Drug Pricing Legislation and Administrative Actions

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Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Transparency	Require CMS to provide Part D payment and rebate data and Medicaid rebate data to MedPAC and MACPAC.[1]	Identical.[2]	
	Require manufacturers to submit a justification and other information to HHS for price increases exceeding a certain threshold.[3]	Similar.[4]	
	Codify the internet dashboard that includes information on prescription drug and biological spending and utilization in Medicare Parts B and D and Medicaid.[5]		CMS redesigned the Drug Spending Dashboards to show year-over-year information on drug pricing and identify manufacturers that have increased prices.[6]
			Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency Final Rule (CMS-4187-F). Require that direct-to-consumer (DTC) TV ads for prescription drugs and biologics that are covered by Medicare or Medicaid include the current list price.[7] District Court ruling vacated the rule.[8]

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Transparency (Cont.)		Require manufacturers to annually report to HHS the total aggregate value and quantity of samples they give to certain health care providers.[9]	
		Direct HHS to submit a Report to Congress on the costs of drugs furnished in the inpatient hospital setting.[10]	
		Require drug manufacturers to submit information to HHS on the average sales price (ASP) for Part B drugs. Also require the HHS Office of Inspector General to issue a Report to Congress on the accuracy of ASP data submitted by manufacturers.[11]	
	Require GAO study on the effect of co-payment coupons and patient assistance programs on drug pricing and expenditures in Medicare and Medicaid.[12]		
Promoting Generic Drugs and Biosimilars	Allow the Federal Trade Commission (FTC) to initiate civil action against persons submitting citizen petitions that are baseless and attempt to use the process to interfere with competition.[13]	Identical.[14]	
	Allow the FDA to approve generic drug applications and provide 180-day exclusivity to the drug if no other generic manufacturers have successfully challenged a brand-name drug's patents.[15]	Similar.[16]	

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Promoting Generic Drugs and Biosimilars (Cont.)	Establish a process for generic manufacturers to obtain samples of brand name drugs for testing.[17]	Identical.[18]	
	Codify the publication in the Purple Book of patents for biologics in a searchable list of information. Require HHS to publish a list of any holders of biological product licenses that failed to submit information for publication.[19]	Similar.[20]	
	Require manufacturers to provide information to the FDA regarding the patents listed for FDA-approved drugs; patents that a court or the Patent Trial and Appeal Board invalidate must be removed from the Orange Book.[21]	Similar.[22]	
	Allow the Food and Drug Administration (FDA) to deny a citizen petition that is submitted with the purpose of delaying a generic drug application and specifies criteria for FDA to make such a determination.[23]		
		Prohibit agreements between brand-name drug manufacturers and generic drug manufacturers that delay entry to the market of a generic drug.[24]	
		Prohibit agreements between manufacturers and other drug companies that delay the entry to market of a generic drug, biosimilar, or interchangeable biologic.[25]	

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Promoting Generic Drugs and Biosimilars (Cont.)	Ensure that biologics that transition to the biologics pathway from the drugs pathway in 2020 cannot receive extended exclusivities. Ensure that FDA can continue to review drug applications submitted six months prior to the transition date that have not received approval.[26]		
	Grant FDA authority to more promptly approve a follow-on or generic drug and include a statement of necessary safety information in its labeling.[27]		
	Require FDA to develop a website to provide educational materials on biological products, including biosimilars.[28]		
	Clarify that manufacturers cannot receive five-year new chemical entity (NCE) exclusivity if the drug contains an activity moiety previously approved in the United States.[29]		
	Clarify that the clinical superiority standard applies to drugs with an orphan drug designation that are approved after the FDA Reauthorization Act of 2017 in order to be awarded seven years of orphan drug exclusivity, regardless of the date of the orphan drug designation.[30]		

