Return to State of the Union Report

Drug Prices

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Section 1: Top 35 Countries with the Lowest Drug Prices

Rank	Country	Drug Price (vs. U.S.)
1	Türkiye (Turkey)	9.7% of U.S. prices
2	România	14% of U.S. prices
3	Polska (Poland)	15% of U.S. prices
4	Magyarország (Hungary)	16% of U.S. prices
5	Česko (Czech Republic)	17% of U.S. prices
6	Ελλάδα Elláda (Greece)	19% of U.S. prices
7	Portugal	21% of U.S. prices
8	Slovensko (Slovakia)	22% of U.S. prices
9	Italia (Italy)	24% of U.S. prices
10	España (Spain)	26% of U.S. prices
11	République française (France)	27% of U.S. prices
12	United Kingdom	28% of U.S. prices
13	Belgique (Belgium)	29% of U.S. prices
14	Nederland (Netherlands)	30% of U.S. prices
15	Sverige (Sweden)	31% of U.S. prices
16	Suomi (Finland)	32% of U.S. prices
17	Norge (Norway)	33% of U.S. prices
18	Danmark (Denmark)	34% of U.S. prices
19	Österreich (Austria)	35% of U.S. prices

Rank	Country	Drug Price (vs. U.S.)
20	Suisse or Schweiz (Switzerland)	36% of U.S. prices
21	Deutschland (Germany)	37% of U.S. prices
22	日本 Nippon (Japan)	39% of U.S. prices
23	한국 Hanguk (South Korea)	40% of U.S. prices
24	New Zealand	41% of U.S. prices
25	Australia	42% of U.S. prices
26	Canada	44% of U.S. prices
27	Éire (Ireland)	45% of U.S. prices
28	México	58% of U.S. prices
29	ישראל Yisra'el (Israel)	60% of U.S. prices
30	Chile	61% of U.S. prices
31	Colombia	64% of U.S. prices
32	Brasil (Brazil)	68% of U.S. prices
33	Argentina	70% of U.S. prices
34	भारत Bharat (India)	73% of U.S. prices
35	中国 Zhongguo (China)	75% of U.S. prices

Source: RAND Corporation / ASPE (U.S. Department of Health and Human Services), International Prescription Drug Price Comparisons, 2022 data (published February 2024). Data Year: 2022.

Rank of the United States: The United States does not appear among the 35 countries with the lowest drug prices because U.S. drug prices are the highest among all OECD nations. According to 2022 RAND/ASPE data, U.S. prices across all prescription drugs were 278% of the average prices in 33 OECD comparison countries, meaning Americans pay $2.78 for every $1.00 paid in other high-income countries. For brand-name drugs, U.S. prices were 422% of comparison-country prices.

The United States ranks last among all OECD nations in prescription drug affordability. The primary reasons for this disparity include:

(1) the absence of government price negotiation authority until the limited Medicare Drug Price Negotiation Program enacted under the Inflation Reduction Act of 2022;

(2) strong patent protections that delay generic competition;

(3) the dominant influence of pharmaceutical lobbying on legislative and regulatory policy;

(4) a fragmented, multi-payer insurance system that prevents unified bargaining power; and

(5) the unique U.S. market structure that allows manufacturers to set launch prices without regulatory approval. In 2024, data from the Peterson-KFF Health System Tracker showed that Medicare negotiated prices for the first 10 high-expenditure drugs were still on average 2.8 times higher than prices achieved by comparable nations.

References and Data Sources:

RAND/ASPE International Prescription Drug Price Comparisons (2022): https://pmc.ncbi.nlm.nih.gov/articles/PMC11147645/

ASPE International Prescription Drug Price Comparisons Report (PDF): https://aspe.hhs.gov/sites/default/files/documents/8e057b0a094e6f9b9d01171fce6698f4/international-price-comparisons.pdf

Peterson-KFF Health System Tracker: Medicare Negotiated Drug Prices vs. Other Countries: https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/

OECD Pharmaceutical Spending Data via Statista: https://www.statista.com/statistics/266141/pharmaceutical-spending-per-capita-in-selected-countries/

Drug Prices by World Region (Sorted by Region, Increasing Order)

Region	**Drug Price Range (vs. U.S.)**
Africa	5-25% of U.S. prices
Asia (Except 中国 Zhongguo (China))	18-55% of U.S. prices
Australia	42% of U.S. prices
Canada	44% of U.S. prices
Central America	35-55% of U.S. prices
中国 Zhongguo (China)	75% of U.S. prices
México (Mexico)	58% of U.S. prices
Middle East	20-45% of U.S. prices
Other	20-80% of U.S. prices
Россия, Rossiya (Russia)	18-30% of U.S. prices
South America	60-75% of U.S. prices
United States	100% (baseline)
Western Europe (Excluding Россия Rossiya (Russia))	24-37% of U.S. prices

