Office of the Inspector General a manufacturer's failure to submit a complete report.

[1] The initial reports must cover the calendar year period beginning with the later of (1) the year in the which the drug was approved, licensed, or received an exemption by the FDA; and (2) the year in which the manufacturer acquired the drug so approved, licensed, or exempted.

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			initial report (allowing for submission 3 years after enactment).			

Prescription Drug Importation Legislation

Legislation	Overview	Characteristics of a Qualifying Prescription Drug	Importation Requirements and/or Restrictions	Notification/Reporting Requirements	Penalties	Miscellaneous
Affordable and Safe Prescription Drug Importation Act (S. 469/H.R. 1245) Sen. Bernie Sanders (I-VT)/Rep. Elijah Cummings (D-MD) *See* Senate Summary	Requires HHS to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from "certified foreign	Allows the importation of drugs from Canada, provided they: • Are approved for use in patients and marketed in Canada; • Are manufactured in an FDA-registered facility; • Have the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; or is biosimilar (identical in makeup to a licensed drug) and has the same method of administration, and strength as the licensed drug; • Is labeled in accordance with the laws of Canada (or another country from which importation is permitted); and • Is labeled in English (and in accordance with all other requirements promulgated by HHS).	*Certified Foreign Sellers*. Requires importers (or individuals who import prescription drugs into the U.S.) to purchase qualifying prescription drugs from a "certified foreign seller" who (1) is certified by HHS,[2] (2) has paid the registration fee, and (3) sells only qualifying prescription drugs. *Individuals*. Allows individuals to import a qualifying prescription drug from Canada (or another country) if it is: • Dispensed (including through an online pharmacy) by a certified foreign seller that is a licensed foreign pharmacy;	*Importers.* Requires importers to submit biannual reports to HHS on each qualifying prescription drug imported into the U.S. that contains: • The facility identifier of the drug's registered manufacturer; • Transaction information (e.g., the name, strength, and dosage; the number of containers and container size; the lot number; the date of transaction and	*Unfair and Discriminatory Acts and Practices*. Prohibits a manufacturer from: • Charging a higher price for a prescription drug sold to a certified foreign seller than the price that is charged to another person that does not import such a drug into the U.S. • Denying, restricting, or delaying supplies of a prescription drug to a certified foreign seller due to his or her status as a certified foreign seller. • Causing there to be a difference between a prescription drug for distribution in the U.S. and the drug for distribution in Canada.	*Preemption.* Does not supplant or preempt state or other federal laws. *Publication of Certified Foreign Sellers.* Requires HHS to publish online a list of certified foreign sellers, including web addresses, physical addresses, and telephone numbers of such sellers. *Drug Testing Laboratories.*

[2] 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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	sellers" (possibly later expanded to include sellers in OECD member countries).	Does not include: • A controlled substance. • An anesthetic drug inhaled during surgery. • A compounded drug.	• Purchased for personal use by the individual (i.e., not for resale) in quantities that do not exceed a 90-day supply; and • Filled only after providing to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in the U.S. *Restrictions.* Currently limited to drugs being imported from Canada, but authorizes HHS (after reviewing the cost savings and increased access) to expand the program to include any country that: • Is an OECD member; • Has standards for the approval and sale of prescription drugs that are comparable to U.S. standards; and • Meets certain other criteria (e.g., authorizes approval of a drug only if a drug is deemed safe and effective by government experts, etc.).	shipment, etc.) as required by HHS; and • The price paid by the importer for the drug. *HHS.* Requires HHS to submit a report one year after the program's effectuation (and every two years thereafter) on the importation of drugs into the U.S. *GAO.* Requires the GAO to compile a report containing an analysis of the bill's implementation, including a review of drug safety, expenses, and cost-savings (e.g., cost-savings to consumers, and trans-shipment and importation tracing processes, resulting from such implementation).	• Engaging in other actions to restrict, prohibit, or delay the importation of a prescription drug. *Suspension of Importation.* Grants HHS the authority to suspend or temporarily suspend importation of a product (or suspend all products from a certified foreign seller or importer) if there is an importation involving • Counterfeit drugs, • Drugs that have been recalled/withdrawn, or • Drugs otherwise in violation of the bill until an investigation is completed and it is determined that the drug, seller, or importer does not endanger the public health. *Penalties*. Imposes penalties on online pharmacies selling adulterated or counterfeit products with the intent to defraud, or mislead, with reckless disregard for safety of the public, or knowingly dispensing drugs without a valid prescription. Such pharmacies will face a penalty of not more than 10 years imprisonment or a fine of not more than $250,000.	Authorizes HHS to approve laboratories to conduct random testing of prescription drugs sold by certified foreign sellers and assess the drugs' chemical authenticity. *Supply Chain Security.* (Generally) requires certified foreign sellers to purchase drugs from registered manufacturers or entities, unless HHS has entered into an MOU with Canada (or the permitted country).
Personal Drug Importation Fairness Act (H.R. 934)	Allows for personal/direct importation or reimportation of certain	Allows drugs to be imported into the U.S./reimported into the U.S. by a person other than the drug's manufacturer, provided it:	To be eligible for importation or reimportation: • The drug must be imported/reimported from a qualified country (i.e.,	N/A	N/A	N/A

