*June 14, 2019*

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# 2019 Federal Drug Pricing Legislation

*Newly Included Legislative and Procedural Updates*

*Legislative Updates*

- May 15: Sen. Ron Wyden (D-OR) introduced the Health Care Price Check Act of 2019 (S. 1497), which aims to improve transparency of out-of-pocket costs for prescription drugs, among other things.
- May 16: Sen. John Cornyn (R-TX) introduced the Medicare Prescription Drug Fraud Prevention Act of 2019 (S. 1505), which requires prescription drug plans and MA-PD plans to report to HHS potential fraud, waste, and abuse under Medicare Part D.
  May 17: Sen. Marsha Blackburn (R-TN) introduced the Pharmacy Benefit Managers Accountability Study Act of 2019 (S. 1532), which requires GAO to submit a study and recommendations on PBMs to Congress.
- May 22: Sen. Patty Murray (D-WA) introduced the Second Look at Drug Patents Act (S. 1617), which modifies the patent process for drug manufacturers.
- May 23: Sen. Mike Enzi (R-WY) introduced the Advancing Education on Biosimilars Act of 2019 (S.1681), which requires FDA establish a website to provide educational materials regarding biological products, among other things.
- May 24: Sen. Rick Scott (R-FL) introduced the Prescription Drug Price Reporting Act (S. 1664), which requires drug manufacturers annually report certain drug pricing information to HHS.
- May 28: Rep. Pete Olson (R-TX) introduced the Improving Low-Income Access to Prescription Drugs Act of 2019 (H.R. 3029), which permanently authorizes the Limited Income Newly Eligible Transition Program.

## I. Single-Issue Legislation (116th Congress - 2019) (*all legislation has been introduced; no further action has been taken, unless noted)*

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

## ***Drug Pricing Transparency Legislation***

| Legislation | Overview | Characteristics of a Qualifying Prescription Drug | Reporting Requirements | Report Content | Penalties | Miscellaneous |
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| ***Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019*** (S. 474)<br><br>Sen. Ron Wyden (D-OR) | Requires manufacturers of certain drugs to publicly report/justify significant price increases and other attendant costs to HHS. | Imposes reporting obligations on manufacturers of FDA-approved, prescription, "applicable drugs"—as determined by HHS—that:<br>• Have a wholesale acquisition cost of at least $10 per dose; and<br>• 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<br>• Are in the top 50th percentile of net spending in Medicare or Medicaid in the past 5 years; and<br>• Had an increased wholesale acquisition cost of at least 50% in the past 5 years or 15% over 1 year.<br><br>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).<br><br>*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.<br><br>*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:<br>• The factors that contributed to the increase;<br>• An explanation of how each factor contributed to the increase;<br>• Total expenditures of the manufacturer (i.e., on the drug's materials and manufacturing, acquiring patents and licensing for each drug, etc.);<br>• The percentage of the manufacturer's total expenditures for R&D that were derived from federal funds;<br>• The manufacturer's total R&D expenditures;<br>• The total revenue and net profit generated from the applicable drug for each calendar year since its approval;<br>• Total marketing and advertising costs; and<br>• 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.<br><br>Subjects a manufacturer who knowingly provides false information to a penalty of up to $100,000 for each piece of false information in the report. | *Publication of Manufacturer Data.* Requires HHS to post the justification and an easily-understandable summary of the justification publicly on the CMS website within 30 days of receiving the justification. |

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

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

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| | | individual for a Medicare-covered drug is at least $26,000 per year or per course of treatment.<br><br>*Exclusions*. Does not apply to "low cost" drugs with a wholesale acquisition cost of less than $10 per unit or less than $100 in average estimated expenditures per individual per year. | | determine executive compensation, additional expenditure information, any additional information related to the drug pricing decisions of the manufacturer, etc.); and<br>• Any other relevant information/supporting documentation necessary to justify the triggering SPIKE increase or as specified by HHS.<br><br>Requires such justifications to be certified by the manufacturer's CEO, CFO, or other individual who has delegated authority to sign for/reports directly to the CEO or CFO. | | • Reporting by manufacturers of certain drugs, devices, biologics, or medical supplies on the total aggregate value/quantity of samples provided to certain health care providers annually, among other things. ***Similar to the Sunshine for Samples Act of 2019***.<br>• An HHS report to Congress on inpatient hospital drug trends, shortages, and costs, among other things.<br>• Reporting by certain manufacturers and HHS on drug pricing under Medicare Part B (and associated penalties for failure to report). ***Similar to the Reporting Accurate Drug Prices Act of 2019***. |
| ***Drug Pricing Transparency Act*** (H. R. 2087)<br><br>Rep. Lloyd Doggett (D-TX) | Requires manufacturers of certain drugs *without* a Medicare rebate agreement to report drug pricing information to HHS. | ***Beginning in 2020***, requires manufacturers of certain drugs covered by Medicare Part B and for others (e.g., drugs for end stage renal disease patients) *without* a Medicare rebate agreement to report drug pricing information to HHS. | *Manufacturers.* Requires all manufacturers of certain drugs under the Medicare program that do not have a rebate agreement in effect to report drug pricing information to HHS.<br><br>*HHS.* Requires HHS to submit a report to Congress regarding the accuracy of average sales price information submitted by manufacturers. | *Manufacturers.* Requires manufacturers of certain drugs without a Medicare rebate agreement to report the following information:<br>• Average sales price and the total number of units;<br>• Wholesale acquisition cost;<br>• Information on those sales that were made at a nominal price or the total number of units of such drug/biological sold by the manufacturer in such quarter, and; | *Manufacturers.* Subjects wholesalers, manufacturers, or direct sellers who refuse to comply with HHS' request for information to a $100,000 civil monetary penalty. | *Verification.* Authorizes HHS to survey wholesalers and manufacturers that directly distribute a manufacturer's drugs to verify prices and average sales prices (including wholesale acquisition cost). |

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| | | | | • Total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug. | If a manufacturer fails to submit the requested information, subjects them to a penalty of $25,000 per day for each day that the report is not submitted.<br><br>Subjects a manufacturer who knowingly provides false information to a penalty of up to $100,000 for each piece of false information in the report. | |
| ***Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019*** (S.1391/H.R. 2296)<br><br>Sen. Tammy Baldwin (D-WI)/Rep. Jan | Requires manufacturers of certain drugs to submit justifications of price increases and other attendant costs to HHS prior to increasing the price of such drugs. | In certain circumstances, imposes reporting obligations on manufacturers of FDA-approved "qualifying drugs" that:<br>• Have a wholesale acquisition cost of $100 or more per month supply or per a course of treatment that lasts less than a month; | *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:<br>• 10% or more over a 12-month period; or<br>• 25% or more over a 36-month period.<br><br>Requires such reports to be submitted to HHS at least 30 days | Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer.<br><br>*Qualifying Drug.* Requires the report to include:<br>• The percentage by which the manufacturer will raise the wholesale acquisition cost;<br>• A justification for/description of each manufacturer's planned price increase;<br>• The identity of the drug's initial developer;<br>• The history of the manufacturer's price increases since the drug's initial FDA approval;<br>• The drug's current list price; | Subjects a manufacturer of a qualifying drug that fails to submit a required report to a penalty of $100,000 for each day that the report fails to be submitted. | *Publication of Manufacturer Data.* Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers no later than 30 days after the report has been received. |