Section 2: What Other Countries Have Done to Decrease Their Lowest Drug Prices

The 8 Top Rated Countries with the Lowest Drug Prices

Rank	Country	Drug Price Specification
1	Türkiye (Turkey)	Prices ~9.7% of U.S. drug prices (2022 RAND/ASPE data)
2	România	Prices ~14% of U.S. drug prices (2022 RAND/ASPE data)
3	Polska (Poland)	Prices ~15% of U.S. drug prices (2022 RAND/ASPE data)
4	Magyarország (Hungary)	Prices ~16% of U.S. drug prices (2022 RAND/ASPE data)
5	Česko (Czech Republic)	Prices ~17% of U.S. drug prices (2022 RAND/ASPE data)
6	Ελλάδα Elláda (Greece)	Prices ~19% of U.S. drug prices (2022 RAND/ASPE data)
7	Portugal	Prices ~21% of U.S. drug prices (2022 RAND/ASPE data)
8	Italia (Italy)	Prices ~24% of U.S. drug prices (2022 RAND/ASPE data)

Türkiye (Turkey)

Türkiye achieves among the lowest drug prices globally through a robust Reference Pricing System administered by the Türkiye Medicines and Medical Devices Agency (TITCK). Under this system, drug prices are benchmarked against the lowest prices in a basket of reference countries, including République française, España, Italia, Elláda, Portugal, and others.

The government mandates that no drug may be priced higher than 66% of the lowest reference country price.

Türkiye's Social Security Institution (SGK) negotiates directly with pharmaceutical companies for drugs covered under the national formulary.

The Pharmaceutical Law No. 6197 and implementing regulations set strict frameworks for pricing, reimbursement, and market authorization. Generic substitution is mandatory at the pharmacy level, with pharmacists required to dispense the lowest-cost bioequivalent.

The Ministry of Health (www.saglik.gov.tr) and TITCK (www.titck.gov.tr) jointly oversee the system.

Price reductions of 10-40% are periodically mandated for drugs that have been on the market for more than ten years.

România (Romania)

România employs a National Health Insurance House (CNAS, www.cnas.ro) reimbursement framework that tightly controls drug prices through international reference pricing.

The National Agency for Medicines and Medical Devices (ANMDMR, www.anm.ro) approves and monitors pharmaceutical prices, requiring companies to submit comparative price data from 12 European Union member states.

România mandates price cuts when reference country prices decline and uses a positive reimbursement list (compensated drugs list) to restrict coverage.

The Ministry of Health (www.ms.ro) sets margins for wholesalers and pharmacies, preventing markup inflation.

Quarterly price revisions are required by law, with automatic reduction triggers when any reference country lowers its price.

The country has also implemented co-payment systems to incentivize patients toward generic medications, which account for a large share of dispensed prescriptions.

Polska (Poland)

Polska's drug pricing regime is governed by the Act on Reimbursement of Medicines, Foodstuffs for Particular Nutritional Purposes, and Medical Devices (Reimbursement Act of 2011), administered by the Ministry of Health (www.gov.pl/web/zdrowie).

Drugs eligible for reimbursement undergo an economic evaluation by the Agency for Health Technology Assessment and Tariff System (AOTMiT, www.aotmit.gov.pl), which produces cost-effectiveness and budget-impact analyses.

The National Health Fund (NFZ, www.nfz.gov.pl) negotiates reimbursement prices through formal agreements with manufacturers.

Polska applies a reference pricing mechanism tied to the lowest prices in EU countries, with mandatory price reductions when European benchmarks fall. Fixed official pharmacy margins and wholesale margins prevent price escalation at the distribution level.

Generic drugs receive expedited reimbursement approval and are prioritized in prescribing guidelines.

Magyarország (Hungary)

Magyarország's pharmaceutical pricing system is overseen by the National Institute of Pharmacy and

Nutrition (OGYEI, www.ogyei.gov.hu) and the National Health Insurance Fund (NEAK, www.neak.gov.hu).

Drug reimbursement prices are determined through a formal submission and negotiation process requiring comparative data from EU member states.

Magyarország applies a dynamic reference pricing framework that triggers automatic price adjustments when reference country prices change.

The Medicines Act and Government Decree 32/2004 establish detailed pricing and reimbursement rules, including step-therapy requirements that mandate patients try lower-cost drugs before accessing more expensive alternatives.

Magyarország has also implemented risk-sharing agreements with manufacturers for high-cost treatments, where manufacturers refund the state if drugs underperform versus clinical expectations.

Pharmacy-level generic substitution is mandatory, with financial incentives for dispensing the lowest-priced generic.

Česko (Czech Republic)

The Česko regulates drug prices through the State Institute for Drug Control (SUKL, www.sukl.cz), which administers the national formulary and reimbursement list.

Under the Act on Public Health Insurance, all reimbursed drugs must undergo a health technology assessment before receiving a maximum reimbursable price.

The Ministry of Health (www.mzcr.cz) sets maximum price limits using a basket of reference countries, ensuring Czech prices do not exceed the lowest prices found across the EU reference basket.