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Rep. Keith Ellison (D-MN)	drugs from countries with safety standards that are at least as strong as those of the U.S.	• Has the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; • May be lawfully marketed in/is imported or reimported from a qualified country; • Is dispensed by a licensed pharmacist; • Is shipped directly to/is imported by the ultimate consumer from a qualified country; • Is shipped or imported in quantities that do not exceed a 90-day supply; and • Is accompanied by a copy of a valid prescription. Does not include controlled substances.	Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, an EU member state, or a country in the European Economic Area); and • HHS must determine that the qualified country has prescription drug safety and effectiveness standards that are at least as protective as U.S. standards.			
Safe and Affordable Drugs from Canada Act of 2017 (S. 64/H.R. 1480) Sen. John McCain (R-AZ)/Rep. Chellie Pingree (D-ME)	Requires HHS to promulgate regulations allowing individuals to import certain drugs from approved Canadian pharmacies.	Authorizes HHS to promulgate regulations allowing the importation of drugs from Canada, provided they: • Are purchased from an approved Canadian pharmacy; • Are dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada; • Are purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;	Authorizes the importation of drugs from Canada only if it is from an approved Canadian pharmacy and dispensed by a licensed pharmacist. To qualify, the pharmacy must be: • Located in Canada; • Certified by the Secretary that (1) the pharmacy is licensed to operate and dispense prescription drugs to individuals in Canada; and (2) certain additional criteria are met.[3]	N/A	N/A	*Publication of Approved Canadian Pharmacies*. In conjunction with the regulations, requires HHS to publish on its website a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which

[3] 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

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		• Are filled using a valid prescription issued by a physician licensed to practice in the U.S.; and • Have the same active ingredient(s), route of administration, dosage form, and strength as prescription drugs approved by the FDA. Does not include: • A controlled substance. • A biological product. • An infused drug (including a peritoneal dialysis solution). • An intravenously injected drug. • A drug inhaled during surgery. • A parenteral drug. • A drug manufactured through one or more biotechnology processes (e.g., a therapeutic DNA plasmid product, a therapeutic synthetic peptide product of not more than 40 amino acids, a monoclonal 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.				individuals may purchase prescription drugs.
Short On Competition Act	Allows HHS to grant	In the event of a drug shortage, authorizes the importation of certain drugs if they:	Authorizes importation of a drug in the event of a shortage for up to 3	*Manufacturers.* Requires manufacturers to certify to	*Denial of Importation*. Authorizes HHS to deny importation of an	*Non-Competitive Markets*. If a

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.

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(S. 183) Sen. Amy Klobuchar (D-MN)	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 noncompetitive market exists). Gives the FDA explicit authority to allow temporary importation from certain countries when HHS determines there is a drug shortage.	• Are prescription drug products (i.e., subject to section 503(b) of the FFDCA); • Are lawfully marketed in an eligible country (i.e., Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, an EU member state, or a country in the European Economic Area); • Contain the same active ingredient as the drug for which there is a shortage; and • Will be subject to certain notification and reporting requirements.	years, or when the drug shortage no longer applies (whichever occurs first).	HHS that they intend to seek approval of the drug. *Importers.* Requires importers to file with HHS information: • Attesting that the requirements for a qualifying drug have been met. • Identifying the drug the importer proposes to import and the manufacturer from which the importer proposes to import such drugs. • Requests authority to import the drug; *HHS.* Requires HHS to include information on the number of drugs authorized for temporary importation in its annual report to Congress.	otherwise qualified drug if it is determined that: • The drug is not safe and effective. • The drug is used in conjunction with a device for which there is no reasonable assurance of safety and effectiveness. • The authorization to market the drug in one or more of the permissible countries has been rescinded or withdrawn because of concerns relating to the safety or effectiveness of the drug.	noncompetitive market exists with respect to an applicable drug (i.e., not a radio pharmaceutical drug product), authorizes HHS to: • Treat the noncompetitive market[4] as creating a drug shortage; • Expedite the review of applications and inspections with respect to the drug; and • Authorizes importation of the drug.