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| Schakowsky (D-IL) | | • Are prescription drug products (i.e., subject to section 503(b) of the FFDCA) or are commonly-administered by hospitals (as determined by HHS);<br>• Are not defined as a drug for a rare disease or condition;<br>• Have not been designated by HHS as a vaccine; and<br>• Earn at least $1 of their total sales from individuals enrolled in Medicare or Medicaid programs. | before the planned effective date of the price increase.<br><br>*HHS.* Requires HHS to submit an annual report to Congress that<br>• Summarizes the information reported by the manufacturer; and<br>• Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. | • The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing;<br>• The percentage of expenditures on R&D from federal funds;<br>• The total of the manufacturer's expenditures on R&D;<br>• 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<br>• The total marketing and advertising costs.<br><br>*Manufacturers*. Requires the report to include:<br>• The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period");<br>• All stock-based performance metrics used to determine executive compensation during the applicable period;<br>• 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<br>• Any other information requested by HHS. | | |
| ***Prescription Drug Price Reporting Act***<br><br>(S. 1664)<br><br>Sen. Rick Scott (R-FL) | Requires drug manufacturers annually report to HHS certain drug pricing information. | All prescription drugs marketed in the U.S. | *Manufacturers.* Requires manufacturers of all drugs marketed in the U.S. to annually report to HHS.<br><br>Requires manufacturers of newly marketed drugs to report the drug code to HHS within 60 days and provide the annual reporting | *Manufacturers.* Requires the annual report to include:<br>• Each applicable National Drug Code (or J-Code), brand name, generic/chemical name and therapeutic class, as applicable;<br>• Current and annual average wholesale acquisition cost per 30-day supply or typical course of treatment; | | *Preemption.* Prohibits states from establishing or continuing to give effect to any law requiring the manufacturer to report or make public prescription drug pricing information. |

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

## ***Prescription Drug Importation Legislation***

| Legislation | Overview | Characteristics of a Qualifying Prescription Drug | Importation Requirements and/or Restrictions | Notification/Reporting Requirements | Penalties | Miscellaneous |
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| ***Affordable and Safe Prescription Drug Importation Act*** (S. 97/H.R. 447) | Requires HHS to issue regulations allowing wholesalers, licensed U.S. pharmacies, and individuals to | Allows the importation of drugs from Canada, provided they:<br>• Are approved for use in patients and marketed in Canada;<br>• Are manufactured in an FDA-registered facility; | *Certified Foreign Sellers*. Requires importers (or individuals who import prescription drugs into the U.S.) to purchase qualifying prescription drugs from a "certified foreign seller" who (1) is certified by HHS,[1] (2) has paid the | *Importers.* Requires importers to submit biannual reports to HHS on each qualifying prescription drug imported into the U.S. that contains: | *Unfair and Discriminatory Acts and Practices*. Prohibits a manufacturer from:<br>• Charging a higher price for a prescription drug sold to a certified foreign seller than the | *Preemption.* Does not supplant or preempt state or other federal laws.<br><br>*Publication of Certified Foreign* |

[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

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| Sen. Bernie Sanders (I-VT)/Rep. Elijah Cummings (D-MD)<br><br>Senate Summary | import qualifying prescription drugs manufactured at FDA-inspected facilities from "certified foreign sellers" (possibly later expanded to include sellers in OECD member countries). | • 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;<br>• Is labeled in accordance with the laws of Canada (or another country from which importation is permitted); and<br>• Is labeled in English (and in accordance with all other requirements promulgated by HHS).<br><br>Does not include:<br>• A controlled substance.<br>• An anesthetic drug inhaled during surgery.<br>• A compounded drug. | registration fee, and (3) sells only qualifying prescription drugs.<br><br>*Individuals*. Allows individuals to import a qualifying prescription drug from Canada (or another country) if it is:<br>• Dispensed (including through an online pharmacy) by a certified foreign seller that is a licensed foreign pharmacy;<br>• Purchased for personal use by the individual (i.e., not for resale) in quantities that do not exceed a 90-day supply; and<br>• 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.<br><br>*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:<br>• Is an OECD member;<br>• Has standards for the approval and sale of prescription drugs | • The facility identifier of the drug's registered manufacturer;<br>• 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<br>• The price paid by the importer for the drug.<br><br>*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.<br><br>*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 | price that is charged to another person that does not import such a drug into the U.S.<br>• 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.<br>• Causing there to be a difference between a prescription drug for distribution in the U.S. and the drug for distribution in Canada.<br>• Engaging in other actions to restrict, prohibit, or delay the importation of a prescription drug.<br><br>*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<br>• Counterfeit drugs,<br>• Drugs that have been recalled/withdrawn, or<br>• Drugs otherwise in violation of the bill<br>until an investigation is completed and it is determined that the drug, seller, or | *Sellers.* Requires HHS to publish online a list of certified foreign sellers, including web addresses, physical addresses, and telephone numbers of such sellers.<br><br>*Drug Testing Laboratories.* Authorizes HHS to approve laboratories to conduct random testing of prescription drugs sold by certified foreign sellers and assess the drugs' chemical authenticity.<br><br>*Supply Chain Security.* (Generally) requires certified foreign sellers to purchase drugs from registered manufacturers or entities, unless HHS has entered into an |

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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| | | | that are comparable to U.S. standards; and<br>• Meets certain other criteria (e.g., authorizes approval of a drug only if a drug is deemed safe and effective by government experts, etc.). | (e.g., cost-savings to consumers, and trans-shipment and importation tracing processes, resulting from such implementation). | importer does not endanger the public health.<br><br>*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. | MOU with Canada (or the permitted country). |
| ***Safe and Affordable Drugs from Canada Act of 2019*** (S. 61/H.R. 478)<br><br>Sen. Chuck Grassley (R-IA)/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:<br>• Are purchased from an approved Canadian pharmacy;<br>• Are dispensed by a pharmacist licensed to practice pharmacy and dispense prescription drugs in Canada;<br>• Are purchased for personal use by the individual, not for resale, in quantities that do not exceed a 90-day supply;<br>• Are filled using a valid prescription issued by a | 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:<br>• Located in Canada;<br>• Certified by the Secretary that (1) the pharmacy is licensed to operate and dispense prescription drugs to individuals in Canada; and (2) certain additional criteria are met.[2] | | | *Publication of Approved Canadian Pharmacies*. In conjunction with the regulations, requires HHS to publish on its website a list of approved Canadian pharmacies, including the Internet Web site address of each such approved Canadian pharmacy, from which individuals may |

[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.