The General Health Insurance Company (VZP, www.vzp.cz) and other health insurers negotiate supplemental discounts and rebates with manufacturers.

Generic drugs are fast-tracked and receive higher reimbursement rates relative to brand-name drugs, actively incentivizing prescribers and patients to choose generics.

Quarterly price reviews and mandatory disclosure of manufacturer transaction prices keep the system updated and transparent.

Elláda (Greece)

Elláda manages drug costs through the National Organization for Medicines (EOF, www.eof.gr) and the National Organization for Health Care Services Provision (EOPYY, www.eopyy.gov.gr). Drug prices are set using a 15-country European reference pricing model, and Elláda uses one of the most competitive reference baskets in the EU. In response to its fiscal crisis, Elláda enacted Law 3816/2010 and subsequent measures implementing mandatory price reductions, clawback mechanisms, and rebate systems.

The clawback system requires manufacturers to refund the state when pharmaceutical expenditures exceed predetermined budget targets.

The Positive List of Reimbursable Medicines is continuously updated by the Ministry of Health (www.moh.gov.gr) and reviewed by independent pharmaceutical advisory committees.

Hospital drug procurement is conducted through centralized tender processes that achieve additional volume-based price reductions.

Elláda mandates prescribing by International Nonproprietary Name (INN), promoting generic use and preventing brand-name-only prescriptions.

Portugal

Portugal's pharmaceutical pricing is administered by Infarmed - National Authority of Medicines and Health Products (www.infarmed.pt) under the Ministry of Health (www.sns.gov.pt).

Portugal applies a reference pricing system that sets reimbursement prices at the level of the third-lowest price among comparable products within therapeutic reference groups.

Manufacturers seeking reimbursement must provide pharmacoeconomic evidence and undergo a mandatory health technology assessment.

The National Health Service (SNS) uses centralized procurement and framework contracts for hospital drugs, achieving significant volume discounts.

Portugal implemented payback and clawback mechanisms under the Health Sustainability Pact, requiring manufacturers to compensate the state when spending exceeds budget caps.

Generic prescribing is promoted through INN-based prescription requirements and incentive schemes for physicians.

The country introduced a Drug Price Monitoring System that tracks real-time price changes across the European reference basket.

Italia (Italy)

Italia's pharmaceutical pricing and reimbursement framework is administered by the Italian Medicines Agency (AIFA, www.aifa.gov.it).

Drug prices for reimbursed products are negotiated directly between AIFA and manufacturers, with negotiations guided by pharmacoeconomic evidence and comparative effectiveness data. Italia applies European external reference pricing to benchmark drug costs.

A system of managed entry agreements, including payment-by-results, cost-sharing, risk-sharing, and capping contracts, is used for innovative or high-cost therapies.

The Ministry of Economy and Finance (www.mef.gov.it) sets overall pharmaceutical expenditure ceilings for the National Health Service (SSN), with automatic payback mechanisms triggered when spending exceeds caps.

AIFA maintains separate expenditure ceilings for territorial (outpatient) and hospital drugs.

Italia employs a therapeutic reference pricing system that establishes reimbursement ceilings for groups of therapeutically equivalent drugs, with patients paying the difference if they choose a higher-priced product.

Generic prescribing is encouraged through automatic substitution rules and physician prescribing guidelines.

Section 3: What the U.S. Can Do to Decrease Its Drug Prices

The United States can decrease drug prices through a comprehensive, multi-pronged strategy encompassing government action, legislative reform, private sector accountability, and public engagement. The following describes in detail what government agencies, government officials, corporations, organizations, and private individuals must do.

Government Agency Actions:

The Centers for Medicare and Medicaid Services (CMS, www.cms.gov) must aggressively expand the Medicare Drug Price Negotiation Program established under the Inflation Reduction Act of 2022, increasing the number of drugs eligible for negotiation each year and lowering the thresholds for eligibility based on market exclusivity periods.

CMS should develop transparent negotiation methodologies incorporating comparative effectiveness research, clinical outcome data, and international reference prices.

The Food and Drug Administration (FDA, www.fda.gov) must accelerate the approval of generic and biosimilar drugs by streamlining the Abbreviated New Drug Application (ANDA) process, resolving backlog applications, and issuing guidance that clarifies interchangeability standards for complex biologics.

The FDA should expand its Purple Book and Orange Book to ensure prescribers and patients can easily identify lower-cost equivalents.

The Federal Trade Commission (FTC, www.ftc.gov) must actively investigate and prosecute anti-competitive practices including pay-for-delay agreements, product hopping, and exclusionary patent strategies that prevent generic market entry.

The Department of Veterans Affairs (VA, www.va.gov) model of negotiated formulary pricing should be adopted as a benchmark and template for broader government purchasing programs.

The Department of Health and Human Services (HHS, www.hhs.gov) should publish an annual international drug price comparison report, create a pharmaceutical price transparency portal, and coordinate interagency efforts to reduce drug costs.