[4] A noncompetitive 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.

Price Gouging Legislation

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
Stop Price Gouging Act (S. 1369/H.R. 2794) Sen. Sherrod Brown (D-OH)/Rep. Mark Pocan (D-WI)	Requires prescription drug manufacturers to report an increase in drug prices/justify such an increase. Imposes an excise tax on (or otherwise penalizes) manufacturers that are deemed by HHS to have engaged in unnecessary price spikes.	*Manufacturer*. Requires manufacturers of prescription drugs to submit a quarterly report (January 17, April 18, June 15, September 15) to the HHS OIG. *HHS OIG*. Requires the HHS OIG to annually (February 28/29): • Complete an assessment of the information submitted by manufacturers; and • Transmit to the IRS a report on its findings (along with its assessment). *Exemptions.* Allows HHS to exempt any prescription drug that was the subject of a price spike during the previous calendar year from the excise tax if the following requirements are met: • HHS determines that a for-cause price increase exemption should apply; or • The prescription drug that was subject to a price spike has an average manufacturer price of not	*Manufacturers.* Requires manufacturers to submit quarterly reports containing the following information: • The total number of units of each prescription, FDA-approved drug that were sold in the last quarter; • The average and median price per unit of each prescription drug sold in the last quarter, broken down by month; • The gross revenues from sales of each prescription drug in the last quarter; and • Any additional information related to anticipated or increased input costs, or public health considerations that the manufacturer may want the HHS OIG to consider in its assessment. *HHS OIG Assessment.* Requires the annual assessment performed by the HHS OIG to include: • Identification of each price spike relating to a prescription drug; • A determination of the price spike revenue; • A determination of the accuracy of the information submitted by the manufacturer regarding increased input costs; and • An assessment of the manufacturer's rationale for the price spike. *HHS OIG Report to the IRS.* Requires the annual HHS OIG report to the IRS to include: • The information received from manufacturers; • The price spike identified;	Imposes an excise tax on each prescription drug deemed to have undergone an unnecessary price spike (i.e., a taxable prescription drug) sold by a manufacturer equal to the greater of: • The annual price spike tax for the prescription drug; or • The cumulative price spike tax for the prescription drug. Subjects manufacturers to a graduated excise tax that depends on the size of the price increase, if it is determined that the manufacturer increased the price	Subjects manufacturers who fail to submit the required reports to the HHS OIG to a civil penalty that is equal to the product of: • An amount determined by the HHS OIG that is (1) not less than 0.5% of the gross revenues from sales of the drug for the calendar year; and (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; and • The number of days in the period between (1) the quarterly submission deadline and (2) the date on which the HHS OIG receives the late report.	*Exemption Reporting*. Directs the HHS Inspector General to submit a recommendation to HHS on each drug that is exempt from the imposition of the excise tax. *Publication of Data*. Requires the HHS OIG to make its report to the IRS available to the public on its website. *Notice Requirements.* Requires HHS to notify the manufacturer no later than 30 days after the completion of the HHS OIG's assessment regarding any drug that has been found to have been subject to a price spike. *Hearing Opportunity*. Allows a manufacturer to request a hearing (only once within a 5 year period) before HHS within 30 days of receiving notice of the price spike determination. *Study on Monopoly of Medical Products.* Requires GAO to conduct a study examining how drug manufacturers establish initial launch prices and suggest best practices for monitoring new drug prices.