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Promoting Generic Drugs and Biosimilars (Cont.)	Clarify that biosimilar applicants can include information in biosimilar submissions to show that the proposed conditions of use for the biosimilar product have been previously approved for the reference product.[31]		
Patents	Codify definitions of "product hopping" and "patent thicketing" and establish a framework for the FTC's litigation authority against manufacturers engaged in these practices.[32]		
	Prohibit patent owners from asserting tribal sovereign immunity to shield a patent from review by the U.S. Patent and Trademark Office.[33]		
Medicaid	Increase the Medicaid inflation rebate cap from 100 percent to 125 percent.[34]		
	Remove authorized generics from the calculation of AMP under the Medicaid Drug Rebate Program.[35]		
	Require HHS to audit the calendar quarter drug pricing information (AMP, ASP, number of units sold, best price and wholesale acquisition) reported by manufacturers.[36]		
	Allow states to include any drug, biologic, or insulin as part of a bundled payment if it is provided on an outpatient basis as part of or incident to physicians' services or hospital outpatient services. [37]		

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Medicaid (Cont.)	Allow states to establish Medicaid risk-sharing value-based agreements with manufacturers for potentially curative one-time treatments. Establish installment-based payments and render the state liable to the manufacturer for payment each installment year. Require HHS to issue guidance containing a model template. [Also appears in "Value-Based Arrangements" section below].[38]		
Part B			International Pricing Index Model for Medicare Part B Drugs Notice of Proposed Rulemaking (Forthcoming). The Agency intends to test whether the following changes would result in higher quality of care for Medicare beneficiaries and reduced spending for the Medicare program: (1) align select Part B drugs and biologics more closely with international prices; (2) allow vendors to negotiate prices for drugs and supply drugs to physicians and hospitals; and (3) eliminate the 4.3 percent drug add-on payment and replacing it with a set payment amount.[39]
	Require prescription drug, biologic and biosimilar manufacturers to exclude the value of coupons provided to individuals from each drug's ASP. [40]		

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Part B (Cont.)	Provide for a WAC plus no greater than three percent payment for new drugs, biologics, and biosimilars when ASP is unavailable. [41]		
	Establish a payment rate for biosimilars for the two-quarter initial period that is the lesser of WAC plus three percent or ASP plus six percent of the reference biologic. [42]		
	Increase the payment for biosimilars to ASP plus eight percent of the reference biologic for five-years. [43]		
	Require prescription drug and biologic manufacturers to pay Medicare a rebate for Part B drug or biologic prices that increase above CPI-U.		
	Define narrowly "bona fide service fees," to limit the fees except from calculation of ASP.[44]		
	Set $1,000 as the maximum add-on payment a provider can be paid for a drug, biologic or biosimilar. [45]		
	Establish physician administration payments at PFS rate instead of the OPPS rate for hospital outpatient departments. [46]		
	Require manufacturers to provide a partial refund to Medicare if unused units of a single-dose vial exceed 10 percent of total units. [47]		

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Part D	Modify the structure effective January 1, 2022, to: (1) eliminate the coverage gap; (2) reduce Medicare costs for band-name drugs from 80 percent to 20 percent in the catastrophic phase (plans pay 60 percent and manufacturers pay 20 percent); (3) establish $3,100 cap on out-of-pocket expenses for beneficiaries. [48]	Modify the structure to: (1) decrease Medicare share of catastrophic coverage over four years to 20 percent from 80 percent; and (2) establish a cap on out-of-pocket expenses for beneficiaries equal to the catastrophic threshold. [49]	
	Mandate pharmaceutical manufacturers provide Medicare with a rebate for each six-month period in which the list price (based on WAC) increased faster than the CPI-U for the same period. [50]		
	Require the Secretary to publicly report discrepancies for DIR submitted by plans and report results of an independent audit of plans, including DIR information. [51]		
	Allow Part D plans to use Parts A and B claims data to inform Part D coverage decisions. [52]		
	Authorize on a permanent basis the Limited Income Newly Eligible Transition (LI NET) program to provide prescription drug coverage for an LIS-eligible individual until covered under a Part D plan. [53]		
	Require Secretary to establish a standardized pharmacy quality metrics program in Part D. [54]		