Government Official Actions:

Members of Congress must enact legislation establishing a national drug price negotiation authority with binding authority covering all federal programs, not just Medicare.

Congress should reform patent laws to limit the practice of evergreening, whereby manufacturers obtain multiple sequential patents on minor drug modifications to extend market exclusivity far beyond the original 20-year patent term.

Legislation should mandate price transparency at every level of the supply chain, including manufacturer list prices, wholesale acquisition costs, pharmacy benefit manager (PBM) rebates, and net prices. Congress must close the non-interference clause that, prior to the Inflation Reduction Act, prevented Medicare from negotiating drug prices.

The President must use executive authority to invoke march-in rights under the Bayh-Dole Act to authorize generic production of federally funded drug discoveries when prices are deemed unreasonable, and should direct HHS to import drugs from Canada and other countries under Section 804 of the Federal Food, Drug, and Cosmetic Act.

State governors and attorneys general must enforce state-level drug price transparency laws, prosecute fraudulent pricing practices, and participate in multi-state drug purchasing compacts to leverage collective bargaining power.

Corporate and Industry Actions:

Pharmaceutical manufacturers must adopt voluntary price caps for essential medicines and commit to pricing based on comparative effectiveness rather than market monopoly leverage.

Corporations must end the practice of paying generic manufacturers to delay market entry (pay-for-delay agreements), which have been shown to cost consumers billions annually.

Pharmacy benefit managers (PBMs) must be required to pass through drug rebates directly to patients at the point of sale rather than retaining them as profit, and must be subject to full transparency reporting requirements.

Hospitals and health systems must participate in group purchasing organizations (GPOs) that negotiate lower drug costs, adopt formulary management practices that prioritize cost-effective generics and biosimilars, and report pharmaceutical expenditure data to enable price benchmarking.

Health insurance companies must redesign benefit structures to reduce patient cost-sharing for essential medications, ensuring that high-deductible plans do not price patients out of life-saving drugs.

Private Organizations and Advocacy Groups:

Organizations such as the National Academy for State Health Policy (www.nashp.org), AARP (www.aarp.org), Families USA (www.familiesusa.org), and the Commonwealth Fund (www.commonwealthfund.org) must continue advocating for drug pricing reform through public education, legislative lobbying, and policy research.

The Institute for Clinical and Economic Review (ICER, www.icer.org) should expand its drug price assessments and make findings more directly actionable in federal and state reimbursement decisions.

Academic medical centers and research universities must advocate for reform of the Bayh-Dole Act's march-in rights to prevent excessive pricing of taxpayer-funded drug discoveries.

Private Citizen and Consumer Actions:

Private individuals must engage in civic action by contacting elected representatives, supporting drug pricing reform legislation, and participating in public comment periods for FDA and CMS rulemaking.

Patients should use price comparison tools such as GoodRx (www.goodrx.com), NeedyMeds (www.needymeds.org), and the Medicare Plan Finder to identify lower-cost drug options.

Consumer advocacy groups should organize campaigns demanding pharmaceutical price transparency and accountability. Individuals should request generic or biosimilar substitutions from prescribers and pharmacists whenever clinically appropriate.

Section 4: References

References for Section 2 and Section 3:

RAND/ASPE International Prescription Drug Price Comparisons, 2022: https://pmc.ncbi.nlm.nih.gov/articles/PMC11147645/

ASPE HHS International Prescription Drug Price Comparisons Report: https://aspe.hhs.gov/sites/default/files/documents/8e057b0a094e6f9b9d01171fce6698f4/international-price-comparisons.pdf

Peterson-KFF Health System Tracker: Drug Price Comparisons: https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/

Turkish Medicines and Medical Devices Agency (TITCK): https://www.titck.gov.tr

Turkish Ministry of Health: https://www.saglik.gov.tr

Turkish Social Security Institution (SGK): https://www.sgk.gov.tr

Romanian National Agency for Medicines (ANMDMR): https://www.anm.ro

Romanian National Health Insurance House (CNAS): https://www.cnas.ro

Romanian Ministry of Health: https://www.ms.ro

Polish Ministry of Health: https://www.gov.pl/web/zdrowie

Polish Agency for Health Technology Assessment (AOTMiT): https://www.aotmit.gov.pl

Polish National Health Fund (NFZ): https://www.nfz.gov.pl

Hungarian National Institute of Pharmacy (OGYEI): https://www.ogyei.gov.hu

Hungarian National Health Insurance Fund (NEAK): https://www.neak.gov.hu

Czech State Institute for Drug Control (SUKL): https://www.sukl.cz

Czech Ministry of Health: https://www.mzcr.cz

Czech General Health Insurance Company (VZP): https://www.vzp.cz

Greek National Organization for Medicines (EOF): https://www.eof.gr

Greek National Organization for Health Care Services (EOPYY): https://www.eopyy.gov.gr