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		greater than $10 for a 30-day supply; and • The drug is marketed by at least three other drug companies and used by the companies as a reference drug.	• The price spike revenue determinations; and • Other determinations and assessments completed by the HHS OIG.	of the drug beyond medical inflation over a one year period or cumulatively.[5]		
Prescription Drug Price Relief Act of 2018 (S. __/ H.R. __) Sen. Bernie Sanders (I-VT)/Rep. Ro Khanna (D-CA) *See* Senate Summary	Requires HHS to annually identify "excessively priced" patented, brand name drugs[6] 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).	*Manufacturers*. Requires manufacturers to submit annual reports (January 15) on pricing information for each brand name drug (and as compared to prices in reference countries). *HHS*. Requires HHS to annually report to Congress on its excessive drug price review for the preceding calendar year. Requires such reports to be made publicly available on the FDA website in a manner that is easy to find and understand.	*Manufacturers*. Requires manufacturers to submit annual reports containing the following information on brand name drugs: • The average manufacturer price of the drug in the U.S. and in the reference countries; • The wholesale acquisition cost of the drug in the U.S. and in the reference countries; • Cumulative global revenues generated by the drug; • 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;	N/A	*Manufacturers.* Subjects manufacturers that fail to submit their annual reports to a civil penalty that is equal to the product of: • An amount determined by HHS that is (1) not less than 0.5% of the gross revenues from sales of the drug for the calendar year; and (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; and • The number of days in the period	*Generic Drugs.* If HHS identifies an excessively priced drug, HHS will: • Waive/void any government-granted exclusivities to the drug's manufacturer with respect to that drug; and • Grant open, non-exclusive licenses allowing generic drug manufacturers to make more affordable versions of the drug. Requires HHS to prioritize review of such generic drug applications (i.e., must be acted upon within 8 months of submission). Requires an entity accepting a license to make a generic version of an excessively priced brand name drug to pay a "reasonable royalty"—as set

[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.

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

Legislation	Overview	Report Requirements	Report Content	Taxes	Penalties	Miscellaneous
	Authorizes HHS to approve cheaper generic versions of those drugs, if manufacturers refuse to lower the price of drugs to the median price.		• Additional information the manufacturer chooses to provide related to drug pricing decisions; and • Additional information required by HHS. *HHS*. Requires HHS' annual report to contain summary data regarding: • The total number of drugs that were reviewed; • The total number of drugs found to be excessively priced (and the name/manufacturer of such drugs); • The total number of drugs found to be excessively priced (listed by manufacturer); • The extent to which the prices of the drugs were higher than reasonable, on average; • The total number of drugs for which an open, non-exclusive license has been granted; • The total number of generic drug applications received/approved that reference an excessively priced drug; • The median approval time for generic drug applications in such circumstances; • The total number of petitions HHS received to make excessive price determinations; • A list of any manufacturers who failed to report information, as required; and • Any other information HHS deems appropriate.		between (1) the annual submission deadline <u>and</u> (2) the date on which HHS receives the late report.	by HHS—to the holder(s) of the original drug patent. *Publication in HHS Database.* Requires HHS to establish/maintain a comprehensive database of brand name drugs and their excessive price determinations. *Anticompetitive Behavior*. Prohibits manufacturers from engaging in "anticompetitive behavior" (i.e., violating Section 5 of the FTC Act).

<u>PBM Transparency Legislation</u>

Legislation	Overview	Transparency Measures	Miscellaneous

Legislation	Overview	Transparency Measures	Miscellaneous
Prescription Drug Price Transparency Act (H.R. 1316) Rep. Doug Collins (R-GA) *See* House Summary	Requires PBMs to adhere to certain standards regarding patient data and ensure the transparency of their drug pricing standards for reimbursement.	*PBMs.* Requires PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor or with a Medicare Advantage ("MA") organization to adhere to the following criteria when handling personally identifiable utilization and claims data, and other sensitive patient data: • Not transmit any personally identifiable utilization, PHI, or claims data with respect to a plan enrollee to a pharmacy owned by a PBM if the plan enrollee has not voluntarily elected in writing or via secure electronic means to fill that particular prescription at the PBM-owned pharmacy. • Not require that a plan enrollee use any pharmacy providing pharmacy services in which the PBM has an ownership interest. • Not provide an incentive to a plan enrollee to use any pharmacy providing pharmacy services in which the PBM has an ownership interest, if the incentive is applicable only to such pharmacies. Requires PBMs to do the following with respect to their drug pricing standards for reimbursement (e.g., their maximum allowable cost lists) for Medicare Part D, TRICARE, and FEHBP: • Update the standard at least once every 7 days, beginning January 1 of each year, to accurately reflect the market price of acquiring the drug; • Disclose to applicable pharmacies and the 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 to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price; and • Provide all such pricing data in a spreadsheet and easily accessible format.	N/A
Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017 (S. 637) Sen. Ron Wyden (D-OR)	Requires public disclosure of the total amount of rebates provided by manufacturers to PBMs and the proportion of those rebates that are	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: • 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.	*Rebating Limits.* Beginning in 2020, requires a PBM that manages prescription drug coverage under a contract with a PDP sponsor, MA organization, or qualified health benefits plan to pass through to the plan sponsor a minimum percent (established by HHS) of the aggregate amount of the rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan. Requires HHS to establish the minimum percent to ensure that patients receive the maximum benefits of rebates, discounts, or price concessions