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| | | physician licensed to practice in the U.S.; and<br>• Have the same active ingredient(s), route of administration, dosage form, and strength as prescription drugs approved by the FDA.<br><br>Does not include:<br>• A controlled substance.<br>• A biological product.<br>• An infused drug (including a peritoneal dialysis solution).<br>• An intravenously injected drug.<br>• A drug inhaled during surgery.<br>• A parenteral drug.<br>• 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.).<br>• A drug required to be refrigerated at any time during manufacturing, packaging, processing, or holding.<br>• A photoreactive drug. | | | | purchase prescription drugs. |
| ***Short on Competition Act*** (S. 844) | Allows HHS to grant expedited reviews/inspections and temporary | 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 years, or when the drug shortage | *Manufacturers.* Requires manufacturers to certify to HHS that they intend to seek approval of the drug. | *Denial of Importation*. Authorizes HHS to deny importation of an otherwise qualified drug if it is determined that: | *Marginally-Competitive Markets*. If a marginally-competitive market |

| Legislation | Overview | Characteristics of a Qualifying Prescription Drug | Importation Requirements and/or Restrictions | Notification/Reporting Requirements | Penalties | Miscellaneous |
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| Sen. Amy Klobuchar (D-MN) | importation when there are fewer than 5 competitors on drugs that have been on the market for at least 10 years (i.e., a marginally-competitive market exists).<br><br>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);<br>• 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);<br>• Contain the same active ingredient as the drug for which there is a shortage; and<br>• Will be subject to certain notification and reporting requirements. | no longer applies (whichever occurs first). | *Importers.* Requires importers to file with HHS information:<br>• Attesting that the requirements for a qualifying drug have been met.<br>• Identifying the drug the importer proposes to import and the manufacturer from which the importer proposes to import such drugs.<br>• Requests authority to import the drug;<br><br>*HHS.* Requires HHS to include information on the number of drugs authorized for temporary importation in its annual report to Congress. | • The drug is not safe and effective.<br>• The drug is used in conjunction with a device for which there is no reasonable assurance of safety and effectiveness.<br>• 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. | exists with respect to an applicable drug (i.e., not a radio pharmaceutical drug product), authorizes HHS to:<br>• Treat the marginally-competitive market[3] as creating a drug shortage;<br>• Expedite the review of applications and inspections with respect to the drug; and<br>• Authorize the importation of the drug. |

## ***Price Gouging Legislation***

| Legislation | Overview | Report Requirements | Report Content | Taxes | Penalties | Miscellaneous |
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| ***Combatting Unreasonable Rises and*** | Requires prescription drug | *HHS.* Requires HHS to notify manufacturers—and request a statement of justification—if it | *Manufacturers.* Provides that the required statement of justification for a price increase may include: | | *HHS.* Authorizes HHS to require a manufacturer found | |

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

| Legislation | Overview | Report Requirements | Report Content | Taxes | Penalties | Miscellaneous |
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| ***Excessively (CURE) High Drug Prices Act*** (S. 637)<br><br>Sen. Richard Blumenthal (D-CT)<br><br>Senate Summary | manufacturers to justify a price increase in "qualifying drugs" (i.e., prescription drugs covered by federal health care programs) that HHS deems to constitute "price gouging."[4] | determines that certain price increases within the last 2 years constitute "price gouging."<br><br>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.<br><br>*Manufacturers.* If a notification is received by a manufacturer, requires the manufacturer to provide a statement of justification for the price increase within 45 days of receiving the notification. | • Itemizing the components of the cost of producing the qualifying drug;<br>• Identifying the circumstances and timing of:<br>- An increase in materials/manufacturing costs that caused the price increase within the 5-year period preceding the date of the price increase;<br>- Any expenditures made by the manufacturer to expand access to the qualifying drug and explaining any improvement in public health associated with those expenditures;<br>• Providing sales and price information for other qualifying drugs with similar therapeutic effects; and<br>• Providing any other information that the manufacturer deems relevant. | | to have engaged in price gouging to:<br>• Reimburse consumers and third-party payors;<br>• Return to the original price for up to one year; or<br>• 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.<br><br>*DOJ.* Authorizes the Attorney General to bring an action in a district court for relief in certain circumstances. | |
| ***Prescription Drug Price Relief Act of 2018*** (S. 102/ H.R. 465) | Requires HHS to annually identify "excessively priced" patented, brand name drugs[5] that | *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). | *Manufacturers*. Requires manufacturers to submit annual reports containing the following information on brand name drugs:<br>• The average manufacturer price of the drug in the U.S. and in the reference countries;<br>• The wholesale acquisition cost of the drug in the U.S. and in the reference countries; | | *Manufacturers.* Subjects manufacturers that fail to submit their annual reports to a civil penalty that is equal to the product of:<br>• An amount determined by HHS that is (1) not less | *Generic Drugs.* If HHS identifies an excessively priced drug, HHS will:<br>• Waive/void any government-granted exclusivities to the drug's |

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

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

| Legislation | Overview | Report Requirements | Report Content | Taxes | Penalties | Miscellaneous |
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| Sen. Bernie Sanders (I-VT)/Rep. Ro Khanna (D-CA)<br><br>Senate Summary | 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).<br><br>Authorizes HHS to approve cheaper generic versions of those drugs, if manufacturers refuse to lower the price of drugs to the median price. | *HHS*. Requires HHS to annually report to Congress on its excessive drug price review for the preceding calendar year.<br><br>Requires such reports to be made publicly available on the FDA website in a manner that is easy to find and understand. | • Cumulative global revenues generated by the drug;<br>• Annual net sales revenue generated by the drug in the U.S. and in the reference countries;<br>• Total expenditures on domestic and foreign drug R&D related to the drug;<br>• Total expenditures on domestic and foreign marketing and advertising related to the drug;<br>• Investments in human clinical trials related to the drug;<br>• The estimated size of the affected patient population;<br>• Additional information the manufacturer chooses to provide related to drug pricing decisions; and<br>• Additional information required by HHS.<br><br>*HHS*. Requires HHS' annual report to contain summary data regarding:<br>• The total number of drugs that were reviewed;<br>• The total number of drugs found to be excessively priced (and the name/manufacturer of such drugs);<br>• The total number of drugs found to be excessively priced (listed by manufacturer);<br>• The extent to which the prices of the drugs were higher than reasonable, on average;<br>• The total number of drugs for which an open, non-exclusive license has been granted;<br>• The total number of generic drug applications received/approved that reference an excessively priced drug;<br>• The median approval time for generic drug applications in such circumstances;<br>• The total number of petitions HHS received to make excessive price determinations; | | 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<br>• The number of days in the period between (1) the annual submission deadline and (2) the date on which HHS receives the late report.<br><br>*Civil Action.* Authorizes HHS to bring civil actions against manufacturers of excessively priced drugs in certain circumstances. | manufacturer with respect to that drug; and<br>• 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.<br><br>Requires HHS to prioritize review of such generic drug applications (i.e., must be acted upon within 8 months of submission).<br><br>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.<br><br>*Publication in HHS Database.* Requires HHS to establish/maintain a comprehensive database of brand name drugs and their excessive price determinations.<br><br>*Anticompetitive Behavior*. Prohibits manufacturers from engaging in "anticompetitive behavior" (i.e., violating Section 5 of the FTC Act). |