Greek Ministry of Health: https://www.moh.gov.gr

Portuguese Infarmed - National Authority of Medicines: https://www.infarmed.pt

Portuguese National Health Service (SNS): https://www.sns.gov.pt

Italian Medicines Agency (AIFA): https://www.aifa.gov.it

Italian Ministry of Economy and Finance: https://www.mef.gov.it

U.S. Centers for Medicare and Medicaid Services (CMS): https://www.cms.gov

U.S. Food and Drug Administration (FDA): https://www.fda.gov

U.S. Federal Trade Commission (FTC): https://www.ftc.gov

U.S. Department of Veterans Affairs (VA): https://www.va.gov

U.S. Department of Health and Human Services (HHS): https://www.hhs.gov

AARP: https://www.aarp.org

Families USA: https://www.familiesusa.org

Commonwealth Fund: https://www.commonwealthfund.org

National Academy for State Health Policy (NASHP): https://www.nashp.org

Institute for Clinical and Economic Review (ICER): https://www.icer.org

GoodRx Drug Price Comparison Tool: https://www.goodrx.com

NeedyMeds Patient Assistance Programs: https://www.needymeds.org

Section 5: Draft of a House Bill

118th CONGRESS

2d Session

H.R. _____

IN THE HOUSE OF REPRESENTATIVES

A BILL

To decrease prescription drug prices in the United States through comprehensive federal action, government oversight, industry accountability, and consumer protections.

SHORT TITLE: THE AMERICAN PRESCRIPTION DRUG AFFORDABILITY ACT

SECTION 1. DEFINITIONS.

As used in this Act:

1. "Biological Product" means a therapeutic drug derived from biological sources, including proteins, antibodies, and gene therapies, subject to regulation under Section 351 of the Public Health Service Act.

2. "Biosimilar" means a biological product that is highly similar to, and has no clinically meaningful differences from, an existing FDA-approved biological product.

3. "Brand-Name Drug" means a prescription drug marketed under the proprietary name granted by the original developer and protected by unexpired patents or market exclusivity.

4. "Clawback Mechanism" means a statutory or contractual provision requiring pharmaceutical manufacturers to return funds to the federal government or a health insurance program when expenditures exceed a predetermined budget threshold.

5. "Comparative Effectiveness Research" means scientific research comparing the health outcomes, clinical effectiveness, and risks and benefits of two or more medical treatments, services, or items.

6. "Drug Price Negotiation" means the formal process by which a government agency, health program, or purchasing authority negotiates the reimbursement or purchase price of a prescription drug with its manufacturer.

7. "Essential Medicine" means a prescription drug designated by the World Health Organization or the Secretary of Health and Human Services as critical to meeting the priority health care needs of a population.

8. "Evergreening" means the practice of obtaining successive patents on minor modifications of an existing drug to extend effective market exclusivity beyond the original patent term.

9. "Generic Drug" means a pharmaceutical product that contains the same active ingredients, dosage form, strength, route of administration, and intended use as a brand-name drug, approved under an Abbreviated New Drug Application (ANDA).

10. "Health Technology Assessment (HTA)" means a multidisciplinary evaluation of clinical, economic, ethical, and social implications of a health technology to inform coverage and reimbursement decisions.

11. "International Reference Pricing" means a method of setting drug prices by reference to the prices of the same drug in a defined basket of comparator countries.

12. "Manufacturer" means any entity that develops, produces, markets, or holds the new drug application or biologics license application for a prescription drug.

13. "March-In Rights" means the authority of a federal agency under 35 U.S.C. Section 203 to license patents on federally funded inventions to third parties when the patent holder has failed to make the invention available on reasonable terms.

14. "Medicare Drug Price Negotiation Program" means the program established under the Inflation Reduction Act of 2022 authorizing the Centers for Medicare and Medicaid Services to negotiate prices for certain high-expenditure Medicare drugs.

15. "Pay-for-Delay Agreement" means any agreement in which a brand-name drug manufacturer provides value to a generic drug manufacturer in exchange for the generic manufacturer's agreement to delay market entry.

16. "Pharmacy Benefit Manager (PBM)" means an entity that administers prescription drug benefits on behalf of health insurers, Medicare Part D drug plans, and other clients, including negotiating drug prices and rebates.

17. "Reference Pricing" means a reimbursement methodology in which a payer establishes a maximum amount it will pay for a group of therapeutically equivalent drugs, with patients responsible for any cost above that amount.

18. "Secretary" means the Secretary of Health and Human Services unless otherwise specified.

19. "Therapeutic Reference Group" means a category of drugs grouped together for reimbursement purposes based on their therapeutic equivalence, clinical similarity, or common indication.

20. "Transparency" means the public disclosure of drug prices, rebates, price concessions, and supply chain data in a manner accessible to patients, prescribers, payers, and policymakers.

SECTION 2. ENACTING CLAUSE.

(a) Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, that this Act shall be known and may be cited as the "American Prescription Drug Affordability Act."