Legislation	Overview	Transparency Measures	Miscellaneous
See Senate Summary	passed on to health plans.		while taking into account the costs of negotiating such rebates, discounts, and price concessions. *Medicare Part D.* Prohibits a PDP sponsor or an MA organization under Medicare Part D from contracting with a PBM that is not in compliance with the rebating limits established by HHS. 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.

Multi-Issue Legislation

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
Affordable Medications Act (S. 3411)/ ***Improving Access to Affordable Prescription Drugs*** (H.R. 1776) Sen. Tina Smith (D-MN)/Rep. Jan Schakowsky (D-IL) *See* Senate Summary	***Similar to the Transparent Drug Pricing Act of 2017*** Requires manufacturers of FDA-approved, prescription drugs to submit certain information in a single, annual report to HHS, including: • The total expenditures of the manufacturer on: - Domestic and foreign drug R&D; - Cost of goods sold (broken out by source and cost of each component and identifying specific costs that reflect internal transfers within the manufacturer's company); - Acquisition costs in total and per unit sold; and - Marketing and advertising for the promotion of the drug; • The gross revenue, net revenue, gross profit, and net profit to the manufacturer; • The total number of units of the prescription drug that were sold in interstate commerce; • Pricing information (e.g., wholesale acquisition cost, net average price realized by PBMs for drugs provided in the U.S., the net	***Similar to the Affordable and Safe Prescription Drug Importation Act*** Allows wholesalers, licensed U.S. pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed/certified foreign sellers,[7] provided certain circumstances are met—after two years, authorizes importation from OECD countries that meet standards comparable to U.S. standards. Identifies such qualifying prescription drugs to include prescription drugs that: • Are approved for use in patients and marketed in Canada (or, ultimately, in another country from which importation is later permitted); • Are manufactured in a registered facility that is in	***Similar to the Stop Price Gouging Act*** Requires manufacturers to submit quarterly reports (January 17, April 17, June 15, September 15) to the HHS OIG containing: • The total number of units of each prescription, FDA-approved drug sold; • The gross revenues from sales of such drugs; and • Any additional information related to anticipated or increased input costs, or public health considerations that the manufacturer may want the HHS OIG to consider in its assessment. Requires the HHS OIG to annually (February 28/29) complete an assessment of the reports received that:	*Failure to Submit Drug Pricing Manufacturer Reports*. 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. *Failure to Submit Price Gouging Reports.* Subjects manufacturers that fail to submit the required quarter reports to a civil penalty equal to the product of: • An amount determined by the HHS OIG that is (1) not less than 0.5% of the gross revenues from sales of the drug for the calendar year; and (2) not greater than 1% of the gross revenues from sales of the drug for the calendar year; and • The number of days in the period between (1) the quarterly submission	*Rebating*. Restores prescription drug rebates for seniors who are dually eligible for Medicare and Medicaid and extends these rebates to other Medicare patients in Medicare low-income subsidy plans. Excludes authorized generic drugs from calculations of average manufacturer price under the Medicaid drug rebate program (***Senate version only***). *Prescription Drug Cost Sharing*. Caps prescription drug cost sharing at $250 per month for individuals and $500 per month for families enrolled in QHPs and employer-based plans (applies for plan years beginning in 2019 and beyond). *Advertising.* Eliminates tax breaks for drug companies for expenses related to direct-to-consumer advertising.