| Legislation | Overview | Report Requirements | Report Content | Taxes | Penalties | Miscellaneous |
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| | | | • A list of any manufacturers who failed to report information, as required; and<br>• Any other information HHS deems appropriate. | | | |
| ***Stop Price Gouging Act*** (S. 378/H.R. 1093)<br><br>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.<br><br>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.<br><br>*HHS OIG.* Requires the HHS OIG to annually (February 28/29):<br>• Complete an assessment of the information submitted by manufacturers; and<br>• Transmit to the IRS a report on its findings (along with its assessment).<br><br>*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:<br>• HHS determines that a for-cause price increase exemption should apply; or<br>• 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:<br>• The total number of units of each prescription, FDA-approved drug that were sold in the last quarter;<br>• The average and median price per unit of each prescription drug sold in the last quarter, broken down by month;<br>• The gross revenues from sales of each prescription drug in the last quarter; and<br>• 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.<br><br>*HHS OIG Assessment.* Requires the annual assessment performed by the HHS OIG to include:<br>• Identification of each price spike relating to a prescription drug;<br>• A determination of the price spike revenue;<br>• A determination of the accuracy of the information submitted by the manufacturer regarding increased input costs; and<br>• An assessment of the manufacturer's rationale for the price spike.<br><br>*HHS OIG Report to the IRS.* Requires the annual HHS OIG report to the IRS to include:<br>• The information received from manufacturers; | Imposes an excise tax on each prescription drug deemed to have undergone an unnecessary price spike (i.e., a taxable prescription drug) sold by a manufacturer equal to the greater of:<br>• The annual price spike tax for the prescription drug; or<br>• The cumulative price spike tax for the prescription drug.<br><br>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:<br>• 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<br>• 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.<br><br>*Publication of Data.* Requires the HHS OIG to make its report to the IRS available to the public on its website.<br><br>*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.<br><br>*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.<br><br>*Study on Monopoly of Medical Products.* Requires GAO to conduct a study examining how drug manufacturers establish initial launch prices and suggest |

| Legislation | Overview | Report Requirements | Report Content | Taxes | Penalties | Miscellaneous |
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| | | greater than $10 for a 30-day supply; and<br>• The drug is marketed by at least three other drug companies and used by the companies as a reference drug. | • The price spike identified;<br>• The price spike revenue determinations; and<br>• Other determinations and assessments completed by the HHS OIG. | of the drug beyond medical inflation over a one year period or cumulatively.[6] | | best practices for monitoring new drug prices. |

## ***PBM Transparency Legislation***

| Legislation | Overview | Transparency Measures | Miscellaneous |
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| ***Prescription Drug Price Transparency Act*** (H.R. 1035)<br><br>Rep. Doug Collins (R-GA) | Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement. | *PBMs.* Prohibits PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor or with a Medicare Advantage ("MA") organization from doing either of the following:<br>• Requiring the plan enrollee use any pharmacy providing pharmacy services in which the PBM has an ownership interest, or ownership interest in; and<br>• 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.<br><br>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:<br>• 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;<br>• 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;"<br>• 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;<br>• 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 | |

[6] Prior to enforcement of the tax, the HHS OIG and the FTC would work with manufacturers to assess the extent to which an increase in price was due to changes in a drug's supply chain or for other justifiable reasons.

| Legislation | Overview | Transparency Measures | Miscellaneous |
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| | | • Provide to applicable pharmacies and respective contracting entities all such pricing data in a spreadsheet and easily accessible format. | |
| ***Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2019*** (S. 476)<br><br>Sen. Ron Wyden (D-OR)<br><br>Senate Summary | Requires public disclosure of the total amount of rebates provided by manufacturers to PBMs and the proportion of those rebates that are passed on to health plans. | Requires HHS to make publicly available on CMS' website certain information regarding a PBM's ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions, beginning in January 2020. Such information includes:<br>• The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiations that are attributable to the patient utilization under the plan;<br>• The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor;<br>• 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<br>• 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.<br><br>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.<br><br>*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.<br><br>Requires cost-sharing for Medicare Part D enrollees to be based off the negotiated price of the drug as agreed to by the drug manufacturer and the PBM. |
| ***S. 657***<br><br>Sen. Mike Braun (R-IN) | Prohibits PBMs from receiving rebates unless certain transparency requirements are met | Prohibits PBMs from receiving rebates/reductions in price from drug manufacturers unless:<br>• The rebates/reductions in price are reflected at the point-of-sale (e.g., the pharmacy counter); and<br>• Any other rebates/reductions in price are flat fee-based service fees that the manufacturer pays to the PBM for services related to the provision of PBM services to a health plan/insurer (i.e., requires fees to be transparent to the health plan or health insurance issuer). | |
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| Legislation | Overview | Transparency Measures | Miscellaneous |
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| ***Fair Care Act of 2019*** (H.R. 1332) (***excerpts***)<br><br>Rep. Bruce Westerman (R-AR)<br><br>House Summary | Requires PBMs to adhere to certain standards when entering into contracts and ensure the transparency of their drug pricing standards for reimbursement, among other things. | *PBMs.* Requires PBMs that enter into a contract with a Prescription Drug Plan ("PDP") sponsor, a Medicare Advantage ("MA") organization, or are part of an FEHBP contract to adhere to the following criteria when handling personally identifiable utilization and claims data, and other sensitive patient data:<br>• 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.<br>• Not require that a plan enrollee use any pharmacy providing pharmacy services in which the PBM has an ownership interest.<br>• 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.<br><br>Requires PBMs to do the following with respect to their drug pricing standards for reimbursement (e.g., their maximum allowable cost lists) for PDP sponsors, TRICARE, and FEHBP:<br>• 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;<br>• 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";<br>• 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;<br>• 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<br>• Provide to applicable pharmacies and respective contracting entities all such pricing data in a spreadsheet and easily accessible format (***largely mirrors the prior version of the*** Prescription Drug Price Transparency Act). | Incorporates other provisions to promote market competition, including:<br>• Targeting delay tactics related to sample-sharing and shared safety protocols that prevent entry of generic drugs into the market (***largely mirrors the CREATES Act***).<br>• Establishing a program to expedite the development of/provide priority review for "generic complex drug products."<br>• Preempting state laws that prohibit a pharmacy from dispensing an FDA-approved biosimilar.<br>• Limiting the exclusivity periods for drugs treating rare diseases and conditions.<br>• Allowing HHS to alter the reimbursement mechanism for drugs provided through the Medicare Part B program.<br>• Prohibiting Medicare prescription drug plan sponsors from retroactively reducing payment on "clean claims" (i.e., those without defects like incomplete documentation) submitted by pharmacies (***mirrors the Improving Transparency and Accuracy in Medicare Part D Spending Act***).<br>• Sunsetting the current maximum rebate amount (100%) for outpatient Medicaid drugs so that they apply only for rebate periods that begin between 2009 and 2025 (***mirrors H.R. 107***).<br>• Permitting HHS to establish a (1) mechanism prohibiting drug manufacturers from contributing financially to patient copays and (2) system of penalizing such behavior.<br>• Enacting transparency provisions specific to the 340B program.<br>• Requiring Congress to vote on all major actions (with an economic impact of $100 million+) proposed by FDA, among other things |
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| Legislation | Overview | Transparency Measures | Miscellaneous |
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| ***Public Disclosure of Drug Discounts Act*** (H.R. 2115)<br><br>Rep. Abigail Spanberger (D-VA) | Requires HHS to make publicly available on its website certain rebate information with respect to generic drugs. | ***Beginning in 2020***, requires HHS to make certain information on generic dispensing rates publicly available on its website, including:<br>• The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed that is paid by the health benefits plan or PBM under the contract;<br>• The aggregate amount/type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to the patient utilization under the plan;<br>• The aggregate amount of the rebates, discounts, or price concessions passed through to the plan; and<br>• 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). | |