(b) Congress finds that:

(1) Prescription drug prices in the United States are significantly higher than in comparable nations, with U.S. prices averaging 278 percent of prices in 33 OECD comparison countries, based on 2022 RAND Corporation data commissioned by the U.S. Department of Health and Human Services.

(2) High drug prices impose severe financial burdens on patients, public health programs, and the national economy.

(3) International evidence demonstrates that government price negotiation, reference pricing, health technology assessment, and robust generic competition can achieve substantial and sustainable drug price reductions without compromising innovation.

(4) Immediate federal action is necessary to bring U.S. prescription drug prices in line with those of other high-income nations while preserving appropriate incentives for pharmaceutical research and development.

(c) The purpose of this Act is to reduce the cost of prescription drugs for all Americans through expanded government negotiation authority, mandatory price transparency, promotion of generic competition, regulation of supply chain practices, and accountability measures for manufacturers and intermediaries.

SECTION 3. REQUIREMENTS BY GOVERNMENT AGENCIES.

(a) Drug Price Negotiation Expansion. The Centers for Medicare and Medicaid Services (CMS) shall:

(1) Expand the Medicare Drug Price Negotiation Program to include no fewer than 50 drugs per year beginning in calendar year 2026, prioritizing high-expenditure drugs without generic or biosimilar competition.

(2) Apply negotiated prices to all federal health programs, including Medicaid, Veterans Affairs, TRICARE, and the Federal Employees Health Benefits Program.

(3) Publish annually the methodology used for drug price negotiations, including comparative international price data and health technology assessment findings.

(b) International Reference Pricing. The Secretary of Health and Human Services (HHS) shall:

(1) Establish a Most Favored Nation (MFN) reference pricing framework under which no federally reimbursed drug may be priced above the volume-weighted average price of the same drug in Australia, Canada, République française, Deutschland, Nippon, the Nederland, Norge, Sverige, Schweiz, and the United Kingdom.

(2) Adjust the MFN price list quarterly based on updated international pricing data.

(3) Create a publicly accessible, searchable database of international drug prices updated no less than quarterly.

(c) Generic and Biosimilar Promotion. The Food and Drug Administration (FDA) shall:

(1) Resolve all pending generic drug Abbreviated New Drug Application backlogs within 18 months of enactment.

(2) Issue final interchangeability designations for biosimilars within 12 months of application submission.

(3) Publicly list all instances of manufacturer conduct that delays generic market entry, including product hopping, citizen petition abuse, and restricted distribution programs.

(4) Create a Priority Generic Review pathway for drugs with fewer than three generic competitors in the market.

(d) Anti-Competitive Enforcement. The Federal Trade Commission (FTC) shall:

(1) Investigate and bring enforcement actions against all pay-for-delay agreements, product hopping, and exclusionary patent strategies within 180 days of this Act's enactment.

(2) Issue rulemaking declaring pay-for-delay agreements presumptively anticompetitive and unlawful.

(3) Publish annually a report on pharmaceutical market competition conditions, including identification of markets with fewer than three competitors.

(e) Health Technology Assessment. HHS shall establish a National Center for Drug Effectiveness and Pricing, which shall:

(1) Conduct or commission independent comparative effectiveness and cost-effectiveness assessments for all drugs subject to federal price negotiation.

(2) Issue value-based pricing benchmarks that shall inform, but not solely determine, negotiated prices.

(3) Publish assessment reports no later than 12 months after a drug's approval or no later than 60 days prior to the commencement of price negotiations.

(f) March-In Rights. The National Institutes of Health (NIH) and relevant federal agencies shall:

(1) Develop and publish criteria for exercising march-in rights under 35 U.S.C. Section 203 when the pricing of a federally funded invention is unreasonable in view of the public health need.

(2) Accept, review, and publicly respond to all march-in petitions within 120 days of submission.

(3) Exercise march-in rights when the price of a drug developed with federal funding exceeds three times the average price paid for the same drug in the reference countries identified in subsection (b)(1).

SECTION 4. REQUIREMENTS BY GOVERNMENT OFFICIALS.

(a) Congressional Reporting. The Comptroller General of the United States shall:

(1) Submit to Congress an annual report assessing the effectiveness of drug price negotiation, generic promotion, and anti-competitive enforcement measures under this Act.

(2) Include in each report a comparison of U.S. drug prices to those in the reference countries specified in Section 3(b)(1).

(b) Executive Directives. The President shall:

(1) Direct the Secretary of HHS to authorize importation of prescription drugs from Canada and other qualifying countries under Section 804 of the Federal Food, Drug, and Cosmetic Act within 90 days of enactment.

(2) Instruct the Director of the Office of Management and Budget (OMB) to incorporate drug price targets into federal procurement standards for all health-related purchasing.

(3) Appoint a Senior Drug Pricing Advisor in the Executive Office of the President to coordinate interagency drug pricing reform efforts.