[7] 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
	price of the drug charged to purchasers in each OECD country); • Certain information related to the receipt of patient assistance programs offered by the manufacturer; • Information on usage of patient assistance offered by the manufacturer; • Any federal health benefits received by the manufacturer (e.g., tax credits, patent applications that benefited from a federal grant); • The percentage of R&D expenditures on: - Activities conducted by the manufacturer; - Activities funded by federal entities; - Activities conducted by other entities such as academic institutions or other drug manufacturers; • Executive compensation for the CEO, CFO, and the 3 other most highly compensated executive officers; • Any additional information the manufacturer chooses to provide related to drug pricing decisions; and • Any other information required by HHS. Requires HHS to collate the manufacturers' reports and submit them to Congress, along with an analysis of the reports containing a summary of the data, consideration of certain factors (e.g., trends on R&D costs, federal benefits, etc.); and the relationship between those factors and prescription drug prices. Requires the reports and the HHS analysis to be publicly available on the HHS website.	compliance with the FDA's good manufacturing practices regulations; • Have the same active ingredient(s), route of administration, and strength as an FDA-approved prescription drug; or is biosimilar to an approved biological product and has the same product of administration and strength as the approved biological product); and • Are labeled in accordance with the laws of Canada (or, ultimately, in another country from which importation is later permitted) <u>and</u> the requirements promulgated by HHS (including labeling in English). Does <u>not</u> include: • Controlled substances; • Anesthetic drugs inhaled during surgery; or • Compounded drugs. Requires importers to submit biannual reports to HHS concerning any drug importation transactions. Requires HHS to report to Congress on the importation of drugs into the U.S.	• Identifies each price spike related to a drug; • Determines the price spike percentage and price spike revenue; • Determines the accuracy of the information submitted by the manufacturer regarding increased input costs; and • Assesses the rationale of the manufacturer's price spike. Requires the HHS OIG to annually (February 28/29) submit a report to the IRS (and later make it publicly available) that includes: • The information received from manufacturers; • The price spikes identified; • The price spike revenue determinations; • The average price of the drug for each month during the most recent calendar year; and • The determinations and assessments made. Requires the IRS to notify manufacturers regarding any drug that has been determined to have been subject to a price spike.	deadline <u>and</u> (2) the date on which the HHS OIG receives the late report. *Prescription Drug Importation Prohibitions.* Classifies certain acts by manufacturers (e.g., engaging in actions to restrict, prohibit, or delay the importation of a prescription drug) as unfair and discriminatory acts and practices. Authorizes HHS to suspend or temporarily suspend importation of a product (or suspend all products from a certified foreign seller or importer) if there is an importation involving counterfeit drugs, drugs that have been recalled/withdrawn, or drugs otherwise not permitted for importation. Imposes penalties of at most 10 years of imprisonment <u>or</u> a fine of at most $250,000 on online pharmacies that either: • Sell online with the intent to defraud, mislead, or with reckless disregard for public safety, an adulterated or counterfeit drug; <u>or</u> • Dispense a drug to an individual in the U.S. who	Other provisions concern: • The operation of, impact of, and costs associated with patient assistance programs. • Negotiating fair prices for Medicare prescription drugs. • Closing the Medicare Part D prescription coverage gap (***House version only***). • 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.

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	Offers an extension for the initial report from small businesses (i.e., those with fewer than 500 employees). Requires manufacturers to disclose to practitioners the wholesale acquisition cost for a 30-day supply of the drug whenever the manufacturer communicates with a practitioner about a drug, including through promotional, education, or marketing communications, meetings, paid events, etc. (***Senate version only***).	Requires GAO to submit a report to Congress on the implementation of the drug importation program, including a review of drug safety, cost savings, and expenses to consumers in the U.S. and trans-shipment and importation tracing processes.	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.[8]	does not possess a valid prescription.	• Promoting/sustaining competitive generic markets (***similar but not identical in House and Senate versions***). • Defining "product hopping" (***House version only***).
Prescription Drug and Medical Device Price Review Board Act of 2018 (H.R. 5739) Rep. Rosa DeLauro (D-CT)	Requires each manufacturer of a prescription drug or medical device that is sold in the U.S. to submit to the Prescription Drug and Medical Device Price Review Board ("Board") on a periodic basis—as determined by the board—the following information: • Each type of prescription drug and medical device that is sold by the manufacturer in the U.S. or an OECD member country; • The price charged by the manufacturer for the prescription drug or medical device in the U.S. or OECD member country; • The costs of the manufacturer to produce and market the prescription drug or medical device for sale in the U.S. or OECD member country.	Requires the Board to promulgate regulations permitting individuals to safely import from an approved country into the U.S. prescription drugs and devices that are comparable to prescription drugs and devices for which the Board has determined that the manufacturer is charging an "excessive price."	Prohibits manufacturers from charging "excessive prices"—as defined by the Board[9]—for prescription drugs or medical devices. Requires the Board to provide the manufacturer with notice (i.e., tell the manufacturer that they are charging an excessive price) and a period to correct the violation. If the manufacturer fails to correct the violation by the end of such period, subjects the manufacturer to enforcement.	If the Board finds the manufacturer of a prescription drug or medical device charged an excessive price, the following are considered available penalties: • A reduced patent term; • Civil penalties; • Enforcement through increased Medicaid rebates; or • Imposition of a tax on excess prescription drug profits. *Reduced Patent Term*. If the manufacturer of a prescription	Establishes, within HHS, the Prescription Drug and Medical Device Price Review Board. Grants the Board the authority to: • Obtain official data directly from any federal agency, provided it is necessary to carry out the Board's duties; • Use the U.S. mail; • Receive/use administrative support services from the GSA; • Contract with/compensate government and private