## ***Multi-Issue Legislation***

| Legislation | Drug Pricing Transparency | Prescription Drug Importation | Price Gouging | Penalties | Miscellaneous |
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| ***Medicare for America Act of 2019*** (H.R. 2452)<br><br>Rep. Rosa DeLauro (D-CT)<br><br>House Summary<br><br>***Part of a larger package that includes a single-*** | ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019***.<br><br>Imposes reporting obligations on manufacturers of FDA-approved, prescription, "qualifying drugs":<br>• That have a wholesale acquisition cost of at least $100 or more per month supply or per course of treatment that lasts less than a month and is (1) prescribed by physicians or commonly administered by hospitals, (2) not designated as a drug for a rare disease or condition, and (3) not designated as a vaccine by HHS; and<br>• For which, during the previous calendar year, at least $1 of their total sales was earned from individuals enrolled in Medicare or Medicaid programs. | | Prohibits manufacturers from charging "excessive prices"—as defined by the Board[7]—for prescription drugs or medical devices.<br><br>Requires the Board to provide the manufacturer with notice (i.e., tell the manufacturer that they are charging an | *Drug Pricing Transparency.* Subjects manufacturers who fail to submit a report justifying a price increase for a qualifying drug to a civil penalty of $100,000 for each day the violation continues. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019***.<br><br>*Price Gouging.* If the Board finds the manufacturer of a prescription drug or medical | *Publication of Manufacturer Data.* Requires HHS to post, in a user-friendly manner, publicly on its website, the report submitted by manufacturers no later than 30 days after the report has been received. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019***.<br><br>*Annual Report*. Requires HHS to submit an annual report to Congress that:<br>• Summarizes the drug pricing information reported by the |

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

| Legislation | Drug Pricing Transparency | Prescription Drug Importation | Price Gouging | Penalties | Miscellaneous |
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| ***payer/public option proposal*** | Requires manufacturers of qualifying drugs to submit reports to HHS within 30 days of a price increase that will result in an increase in the wholesale acquisition cost that is equal to:<br>• 10% or more over a 12-month period; or<br>• 25% or more over a 36-month period.<br><br>Requires manufacturers' reports to, at a minimum, include specific information on both the qualifying drug and the manufacturer.<br><br>*Qualifying Drug*. Requires the report to include:<br>• The percentage by which the manufacturer will raise the wholesale acquisition cost;<br>• A justification for/description of each manufacturer's planned price increase;<br>• The identity of the drug's initial developer;<br>• The history of the manufacturer's price increases since the drug's initial FDA approval;<br>• The drug's current list price;<br>• The total of the manufacturer's expenditures on materials/manufacturing and patents/licensing;<br>• The percentage of expenditures on R&D from federal funds;<br>• The total of the manufacturer's expenditures on R&D;<br>• 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;<br>• The total marketing and advertising costs; and<br>• Any other information requested by HHS.<br><br>*Manufacturers*. Requires the report to include:<br>• The manufacturer's total revenue and net profit for the 12 or 36-month period (i.e., the "applicable period");<br>• All stock-based performance metrics used to determine executive compensation during the applicable period; | | excessive price) and a period to correct the violation.<br><br>If the manufacturer fails to correct the violation by the end of such period, subjects the manufacturer to enforcement. | device charged an "excessive price," the following are considered available penalties:<br>• A reduced patent term;<br>• Civil penalties; or<br>• Imposition of a tax on excess prescription drug and medical device profits.<br><br>*Reduced Patent Term*. If the manufacturer of a prescription drug or medical device is also an owner of a patent for such drug or device, authorizes the Board to:<br>• Reduce the term of any patent relating to the drug or device by not more than 5 years; or<br>• 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.<br><br>*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. | manufacturer of a qualifying drug; and<br>• Includes copies of the reports/supporting detailed economic analysis that are otherwise submitted. ***Mirrors the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019***.<br><br>*Prescription Drug and Medical Device Price Review Board.* Establishes, within HHS, the Prescription Drug and Medical Device Price Review Board.<br><br>Grants the Board the authority to:<br>• Obtain official data directly from any federal agency, provided it is necessary to carry out the Board's duties;<br>• Use the U.S. mail;<br>• Receive/use administrative support services from the GSA;<br>• Contract with/compensate government and private agencies to conduct research, surveys, etc.;<br>• Undertake investigations; and<br>• Issue subpoenas.<br><br>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. |

| Legislation | Drug Pricing Transparency | Prescription Drug Importation | Price Gouging | Penalties | Miscellaneous |
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| | • 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<br>• Any other information requested by HHS. | | | *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. | *Direct-to-Consumer Drug Advertising.* Prohibits direct-to-consumer advertising of new prescription drugs during a 3-year period beginning on the date of the drug application approval, unless HHS approves a waiver. |

| Legislation | Transparency | FDA Reform | PBM Reforms | Penalties |
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| ***Lower Health Care Costs Act of 2019*** (Discussion Draft)<br><br>Sen. Lamar Alexander (R-TN)<br><br>Senate Summary | *PBMs.* Prohibits group health plans and group or individual health insurers from entering into agreements with PBMs that do not provide plan sponsors with quarterly reports, which include:<br>• A description of all formulary tiers and utilization mechanisms (e.g., authorization or step therapy) for each therapeutic class within such tier;<br>• A list of each covered drug dispensed during the reporting period, including the drug name, number of enrollees for whom the drug was filled, and cost/price information (e.g., list price, net price, rebates, net spending, out-of-pocket spending by enrollees, etc.)<br><br>*Gag Clauses*. Prohibits gag clauses between providers and health plans that prevent individuals from seeing costs/data; prohibits gag clauses between providers and insurance plans that prevent plan sponsors from accessing de-identified claims data (e.g., data that could be shared under HIPAA business associate agreements).<br><br>*Transparency Organization.* Appropriates $20 million for 2020 and $15 million for 2021-2025 for HHS to contract with a nonprofit entity to establish and maintain a database on de-identified health care claims information, which would, among other things: | Codifies the publication of the FDA's "Purple Book" as a single, searchable list; requires additional information to be published in the Purple Book; and limits the enforceability of late-filed patents when a biosimilar application has already been filed with the FDA. ***Mirrors the Biologic Patent Transparency Act***<br><br>Authorizes FDA to remove or add patents from the "Orange Book;" imposes transparency requirements related to patents. ***Mirrors the Orange Book Transparency Act***<br><br>Permits FDA to reject citizen petitions if they believe that the primary purpose of the petition is to delay the approval of a drug application based on specific factors; and permits FDA to establish a time period for petitions to be submitted/allows petitions outside that period to be denied. ***Mirrors the Ensuring Timely Access to Generics Act***<br><br>Limits drug exclusivities for biological products, which codifies part of FDA's 2018 guidelines for biosimilars, among other things. | Prohibits PBMs from engaging in spread pricing or charging more for a drug than the PBM paid to acquire the drug; and requires PBMs to pass on 100% of any rebates or discounts to the plan sponsor. | *PBMs*. Subjects PBMs to a civil monetary penalty of not more than $10,000 for each day the reporting violation continues; and subjects PBMs that knowingly report false information to a civil monetary penalty of not more than $100,000 for each false item. |