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Part D (Cont.)	Require Star Rating system quality metrics for Part D plan sponsors to include assessment of plan benefit and formulary design in encouraging patient access to biosimilars. [55]		
	Require HHS study on whether pharmaceutical manufacturer distribution models incentivize a provider to prescribe a drug and a report on whether the distribution models violate existing federal law. [56]		
	Senate Finance Committee Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) indicated their intent to include a version of the rebate rule in the PDRPA before it moves to the floor. [Also appears in "Pharmacy Benefit Managers" section below].		Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection Proposed Rule (Withdrawn). [Also appears in "Pharmacy Benefit Managers" section below]
	Require Part D plan sponsors to provide a real-time benefit tool to facilitate the electronic transmittal of formulary and benefit information to an enrollee's prescribing physician.[57]		
	Prohibit plan sponsors from including banding information on Part D benefit cards. [58]		
	Require Part D plan sponsors to report suspected cases of waste, fraud, and abuse. [59]		

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Pharmacy Benefit Managers	Require the FTC and the House and Senate Judiciary Committees to submit a report to Congress on whether PBMs: (1) charge payers more than they reimburse pharmacies; (2) steer patients to any pharmacy; (3) use proprietary pharmacy data to increase revenue or market share; or (4) or use formulary design changes to increase market share of high cost drugs or reduce market share of lower cost drugs. The report must identify trends regarding competition in the supply change, how payers assess benefits and risks of contracting with intermediaries, and whether the FTC faces barriers in enforcing antitrust and consumer protection laws. The report must also include specific policy or legislative recommendations. [60]	Identical. [61]	
	Require HHS to disclose publicly the aggregate rebates, discounts, and other concessions negotiated by pharmacy benefits managers (PBMs). [62]	Similar.[63]	

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Pharmacy Benefit Managers (Cont.)	Increase insurance oversight of PBMs: (1) prohibit PBMs from engaging in spread pricing; (2) mandate that plan sponsors receive a report each quarter on the costs and rebate information pertaining to their PBM contracts; (3) establish reporting and pricing requirements for PBMs that own mail-order, specialty, or retail pharmacies; (4) require PBMs to provide 100 percent of any rebates or discounts to the plan sponsor. [64]		
	Require Part D plan sponsors to conduct financial audits of data related to PBM contracts to monitor PBM compliance with contract terms. [65]		
	Senate Finance Committee Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) indicated their intent to include a version of the rebate rule in the PDRPA before it moves to the floor. [Also appears in “Part D” section above]		Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection Proposed Rule (Withdrawn). [Also appears in “Part D” section above]

Major Areas of Reform	Senate Major Provisions	House Major Provisions	Administration Actions
Value-Based Arrangements	Allow states to establish Medicaid risk-sharing value-based agreements with manufacturers for potentially curative one-time treatments. Establish installment-based payments and render the state liable to the manufacturer for payment each installment year. Require HHS to issue guidance containing a model template. [Also appears in "Medicaid" section above][66]		
Importation			Two pathways for allowing the importation of lower-cost prescription drugs from other countries: (1) HHS and the Food and Drug Administration (FDA) would use a Notice of Proposed Rulemaking (NPRM) to authorize state demonstration projects to import drugs from Canada; and (2) FDA would use guidance to provide recommendations to manufacturers who seek to import into the United States versions of drugs that they sell in foreign countries.[67]

[1]The Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance Committee on July 25, 2019)

[2]H.R. 1781, Payment Commission Data Act (Reported out of House Energy & Commerce Committee on April 3, 2019)

[3]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[4]H.R. 2113, Prescription Drug STAR Act (Reported out of House Ways & Means Committee on April 9, 2019) and H.R. 2296, METRIC Act (Reported out of House Energy & Commerce Committee on July 17, 2019). There are some key differences between the two bills. H.R. 2113 is effective in 2021 and includes a five-year look-back period. In addition to reporting requirements for price increases over one- and three-year periods, H.R. 2113 also includes a $26,000 threshold for launch prices.