(c) State Officials. Governors and State Attorneys General shall:

(1) Enact and enforce state drug price transparency laws requiring manufacturers to report list prices, net prices, and price increase justifications to state health departments.

(2) Participate in multi-state prescription drug purchasing compacts to leverage collective bargaining power.

(3) Establish state drug affordability review boards with authority to set upper payment limits for drugs purchased by state health programs.

(d) Congressional Action. Members of Congress shall:

(1) Enact patent reform legislation limiting evergreening by capping the number of Orange Book-listed patents per drug to those directly covering the active ingredient, dosage form, and primary delivery mechanism.

(2) Amend the Bayh-Dole Act to require as a condition of federally funded drug development that the resulting product be made available at a reasonable price, with march-in rights automatically triggered upon a finding of unreasonable pricing.

(3) Mandate full rebate pass-through by pharmacy benefit managers to patients at the point of sale.

(4) Enact legislation prohibiting pay-for-delay agreements and requiring any settlement of pharmaceutical patent litigation to be reviewed and approved by the FTC and the Department of Justice.

SECTION 5. REQUIREMENTS BY CORPORATIONS.

(a) Price Transparency. Each manufacturer of a prescription drug that is reimbursed in whole or in part by a federal health program shall:

(1) File with the Secretary, no later than January 31 of each year, a report disclosing the average manufacturer price, wholesale acquisition cost, net price after all rebates and price concessions, the research and development costs attributable to the drug, and the federal funding received in support of the drug's development.

(2) Provide at least 60 days' advance written notice to the Secretary before implementing any price increase that exceeds the Consumer Price Index for medical care.

(3) Publicly disclose, in plain language, the justification for any price increase exceeding five percent in a 12-month period.

(b) Prohibited Practices. No manufacturer shall:

(1) Enter into any agreement that compensates a generic or biosimilar manufacturer to delay or refrain from entering the market.

(2) Engage in product hopping — reformulating a drug without meaningful clinical benefit and withdrawing the original formulation for the primary purpose of impeding generic competition.

(3) Use restricted distribution programs to deny generic manufacturers samples necessary to conduct bioequivalence testing, except as required by an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS).

(c) Pharmacy Benefit Manager Reforms. Each pharmacy benefit manager (PBM) shall:

(1) Pass through to enrollees at the point of sale 100 percent of all rebates, fees, and price concessions received from drug manufacturers.

(2) Provide health plan sponsors with full, auditable accounting of all rebates, fees, and other compensation received from manufacturers.

(3) Refrain from any practice that restricts a patient's access to a lower-cost drug or that creates financial incentives favoring higher-priced drugs.

(d) Insurer Obligations. Health insurance issuers participating in federal or state health programs shall:

(1) Cap monthly out-of-pocket costs for essential medicines at $35 per drug.

(2) Place no prescription drug on a formulary tier that requires a cost-sharing amount exceeding $35 per month for a 30-day supply of an insulin product.

(3) Ensure that no prior authorization requirement delays access to a drug for more than 72 hours in non-urgent situations and 24 hours in urgent clinical situations.

(4) Report annually to HHS the total rebates received, total rebates passed through to enrollees, and the net cost of the ten highest-expenditure drugs in their formulary.

SECTION 6. REQUIREMENTS BY PRIVATE CITIZENS.

(a) Consumer Rights and Responsibilities. Patients and private individuals shall:

(1) Have the right to be informed by their pharmacist, at the point of dispensing, of the availability and price of generic, biosimilar, or therapeutically equivalent alternatives.

(2) Have the right to request and receive, at no additional cost, any lower-priced bioequivalent or interchangeable drug in lieu of a prescribed brand-name drug.

(3) Have the right to access a federally maintained, publicly available drug price comparison database enabling price comparisons across pharmacies, insurers, and geographic regions.

(b) Public Participation. Citizens are encouraged to:

(1) Submit public comments during all federal rulemaking proceedings related to drug pricing, formulary design, and pharmaceutical regulation.

(2) Report suspected violations of this Act's price transparency, rebate pass-through, and prohibited practices provisions to the HHS Office of Inspector General, the FTC, or the relevant state attorney general.

(3) Utilize patient assistance programs, drug discount programs, and price comparison tools made available by federal and state agencies.

SECTION 7. PENALTY CLAUSES.

(a) Civil Monetary Penalties. Any manufacturer, PBM, or insurer that violates a provision of this Act shall be subject to:

(1) A civil monetary penalty of not less than $1,000,000 and not more than $10,000,000 per violation, as determined by the Secretary in consultation with the FTC and the Department of Justice.

(2) An excise tax equal to 95 percent of sales revenues for any drug during any period in which the manufacturer has failed to comply with price transparency reporting requirements under Section 5(a).

(3) Exclusion from participation in Medicare, Medicaid, and all other federal health programs for a period of not less than five years upon a finding of a willful pay-for-delay violation.