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| | • Create an advisory committee to establish the entity's research and reporting objectives;<br>• Create reports for employers/employee organizations seeking to use the database; and<br>• Authorize grants to states maintaining or creating similar transparency initiatives. | ***Mirrors the Protecting Access to Biosimilars Act***<br><br>Amends the FDA's market exclusivity rules by preventing generic drug manufacturers from "parking" applications and delaying the start of their exclusivity. ***Mirrors the Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019*** | | |

## ***Miscellaneous Legislation***

| Legislation | Issue Area | Overview |
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| ***National Public Health Act of 2019*** (H.R. 2095)<br><br>Rep. Mark DeSaulnier (D-CA) | *Access* | Requires manufacturers of newly approved drugs that are determined to have a fiscal impact on public health (i.e., a drug or a drug collectively taken with a similar drug that amounts to $50 million or more per year) provide the drug to the public within 180 days of FDA approval; subjects manufacturers to a civil penalty up to $20,000 for each day the drug is in violation of the law. |
| ***Biologic Patent Transparency Act*** (S. 659)<br><br>Sen. Susan Collins (R-ME)<br><br>Senate Summary | *FDA Process Reform* | Codifies the publication of the FDA's "Purple Book" as a single, searchable list; requires additional information to be published in the Purple Book (e.g., patents that claim/relate to FDA-approved biological products, information related to biosimilarity and interchangeability, information related to exclusivities, and approved indications); and limits the enforceability of late-filed patents when a biosimilar application has already been filed with the FDA. |
| ***Efficiency and Transparency in Petitions Act*** (S. 660)<br><br>Sen. Mike Braun (R-IN) | *FDA Process Reform* | Requires any petition on a pending generic drug submitted to the FDA within 1 year of when the petitioner/drug manufacturer discovers the issue that is the basis for the petition; authorizes HHS to amend this 1 year deadline for certain petitions. |
| ***Purple Book Continuity Act of 2019*** (H.R. 1520)<br><br>Rep. Anna Eshoo (D-CA) | *FDA Process Reform* | Requires HHS to (1) publish and make publicly available certain information on licensed biological products; and (2) revise the information, every 30 days, to include newly licensed biological products among other things.<br><br>*March 27 – Approved by the Energy and Commerce Subcommittee on Health—as amended—by voice vote.* |

| Legislation | Issue Area | Overview |
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| | | *April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.*<br><br>*May 8 – Approved by the House—as amended—by a vote of 229-192.* |
| ***Orange Book Transparency Act*** (H.R. 1503)<br><br>Rep. Robin Kelly (D-IL) | *FDA Process Reform* | Authorizes FDA to remove or add patents from the "Orange Book" (i.e., list of FDA approved drug products, etc.); imposes transparency requirements related to patents (i.e., requires drug application holders to promptly submit a patent withdrawal or removal to FDA for patents found to be invalid, etc.).<br><br>*March 27 – Approved by the Energy and Commerce Health Subcommittee by voice vote.*<br><br>*April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.*<br><br>*May 8 – Approved by the House—as amended—by a vote of 231-191.* |
| ***Accelerated Drug Approval for Prescription Therapies (ADAPT) Act*** (S. 658)<br><br>Sen. Mike Braun (R-IN) | *FDA Process Reform* | Permits FDA to expedite applications for approval of certain drugs if there is evidence that:<br>• The drug is authorized to be marketed in specific countries (e.g., European Union members, Israel, Australia, Canada, and Japan)<br>• The drug is safe and clinically effective and a satisfactory history of clinical trials and data<br>• The manufacturer is capable of manufacturing the drug safely and consistently, and can assure the safety of the supply chain outside the United States<br>• All relevant United States patents or legal exclusivities are expired<br>• The drug is not approved for marketing in the United States<br>• HHS has not rescinded or withdrawn any such approval<br>• There is a public health or unmet medical need for the drug in the United States<br><br>Requires FDA to make a determination on a drug application no later than 180 days after submission. |
| ***Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act*** (S. 1209)<br><br>Sen. Bill Cassidy (R-LA) | *FDA Process Reform* | Prohibits FDA from immediately approving new drug substance patents to facilitate generic market entry; requires the Orange Book to be updated to reflect when a patent has been invalidated by the U.S. Patent and Trademark Office, among other things. |
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| Legislation | Issue Area | Overview |
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| ***Ensuring Timely Access to Generics Act*** (S. 1169/H.R. 2455)<br><br>Sen. Cory Gardner (R-CO)/Rep. John Joyce (R-PA) | *FDA Process Reform* | Permits FDA to reject citizen petitions if they believe that the primary purpose of the petition is to delay the approval of a drug application based on specific factors (e.g., appearance of a false date on a petition, submission of multiple petitions on issues that could have reasonably been known during earlier petitions, etc.); and permits FDA to establish a time period for petitions to be submitted/allows petitions outside that period to be denied. |
| ***Second Look at Drug Patents Act*** (S. 1617)<br><br>Sen. Patty Murray (D-WA) | *FDA Process Reform* | Requires drug manufacturers submit all new patents to the U.S. Patent and Trademark Office within 30 days of FDA approval; and permits patents to be listed in the FDA's "Orange Book" (i.e., list of FDA approved drug products, etc.) on a provisional basis, unless the Patent Trial Appeal Board confirms the patent to be patentable or if the patent is not challenged within 300 days after the drug application is approved. |
| ***Advancing Education on Biosimilars Act of 2019*** (S.1681)<br><br>Sen. Mike Enzi (R-WY) | *FDA Process* | Requires FDA to establish a website to provide educational materials and other information regarding biological products for consumers and providers, including, among other things:<br>• The FDA action package (e.g., documents related to the drug application approval such as the approval letter) for each biological product within 30 days of the drug application approval;<br>• Review summary of each biological product within 48 hours of approval of the application; and<br>• History and timing of manufacturing changes with respect to biological products. |
| ***Bringing Low-Cost Options and Competition While Keeping Incentives for New Generics (BLOCKING) Act of 2019*** (H.R. 938)<br><br>Rep. Kurt Schrader (D-OR) | *Market Competition* | Amends the FDA's market exclusivity rules by preventing generic drug manufacturers from "parking" applications (i.e., holding onto 180-day exclusivity in order to block other generic drugs from entering the market) and delaying the start of their exclusivity.<br><br>*March 27 – Approved by the Energy and Commerce Subcommittee on Health by voice vote.*<br><br>*April 3 – Approved by the Energy and Commerce Committee by voice vote.* |
| ***Competitive Deals Resulting in Unleashed Generics and Savings (DRUGS) Act of 2019*** (H.R. 1344)<br><br>Rep. Lloyd Doggett (D-TX) | *Market Competition* | Eliminates tax benefits and deductions for prescription drug manufacturers of newly-approved, brand-name drugs that engage in pay-for-delay deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market). |
| ***Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019*** (S. 340/H.R. 965) | *Market Competition* | Aims to promote competition in the pharmaceutical drug market by (1) requiring brand name drug manufacturers to sell "sufficient quantities" at "commercially reasonable" prices to generic competitors who need samples for bioequivalency testing as part of the Abbreviated New Drug Applications; (2) creating a legal framework to provide generics with the ability to get injunctive relief |