[8] 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.

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

Legislation	Drug Pricing Transparency	Prescription Drug Importation	Price Gouging	Penalties	Miscellaneous
	Requires CBO to submit an annual report to the Board on trends in the prices charged for prescription drugs and medical devices.			drug or medical device is also an owner of a patent for such drug or device, authorizes the Board to: • Reduce the term of any patent relating to the drug or device by not more than 5 years; or • If the term of each patent for the drug or device has expired, reduce the term by not more than 5 years of another patent owned by the patent owner. *Civil Penalties*. Authorizes the Board to impose a civil penalty on the manufacturer of not more than 10% of the manufacturer's gross sales of the drug or device during the period in which an excessive price is first charged and ending on the date on which the manufacturer ceases to charge an excessive price. *Tax*. Authorizes the imposition of a tax equal to the difference between the price at which such drug or device is sold and the reasonable price determined by the Board for such drug or device.	agencies to conduct research, surveys, etc.; • Undertake investigations; and • Issue subpoenas. Requires the Board to annually submit to other federal agencies that dispense/make payments for the dispensing of prescription drugs, a report containing: • A list of each prescription drug and medical device for which an excessive price was charged during the preceding calendar year; • Recommendations to the federal agency against dispensing or making payments for the dispensing of the prescription drug or medical device; and • Recommendations to the federal agency to substitute a similar prescription drug or medical device that is not sold at an excessive price. Requires the Board to annually submit a report to Congress describing the Board's activities for the preceding year.

Miscellaneous Legislation

Legislation	Issue Area	Overview
Patient Right to Know Drug Prices Act of 2018 (S. 2554/H.R. 6143) – ***Enacted 2018*** Sen. Susan Collins (R-ME)/Rep. Lloyd Doggett (D-TX)	*Gag Clauses*	Prohibits insurers and PBMs from restricting or penalizing pharmacies for providing enrollees with certain information, including: • Any difference between the enrollee's out of pocket cost under the plan/coverage with respect to the acquisition of the drug; and • The amount an individual would pay for acquisition of the drug without a health plan/health insurance coverage. Applies to plans offered through exchanges and by private employers; streamlines HHS reporting requirements for biosimilar and biological products.
Know the Lowest Price Act of 2018 (S. 2553/H.R. 6144) – ***Enacted 2018*** Sen. Debbie Stabenow (D-MI)/Rep. Lloyd Doggett (D-TX)	*Gag Clauses*	Effective 2020, prohibits PDP sponsors or MA organizations from restricting or penalizing pharmacies for providing enrollees with information on prescription drugs including: • Any difference between the negotiated price or copayment/coinsurance for the drug available to the enrollee under the plan; and • A lower price the individual would pay for a drug if the enrollee obtained it without health insurance coverage.
Know the Cost Act of 2018 (H.R. 6733) Rep. Buddy Carter (R-GA)	*Gag Clauses*	Prohibits PBMs, insurers, PDP sponsors, and MA organizations from restricting pharmacies that dispense prescription drugs to enrollees from informing such enrollees regarding certain cost-related information from enrollees; requires PDP sponsors and MA organizations to disclose the potential effects that purchasing a prescription drug without benefits provided under the plan would have on enrollees.
True Cost-Sharing of Seniors' Drugs Transparency (COST) Act (H.R. 6641) Rep. Erik Paulsen (R-MN)	*Gag Clauses*	Prohibits PDP sponsors, MA organizations, and insurers from preventing or penalizing a pharmacy for disclosing alternative/cheaper methods for purchasing prescription drugs; requires such PDP sponsors, MA organizations, and insurers to ensure that pharmacies provide certain additional information to enrollees purchasing prescription drugs (i.e., the effect that purchasing the drug would have on an individual's deductible, etc.).
Competitive Deals Resulting in Unleashed Generics and Savings (DRUGS) Act of 2017 (H.R. 4117) Rep. Lloyd Doggett (D-TX)	*Market Competition*	Eliminates tax benefits and deductions for prescription drug manufacturers of newly-approved, brand-name drugs that engage in pay-for-delay deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market).
Price Relief, Innovation, and Competition for Essential Drugs (PRICED) Act (H.R. 6577)	*Market Competition*	Reducing the market exclusivity for biologics from 12 years to 7 years.