[5]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[6]CMS Unveils Enhanced "Drug Dashboards" to Increase Transparency on Drug Prices, https://www.cms.gov/newsroom/press-releases/cms-unveils-enhanced-drug-dashboards-increase-transparency-drug-prices (May 15, 2018)

[7]Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency Final Rule (CMS-4187-F)

[8]U.S. District Court for the District of Columbia Ruling in *Merck & Co., Inc., et al. v. United States Department of Health and Human Services, et al.*, https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2019cv1738-32

[9]H.R. 2113, Prescription Drug STAR Act (Reported out of House Ways & Means Committee on April 9, 2019) and H.R. 2296, METRIC Act (Reported out of House Energy & Commerce Committee on July 17, 2019)

[10]H.R. 2113, Prescription Drug STAR Act (Reported out of House Ways & Means Committee on April 9, 2019)

[11]H.R. 2113, Prescription Drug STAR Act (Reported out of House Ways & Means Committee on April 9, 2019) and H.R. 2296, METRIC Act (Reported out of House Energy & Commerce Committee on July 17, 2019)

[12]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[13]S. 1224, Stop STALLING Act (Reported out of Senate Judiciary on June 27, 2019)

[14]H.R. 2374, Stop STALLING Act (Reported out of House Judiciary Committee on April 30, 2019)

[15]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[16]H.R. 938, BLOCKING Act (Reported out of House Energy & Commerce Committee on April 3)

[17]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[18]H.R. 965, CREATES Act (Reported out of House Energy & Commerce Committee on April 3, 2019 and reported out of House Judiciary Committee on April 30, 2019)

[19]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[20]H.R. 1520, Purple Book Continuity Act (Reported out of House Energy & Commerce Committee on April 3, 2019)

[21]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[22]H.R. 1503, Orange Book Transparency Act (Reported out of House Energy & Commerce Committee on April 3, 2019)

[23]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[24]H.R. 1499, Protecting Consumer Access to Generic Drugs Act (Reported out of House Energy & Commerce Committee on April 3, 2019)

[25]H.R. 2375, Preserve Access to Affordable Generics and Biosimilars Act (Reported out of House Judiciary Committee on April 30, 2019)

[26]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[27]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[28]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[29]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[30]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[31]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[32]S. 1416, Affordable Prescriptions for Patients Act (Reported out of Senate Judiciary Committee on June 27, 2019)

[33]S. 440, PACED Act (Reported out of Senate Judiciary Committee on June 27, 2019)

[34]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[35]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[36]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[37]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[38]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[39]Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM) (October 30, 2018)

[40]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[41]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[42]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[43]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[44]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[45]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[46]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[47]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[48]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[49]House Ways and Means Committee and House Energy and Commerce Committee Draft Legislation, “To amend title XVIII of the Social Security Act to reduce the Medicare part D reinsurance subsidies, eliminate beneficiary out-of-pocket costs above the Medicare part D catastrophic threshold, and for other purposes” (Released May 23, 2019)

[50]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[51]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[52]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[53]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[54]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

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[56]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[57]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[58]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[59]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[60]S. 1227, Prescription Pricing for the People Act (Reported out of Senate Judiciary Committee on June 27, 2019)

[61]H.R. 2376, Prescription Pricing for the People Act (Reported out of House Judiciary Committee on April 30, 2019)

[62]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[63]H.R. 2113, Prescription Drug STAR Act (Reported out of House Ways & Means Committee on April 9, 2019) and H.R. 2296, METRIC Act (Reported out of House Energy & Commerce Committee on July 17, 2019)

[64]S. 1895, Lower Health Care Costs Act (Reported out of Senate HELP Committee on June 26, 2019)

[65]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[66]Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (Reported out of Senate Finance on July 25, 2019)

[67]U.S. Department of Health and Human Services Safe Importation Action Plan (issued July 31, 2019)