| Legislation | Issue Area | Overview |
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| Sen. Patrick Leahy (D-VT)/Rep. David Cicilline (D-RI)<br><br>Senate Summary | | faster from the courts; and (3) allowing judges to award payments to generics to deter anticompetitive behavior by brand name drug companies, among other things.<br><br>*March 27 – H.R. 965 was approved by the Energy and Commerce Subcommittee on Health by voice vote.*<br><br>*April 3 – H.R. 965 was approved by the Energy and Commerce Committee—as amended—by a vote of 51-0.*<br><br>*April 30 – H.R. 965 was approved by the Judiciary Committee by voice vote.* |
| ***Fair Access for Safe and Timely (FAST) Generics Act of 2019*** (H.R. 985)<br><br>Rep. Peter Welch (D-VT) | *Market Competition* | Prohibits drug manufacturers from restricting access to reference products (i.e., products that are necessary to demonstrate a drug's sameness, biosimilarity or interchangeability) to develop drugs, generic drugs, or biosimilars, among other things. |
| ***Forcing Limits on Abusive and Tumultuous (FLAT) Prices Act*** (S. 366/H.R. 1188)<br><br>Sen. Richard Durbin (D-IL)/Rep. Jared Golden (D-ME) | *Market Competition* | Reduces a prescription drug's market exclusivity by 180 days if a drug manufacturer increases the wholesale acquisition cost of the drug by more than: (1) 10% over 1 year, (2) 18% over 2 years, or (3) 25% over 3 years; reduces the market exclusivity by an additional 30 days for every additional 5% increase; requires a drug manufacturer that increases the wholesale acquisition cost by such percentages to report the increase to HHS within 30 days; reduces a manufacturer's market exclusivity by 30 days each day that the manufacturer fails to report to HHS, among other things. |
| ***Preserve Access to Affordable Generics and Biosimilars Act*** (S. 64)<br><br>Sen. Amy Klobuchar (D-MN) | *Market Competition* | Prohibits drug and biologics manufacturers from engaging in "pay-for-delay" deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market)/"reverse-payment" settlement (i.e., agreements in which branded companies pay generic companies not to compete as part of a patent settlement); grants the FTC authority to initiate enforcement proceedings against parties engaging in such agreements, among other things. |
| ***Protecting Consumer Access to Generic Drugs Act of 2019*** (H.R. 1499)<br><br>Rep. Bobby Rush (D-IL) | *Market Competition* | Prohibits drug and biologics manufacturers from engaging in "pay-for-delay" deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market); retroactively penalizes manufacturers that engage in such deals, among other things.<br><br>*April 3 – Approved by the Energy and Commerce Committee—as amended—by voice vote.* |
| ***Protecting Access to Biosimilars Act*** (S. 1140/H.R. 2011)<br><br>Sen. Tina Smith (D-MN)/Rep. Diana DeGette (D-CO) | *Market Competition* | Limits drug exclusivities for biological products, which codifies part of FDA's 2018 guidelines for biosimilars, among other things. |

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| ***State-Based, Market-Oriented Prescription Drug Negotiations Act*** (H.R. 2038)<br><br>Rep. Mark Meadows (R-NC) | *Market Competition* | Allows insurers and drug manufacturers to negotiate wholesale acquisition prices by creating a safe harbor from antitrust liability for private health insurers, as long as the wholesale acquisition price is jointly negotiated by the insurer and manufacturer. |
| ***Stop STALLING Act*** (S. 1224/H.R. 2374)<br><br>Sen. Amy Klobuchar (D-MN)/Rep. Hakeem Jeffries (D-NY) | *Market Competition* | Authorizes the FTC to enforce civil penalties on those who submit "sham" drug petitions (i.e., baseless attempts to interfere with the business of a competitor using the FDA's petition process) for anticompetitive purposes.<br><br>*April 30 – Approved by the Judiciary Committee by voice vote.* |
| ***Preserve Access to Affordable Generics and Biosimilars Act*** (H.R. 2375)<br><br>Rep. Jerry Nadler (D-NY) | *Market Competition* | Authorizes the FTC to enforce penalties on drug and biologics manufacturers that engage in "pay-for-delay" deals (i.e., agreements that delay the entry of less expensive, generic drugs into the market), among other things.<br><br>*April 30 – Approved by the Judiciary Committee by voice vote.* |
| ***Lowering Prescription Drug Costs and Extending Community Health Centers and Other Public Health Priorities Act*** (H.R. 2700)<br><br>Rep. Michael Burgess (R-TX) | *Market Competition* | Aims to improve generic drug competition, among other things, by:<br>• Requiring FDA to make determinations for new drug applications within 180 days of certain conditions being met (i.e., at least 30 months have passed since the application was submitted);<br>• Prohibiting filers of new drug applications and biologics license applications from entering into agreements on patent infringement if (1) a subsequent filer receives anything of value, including a drug license; and (2) a subsequent filer agrees to limit or forego research, development, manufacturing, marketing, or sales;<br>• Authorizing the FTC to enforce and commence civil action for violators of such agreements;<br>• Allowing drug manufacturers to bring civil action against a drug license holder if they fail to provide sufficient quantities of a drug (i.e., enough to conduct testing for a new drug application or fulfill any regulatory requirements relating to the approval of such application). |
| ***Affordable Prescriptions for Patients Act of 2019*** (S. 1416)<br><br>Sen. John Cornyn (R-TX) | *Market Competition* | Codifies the definitions of "product hopping" (i.e., holding onto 180-day exclusivity in order to block other generic drugs from entering the market) and "patent thicketing" (i.e., filing numerous patents on one drug to extend drug exclusivity); and authorizes the FTC to bring antitrust suits against drug manufacturers that attempt such anti-competitive activities. |
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| Legislation | Issue Area | Overview |
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| ***H.R. 107***<br><br>Rep. Michael Burgess (R-TX) | *Medicaid Rebate* | Sunsets the current maximum rebate amount (100%) for outpatient Medicaid drugs by so that they apply only for rebate periods that begin between 2009 and 2020. |
| ***Right Rebate Act of 2019*** (S. 205/H.R. 937)<br><br>Sen. Ron Wyden (D-OR)/Rep. Kurt Schrader (D-OR)<br><br>Senate Summary | *Medicaid Rebate* | Aims to prevent the misclassification of drugs under the Medicaid drug rebate program by:<br>• 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<br>• Creating oversight mechanisms for the program (e.g., manufacturer reports to HHS, HHS reports to Congress, etc.), among other things. |
| ***Keeping Health Insurance Affordable Act of 2019*** (S. 3)<br><br>Sen. Ben Cardin (D-MD) | *Medicare Part D & Medicare Rebate* | Requires drug manufacturers to provide rebates to Medicare in a specific amount (i.e., equal to total number of units for form and strength of drug, etc.) to HHS for covered Medicare Part D drugs; authorizes HHS to negotiate drug prices with manufacturers, among other things. |
| ***Payment Commission Data Act of 2019*** **(**S. 801/H.R. 1264/H.R. 1781)<br><br>Sen. Catherine Cortez Masto (D-NV), Rep. Lloyd Doggett (D-TX), and Rep. Buddy Carter (R-GA) | *Medicare Part D & Medicaid Rebate* | Provides the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission with access to certain drug payment information for outpatient Medicare Part D & Medicaid drugs, including certain rebate information, among other things.<br><br>*April 3 – H.R. 1781 was approved by the Energy and Commerce Committee—as amended—by voice vote.* |
| ***Empowering Medicare Seniors to Negotiate Drug Prices Act*** (S. 62)<br><br>Sen. Amy Klobuchar (D-MN) | *Medicare Part D* | Allows HHS to negotiate Medicare Part D prescription drug prices with drug manufacturers, PDP sponsors, and pharmacies. |
| ***Medicare Drug Price Negotiation Act*** (S. 99/H.R. 448)<br><br>Sen. Bernie Sanders (D-VT)/Rep. Elijah Cummings (D-MD)<br><br>*See* Senate Summary | *Medicare Part D* | Directs HHS to negotiate Medicare Part D prescription drug prices; establishes "fallback prices" for drugs if HHS is unsuccessful in negotiating an appropriate price with the manufacturer; allows HHS to establish one national drug formulary for use by all PDP sponsors, among other things. |
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| ***Medicare Negotiation and Competitive Licensing Act of 2019*** (S. 377/H.R. 1046)<br><br>Sen. Sherrod Brown (D-OH)/Rep. Lloyd Doggett (D-TX) | *Medicare Part D* | Aims to lower Medicare Part D drug prices by:<br>• Requiring HHS to negotiate Medicare Part D prescription drug prices with drug manufacturers; and<br>• 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. |
| ***Medicare Prescription Drug Negotiation Act of 2019*** (H.R. 275)<br><br>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 2019*** (S. 475)<br><br>Sen. Ron Wyden (D-OR) | *Medicare Part D* | Eliminates the prescription drug cost-sharing requirement for seniors eligible under Medicare Part D. |
| ***Improving Transparency and Accuracy in Medicare Part D Spending Act*** (S. 988)<br><br>Sen. Shelley Moore Capito (R-WV) | *Medicare Part D* | Prohibits PDP sponsors and MA-PD organizations from retroactively reducing payments on clean claims (i.e., a Medicare claim that is free of defects such as incomplete documentation) submitted by pharmacies. |
| ***Creating Lower Cost Alternatives for Your Prescription Drugs (CLAY) Act*** (H.R. 2757)<br><br>Rep. Joe Cunningham (D-SC) | *Medicare Part D* | Reduces generic drug cost-sharing to $1 or less and all other prescription drugs to $3 or less for low-income subsidy beneficiaries of Medicare Part D; eliminates all prescription drug cost-sharing for such beneficiaries beginning in 2021. |
| ***Medicare Prescription Drug Fraud Prevention Act of 2019*** (S. 1505)<br><br>Sen. John Cornyn (R-TX) | *Medicare Part D* | Requires prescription drug plans and MA-PD plans to report to HHS potential fraud, waste, and abuse of Medicare Part D benefits. |