Legislation	Issue Area	Overview
Rep. Jan Schakowsky (D-IL)		
Increasing Competition in Pharmaceuticals Act (S. 297)/***Lower Drug Costs Through Competition Act*** (H.R. 749) – ***similar though not identical*** Sen. Susan Collins (R-ME)/Rep. Kurt Schrader (D-OR)	*Market Competition*	Establishes clear timeframes for FDA to expedite review of certain applications for generic drugs (i.e., requires FDA to act within 150 days of submission *(Senate)* or 180 days *(House)*); requires FDA to report on a quarterly basis to Congress on the number of new drug applications filed for review prior to October 1, 2015; creates a new "generic priority voucher" that would be awarded to the sponsor of a successful application for a medical shortage drug that makes it to market; authorizes HHS to require a study of the FDA's risk and evaluation mitigation strategy program.
Drug-Price Transparency in Communications Act (S. 2157/H.R. 6576) Sen. Dick Durbin (D-IL)/Rep. Jan Schakowsky (D-IL)	*Marketing*	Requires drug manufacturers to disclose the wholesale acquisition cost of drugs in direct-to-consumer advertisements in a consumer-friendly manner; directs the FDA to issue regulations on the specific manner in which the cost must be disclosed (e.g., single price, visual/audio listings, brief explanations, etc.); requires pharmaceutical communications with health care practitioners to include the wholesale acquisition cost of the drug; and subjects manufacturers who fail to provide such disclosures to enforcement by the FTC.
Low Drug Prices Act (S. ___) Sen. Jeff Merkley (D-OR)	*Reference-Based Pricing*	Requires HHS to annually establish reference prices for all prescription drugs (both brand name and generic) by determining the median price for the drug among the so-called "reference countries" (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; 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.
H.R. 6642 Rep. Michael Burgess (R-TX)	*Medicaid Rebate*	Sunsets the current maximum rebate amount (100%) for outpatient Medicaid drugs by 2019.
Keeping Health Insurance Affordable Act of 2017 (S. 1511) Sen. Ben Cardin (D-MD)	*Medicare Part D & Medicare Rebate*	Requires drug manufacturers to provide rebates to Medicare in a specific amount (i.e., equal to total number of units for form and strength of drug, etc.) to HHS for covered Medicare Part D drugs; authorizes HHS to negotiate drug prices with manufacturers, among other things.
Phair Pricing Act of 2018 (H.R. 5958) Rep. Doug Collins (R-GA)	*Medicare Part D*	Requires negotiated price concessions, payments and adjustments (e.g., rebates, discounts, fees, reconciliation adjustments, etc.) to be available/calculated at the point-of-sale for Medicare Part D drugs; if price concessions cannot be calculated at the point of sale,

Legislation	Issue Area	Overview
		requires the PDP sponsor to use an estimated negotiated price, including all payments, adjustments, etc.; directs HHS to establish a working group to determine the quality measuers that apply to pharmacy operations.
Medicare Prescription Drug Negotiation Act of 2017 (S. 41/H.R. 242) Sen. Amy Klobuchar (D-MN)/Rep. Peter Welch (D-VT)	*Medicare Part D*	Directs HHS to negotiate drug prices (including discounts, rebates and other price concessions) with manufacturers for covered Medicare Part D drugs, while maintaining the same rule for formularies; requires HHS to submit a report to Congress on the prices negotiated.
Reducing Existing Costs Associated with Pharmaceuticals for Seniors (RxCap) Act of 2017 (S. 1347) Sen. Ron Wyden (D-OR)	*Medicare Part D*	Eliminates the prescription drug cost-sharing requirement for seniors eligible under Medicare Part D.