(b) Criminal Penalties. Any person who willfully and knowingly engages in a pay-for-delay agreement prohibited under Section 5(b)(1) shall be subject to:

(1) A fine of not more than $10,000,000 for each such agreement.

(2) Imprisonment of not more than 10 years.

(3) Both such fine and imprisonment.

(c) Enforcement Authority. The FTC, the Department of Justice, and the HHS Office of Inspector General shall have concurrent enforcement authority over violations of this Act. State attorneys general may bring civil enforcement actions on behalf of their residents for violations affecting residents of their states.

SECTION 8. EFFECTIVE DATES AND IMPLEMENTATION.

(a) Immediate Provisions. The following provisions shall take effect upon enactment:

(1) The prohibition on pay-for-delay agreements under Section 5(b)(1).

(2) The requirement that manufacturers provide 60-day advance notice of price increases under Section 5(a)(2).

(3) The requirement to cap monthly out-of-pocket insulin costs at $35 under Section 5(d)(2).

(b) Phased Implementation.

(1) Within 90 days of enactment: The Secretary shall issue interim final rules implementing the international reference pricing framework under Section 3(b).

(2) Within 180 days of enactment: CMS shall begin expanded drug price negotiations covering no fewer than 50 drugs per year under Section 3(a).

(3) Within 12 months of enactment: The National Center for Drug Effectiveness and Pricing shall be fully operational under Section 3(e). (4) Within 24 months of enactment: All PBM rebate pass-through requirements under Section 5(c) shall be fully effective.

(c) Regulatory Authority. The Secretary of HHS, the Commissioner of the FDA, and the Chair of the FTC are each authorized to issue such regulations, guidance documents, and other sub-regulatory materials as are necessary to carry out the provisions of this Act.

SECTION 9. APPROPRIATIONS OR BUDGETARY NOTES.

(a) Authorization of Appropriations. There are authorized to be appropriated to carry out this Act:

(1) $750,000,000 for fiscal year 2025 and such sums as may be necessary for each fiscal year thereafter, to be allocated to the Centers for Medicare and Medicaid Services for expanded drug price negotiation activities.

(2) $250,000,000 for fiscal year 2025 and such sums as may be necessary for each fiscal year thereafter, to be allocated to the Food and Drug Administration for accelerated generic and biosimilar review programs.

(3) $100,000,000 for fiscal year 2025 and such sums as may be necessary for each fiscal year thereafter, to be allocated to the Federal Trade Commission for pharmaceutical market competition enforcement.

(4) $150,000,000 for fiscal year 2025 and such sums as may be necessary for each fiscal year thereafter, to be allocated to the National Center for Drug Effectiveness and Pricing established under Section 3(e).

(b) Budgetary Offsets. The Congressional Budget Office shall:

(1) Score the net budgetary impact of this Act within 60 days of enactment, incorporating estimated savings from drug price negotiations, generic promotion, and reduced federal health program expenditures.

(2) Report annually to Congress on actual versus projected savings from implementation of this Act.

(c) Estimated Impact. Based on available RAND Corporation and HHS data, the Congressional Budget Office is expected to find that this Act, if fully implemented, would reduce federal prescription drug expenditures by no less than $500,000,000,000 over a 10-year period, consistent with the savings potential identified in the RAND Corporation's 2022 International Prescription Drug Price Comparisons study.

ENDNOTES

1. International reference pricing frameworks modeled on practices employed in Australia (Pharmaceutical Benefits Scheme),
2. Canada (Ontario Drug Benefit formulary),
3. République française (Comite Economique des Produits de Sante),
4. Deutschland (Gemeinsamer Bundesausschuss, Federal Joint Committee),
5. Nippon (Central Social Insurance Medical Council),
6. Norge (Norwegian Medicines Agency),
7. Sverige (Dental and Pharmaceutical Benefits Agency), and
8. Suomi (Kela - Social Insurance Institution).
9. Source: OECD Health at a Glance 2023, https://www.oecd.org/health/health-at-a-glance.htm

10. Clawback and payback mechanisms modeled on practices in Elláda (payback laws enacted 2010-2014), Italia (AIFA budget ceiling system), and Portugal (Health Sustainability Pact rebate system).
11. Sources: Greek Ministry of Health, www.moh.gov.gr; AIFA Italia, www.aifa.gov.it; Infarmed Portugal, www.infarmed.pt

12. Mandatory INN (International Nonproprietary Name) prescribing requirements modeled on République française, España, and Elláda.
13. Source: European Medicines Agency, www.ema.europa.eu

14. Comprehensive health technology assessment requirements modeled on England (NICE - National Institute for Health and Care Excellence, www.nice.org.uk), Deutschland (IQWiG - Institute for Quality and Efficiency in Health Care, www.iqwig.de), and République française (HAS - Haute Autorite de Sante, www.has-sante.fr).

15. March-in rights provisions based on Bayh-Dole Act, 35 U.S.C. Section 203.

    Source: U.S. Government Publishing Office, www.govinfo.gov