| Legislation | Issue Area | Overview |
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| ***Improving Low-Income Access to Prescription Drugs Act of 2019*** (H.R. 3029)<br><br>Rep. Pete Olson (R-TX) | *Medicare Part D* | Permanently authorizes the Limited Income Newly Eligible Transition Program, which provides temporary prescription drug coverage for low-income beneficiaries who have not yet enrolled in a prescription drug plan or an MA-PD plan, or who has enrolled but the plan has not yet taken effect; permits HHS to waive certain eligibility requirements to carry out the program. |
| ***Prescription Drug Rebate Reform Act of 2019*** (S. 1384)<br><br>Sen. Mitt Romney (R-UT) | *Pricing/Rebates* | Requires patient coinsurance obligations be based on the net price of the prescription drug, rather than list price, before or after a deductible is met. |
| ***Pharmacy Benefit Managers Accountability Study Act of 2019*** (S. 1532)<br><br>Sen. Marsha Blackburn (R-TN) | *Limited PBM Transparency Requirements* | Requires GAO to provide a study with legislative recommendations to Congress, including, among other things:<br>• The role of PBMs in the pharmaceutical supply chain;<br>• State of competition among PBMs and market share of the 10 largest PBMs;<br>• Use of rebates and fees, including, for each drug in the formularies of the 10 largest PBMs, the amount of the rebate passed on to patients and payers, the amount kept by PBMs, and the role of fees charged by the PBM;<br>• Structuring formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives;<br>• Average prior authorization approval time for the 10 largest PBMs; and<br>• Factors affecting the use of step therapy for the 10 largest PBMs. |
| ***Prescription Drug Pricing Dashboard Act*** (S. 709)<br><br>Sen. Bob Casey (D-PA) | *Limited Transparency Requirements* | Requires HHS to establish, annually update, and make publicly available an internet website-based dashboard on the price and utilization of prescription drugs purchased by federal programs, among other things. |
| ***Transparent Drug Pricing Act*** (S. 977)<br><br>Sen. Rick Scott (R-FL) | *Limited Transparency Requirements* | Requires pharmacists disclose to customers at the point of sale a customer's out-of-pocket cost with respect to such drug and the cost of the drug without using the health plan; requires insurers credit the full amount of out-of-pocket costs for prescription drugs towards deductibles; requires insurers publish a list of copayment amounts 60 days before each annual enrollment period; prohibits insurers from changing copayment amounts until the next plan year; requires insurers provide a mechanism enabling enrollees to determine their projected total out-of-pockets costs for each prescription drug covered; and prohibits the retail list price of an FDA-approved drug from exceeding the lowest retain price for the same drug in Canada, France, the United Kingdom, Japan, or Germany (this requirement would sunset after 5 years). |
| ***Sunshine for Samples Act of 2019*** (H.R. 2064) | | |

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| Rep. Judy Chu (D-CA) | *Limited Transparency Requirements* | Requires manufacturers of certain drugs, devices, biologics, or medical supplies to annually report the total aggregate value/quantity of samples provided to certain health care providers; requires the report information be publicly available on a website that can be easily understood, searched, and downloaded, among other things. |
| ***Prescription Pricing for the People Act of 2019*** (S. 1227/H.R. 2376)<br><br>Sen. Chuck Grassley (R-IA)/Rep. Doug Collins (R-GA) | *Limited Transparency Requirements* | Requires the FTC to conduct a study/provide recommendations to Congress on the role of PBMs and assess potential anticompetitive practices in the drug supply chain.<br><br>*April 30 – Approved by the Judiciary Committee by voice vote.* |
| ***Drug-price Transparency in Communications (DTC) Act*** (S. 1437)<br><br>Sen. Richard Durbin (D-IL) | *Limited Transparency Requirements* | Codifies the HHS final rule requiring drug manufacturers to disclose drug prices within direct-to-consumer advertisements. |
| ***Health Care Price Check Act of 2019*** (S. 1497)<br><br>Sen. Ron Wyden (D-OR) | *Limited Transparency Requirements* | Requires group and individual health plan insurers that have a contract with another entity that offers prescription drug management services to establish a toll-free telephone number for enrollees to directly receive information regarding the out-of-pocket costs for a covered prescription drug, including the variations in out-of-pocket-costs by:<br>• Pharmacy options (e.g., preferred pharmacy, mail order, and other pharmacies in a designated geographic area); and<br>• Generics or other therapeutically equivalent alternatives. |