

Lawmakers have focused on increasing competition and transparency

Lawmakers are considering different ways of lowering drug prices

- » Bipartisan bills would end drugmaker tactics to delay generics from entering market and expand access to samples needed for testing generics
- » Several measures focus on increasing pricing transparency
- » Proposals to allow Medicare to negotiate drug prices or import drugs from abroad are largely backed by Democrats
- » Lawmakers could also look at preventing manufacturers from making minor changes to products to extend patents, known as “evergreening”

Congress has enacted recent laws to increase drug development

- » 21st Century Cures Act ([Public Law 114-255](#)) provided funding and other tools to spur drug development
- » FDA user fee reauthorization ([Public Law 115-52](#)) required FDA to expedite generic drug reviews

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President Trump’s drug pricing “blueprint” – key initiatives

Persuade other countries to pay more for Rx – or borrow their price controls

- » Create a Medicare Part B “international pricing index” model

Try to lower drug prices for Medicare

- » Pursue “value-based purchasing” arrangements
- » Make generic medicines free for some low-income Medicare beneficiaries*
- » Remove some protections from the “protected classes”

Add new regulations on drug advertisements

- » Require companies to publish the drug's list price in advertisements

Ban “gag clauses” for pharmacists

Put a halt to patent “games”

- » End “pay for delay” settlements

Fix the current rebate system

- » Consider whether rebates should be illegal under anti-kickback statutes

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PENDING BILLS IN CONGRESS

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Bills aimed at increasing generic competition have bipartisan support, but haven't advanced

Bill	Description	Sponsors
Preserve Access to Affordable Generics Act (S. 124)	Limit "pay-for-delay" settlements in which branded drug makers pay generic companies not to enter market for period of time	Sens. Amy Klobuchar (D-Minn.) and Charles Grassley (R-Iowa)
CREATES Act (S. 974, H.R. 2212)	Allow generic drug makers to bring civil action against brand-name companies that limit access to samples needed to test products	Sen. Patrick Leahy (D-Vt.) with 14 Democrats and 15 Republicans; Rep. Tom Marino (R-Pa) with 13 Democrats and 12 Republicans
FAST Generics Act (H.R. 2051)	Require drug makers to provide access to samples for testing and allow generic companies to sue if they are aggrieved	Rep. David McKinley (R-W.Va.) with 9 Democrats and 3 Republicans

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Drug importation bills for personal use have bipartisan support

Bill	Description	Sponsors
Safe and Affordable Drugs from Canada Act (S. 92, H.R. 1480)	Allow individuals to import prescription drugs from Canada for personal use	Late Sen. John McCain (R-Ariz) with 9 Democrats and 1 Republican, Rep. Chellie Pingree (D-Maine) with 5 Democrats and 4 Republicans
Personal Drug Importation Fairness Act (H.R. 934)	Allow individuals to import drugs from several specified countries that are the same as an FDA-approved prescription drug	Reps. Keith Ellison (D-Minn.) and Dana Rohrabacher (R-Calif.)
Affordable and Safe Prescription Drug Importation Act (H.R. 1245, S. 469)	Allow wholesalers, pharmacies, and individuals to import prescription drugs from Canada and other OECD countries	Rep. Elijah Cummings (D-Md.) with 28 Democrats; Sen. Bernie Sanders (I-Vt.) with 21 Democrats

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Medicare negotiation, other bills supported largely by Democrats

Bill	Description	Sponsors
Medicare Prescription Drug Price Negotiation Act (H.R. 242, S. 41)	Require HHS to negotiate drug prices for Medicare Part D	Rep. Peter Welch (D-Vt.) with 43 Democrats and 1 Republican; Sen. Amy Klobuchar (D-Minn.) with 13 Democrats
Medicare Drug Price Negotiation Act (H.R. 4138, S. 2011)	Require Medicare negotiations and establish formulary to set fallback prices; require rebates for drugs provided to low-income individuals	Rep. Elijah Cummings (D-Md.) with 19 Democrats; Sen. Bernie Sanders (I-Vt.) with 7 Democrats
Empowering Medicare Seniors to Negotiate Drug Prices Act (S. 1688)	Remove prohibition on HHS interference in price negotiations and setting formularies	Sen. Klobuchar with 34 Democrats
Stop Price Gouging Act (S. 1369, H.R. 2974)	Establish an excise tax on prescription drugs when prices spike	Sen. Sherrod Brown (D-Ohio) with 8 Democrats; Rep. Mark Pocan (D-Wis.) with 4 Democrats
S.1681 and H.R. 3536 (no short title)	Require individuals who conduct federally funded R&D to enter into "reasonable" price agreements	Sen. Bernie Sanders (I-Vt.); Rep. Peter DeFazio (D-Ore.) with 7 Democrats

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Other bills focus on disclosing how drug prices are set

Bill	Description	Sponsors
Prescription Drug Price Transparency Act (H.R. 1316)	Require pharmacy benefit managers to frequently update and disclose information used to determine pharmacy reimbursements	Rep. Doug Collins (R-Ga.) with 42 Republicans and 14 Democrats
Creating Transparency to Have Drug Rebates Unlocked Act (S. 637)	Require CMS to disclose pharmacy benefit managers' rebates and discounts; provide minimum portion to health plan sponsors	Sen. Ron Wyden (D-Ore.) with 4 Democrats
Stopping the Pharmaceutical Industry from Keeping Drugs Expensive Act (S. 1348)	Require drug makers to justify price increases of specified percentages to HHS and pay penalties if they don't	Wyden with 9 Democrats
Fair Accountability and Innovative Research Drug Pricing Act (S. 1131, H.R. 2439)	Require manufacturers to report specified price increases for products sold through Medicare and Medicaid to HHS	Sens. Tammy Baldwin (D-Wis.) and the late John McCain (R-Ariz.); Rep. Janice Schakowsky (D-Ill.) with 21 Democrats and 2 Republicans
Transparent Drug Pricing Act (H.R. 4116)	Require drug makers to report annually on costs, revenue, sales, and other information	Rep. Lloyd Doggett (D-Texas) with 32 Democrats

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AMCP positions and points of engagement on drug pricing issues

- Congress must pass the Pharmaceutical Information Exchange Act (PIE Act, H.R. 2026) to allow payors and manufacturers to communicate health care economic information prior to FDA approval of a product. Passage of the PIE Act would provide the necessary legal underpinning for FDA's recent guidance, which largely follows AMCP's Partnership Forum recommendations.
- HHS should consider pharmacists as key stakeholders in improving outcomes and managing Rx costs
- CMS should carefully consider ways to effectively manage medications in Part B, transition coverage of select medications from Part B to Part D and carefully evaluate the impact of beneficiary out-of-pocket costs, access to care, and Medicare Advantage
- Part D plans should have full formulary flexibility to manage high-cost medications, including the classes of clinical concern ("protected classes")

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AMCP positions and points of engagement on drug pricing issues

- CMS should adopt the Medicare Part D formulary coverage policy (coverage of one drug per class, versus two per class) as proposed in the President's FY2019 budget
- AMCP supports efforts to curb the inappropriate use of shared system Risk Evaluation and Mitigation Strategy program (REMS) to deter generic entry
- Food and Drug Administration (FDA) policies should promote biosimilar development and adoption
- Stakeholder collaboration and reexamination of current policies are needed to encourage VBC, including the need for a common definition of VBC, best practices, and legal and regulatory infrastructure to support VBC

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QUESTIONS?

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