FLORIDA HOU.S.E OF REPRESENTATIVES
BILL ANALYSIS

This bill analysis was prepared by nonpartisan committee staff and does not constitute an official statement of legislative intent.

BILL #: HB 697	**COMPANION BILL:** SB 1158 (Grall)
TITLE: Drug Prices and Coverage	**LINKED BILLS:** None
SPONSOR(S): Kincart Jonsson	**RELATED BILLS:** SB 1158 (Grall)

Committee References

Health Care Facilities & Systems 15 Y, 1 N	➤ Budget 27 Y, 2 N	➤ Health & Human Services

SUMMARY

Effect of the Bill:
HB 697, creates the Prescription Reduction Incentives and Competition Enhancement (PRICE) Act, which establishes a most-favored-nation (MFN) upper payment limit for prescription drugs and biological products in Florida. The Agency for Health Care Administration set the upper payment limit based on an index of reference prices in certain international markets, reflecting the lowest price paid for those same pharmaceuticals in countries of similar wealth with market-based health care systems. The upper payment limit will apply to reimbursement for these drugs Florida-regulated health plan sponsors, to the amount cash-paying patients would pay at the pharmacy.

The bill also creates new requirements for contracts between pharmacy benefit managers (PBMs) and pharmacies and prohibits certain business activity. The bill also prohibits insurers and PBMs from adversely changing their drug coverage formularies during the plan year, if they can negotiate a drug price that will apply for the whole plan year.

Fiscal or Economic Impact:
The bill will have a significant negative fiscal impact on AHCA to contract with an entity to perform MFN upper payment limit analyses. The MFN portion of the bill may have a positive fiscal impact on employers (including government employers) offering drug coverage to their employees, individual policy insurers, and patients paying cash for prescription drug, due to reduced drug costs. coverage for employees to the extent these local governments experience savings.

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ANALYSIS

EFFECT OF THE BILL:

The Prescription Reduction Incentives and Competition Enhancement (PRICE) Act

HB 697 limits what patients and insurers may pay for prescription drugs based on benchmark prices in other countries similar to Florida in economic scale and market-based health care systems. The bill also creates new regulatory requirements for insurers and pharmacy benefit managers (PBMs) concerning pharmacy contracts and business practices, and related to prescription drug formularies.

Most-Favored-Nation Upper Payment Limit

The bill establishes a Most-Favored-Nation (MFN) policy for prescription drug payments in Florida. The bill requires the state to establish an upper payment limit by identifying the lowest net price accepted by drug manufacturers in other countries with similar size economies and similar market style to Florida. The bill then establishes that international benchmark price as an upper payment limit, applicable to commercial third-party payers regulated by the state, to government health coverage programs, and to point-of-sale pharmacy charges for patients paying cash for prescription drugs.

Index Development

The bill requires the Agency for Health Care Administration (AHCA) to build the most-favored-nation (MFN) reference price index of prescription drugs and biological products for the commercial health insurance and Medicaid markets. The bill requires AHCA to contract with a vendor who will engineer, implement, and operate Florida's MFN reference price index. The bill details a three-pronged approach to building and maintaining the index: country selection, drug pricing data acquisition, and reference price calculations.

Country Selection

The bill requires AHCA, through its contracted vendor, to designate a group of eligible countries that will comprise Florida's MFN reference price index. AHCA must only consider international markets that meet certain threshold criteria:

- Countries with a real gross domestic product (GDP) per capita of at least 60% of U.S. GDP per capita, and
- Countries with market-based prescription drug pricing or without single-payer health systems (that is, without whole-market government price-setting for prescription drugs).

The real GDP per capita metric allows Florida to make a true assessment of purchasing power parity across all countries with the common denominator being the U.S. GDP per capita. The U.S. GDP per capita is $75,500 according to the most recent (2024) estimate in the U.S. Central Intelligence Agency World Factbook, which sets 60% of U.S. GDP per capita at $45,300.

The table below identifies a non-exhaustive list of countries that currently meet the 60% GDP per capita threshold[1] and do not appear to have single-payer health systems.[2]

[1] U.S. Central Intelligence Agency, *The World Factbook*, https://www.cia.gov/the-world-factbook/field/real-gdp-per-capita/ (last visited Jan. 22, 2026). There are other countries that meet the 60% of U.S. Real GDP per capita threshold, but AHCA's contracted vendor will need to analyze whether those other countries have single-payer health systems.

[2] Avik Roy, "What Medicare Can Learn From Other Countries on Drug Pricing: Market-based policies from countries like Denmark and Singapore can make medicines more affordable in the U.S.," *The Foundation for Research on Equal Opportunity*, (Jan. 11, 2019) https://freopp.org/whitepapers/what-medicare-can-learn-from-other-countries-on-drug-pricing/ (last visited Jan. 22, 2026). *See* "Health System Features: International Health Care System Profiles," *The Commonwealth Fund* (Jun. 2020) https://www.commonwealthfund.org/international-health-policy-center/system-features (last visited Jan. 22, 2026).

Country	Real GDP per capita (2023 or 2024)	% of U.S. GDP per capita (2024)
Austria	$63,300	83.8%
Belgium	$63,100	83.5%
Czechia	$48,000	63.5%
Denmark	$73,700	79.0%
France	$54,500	72.1%
Germany	$62,800	83.1%
Ireland	$115,300	152.7%
Israel	$47,300	62.6%
Japan	$46,100	61.0%
Netherlands	$70,900	93.9%
Singapore	$132,600	175.6%
Switzerland	$82,000	94.0%
United States	$75,500	100.0%

The contracted vendor must reevaluate the selection of countries annually. If a sourced country falls below the 60% threshold, it would be excluded for the next year. If a country meets or exceeds the 60% threshold but operates a single payer health care system, that country will be excluded. If a previously excluded country later meets the bill criteria, that country will be included for the next year.

The bill requires AHCA, through its contracted vendor, to categorize the selected countries in two or more tiers, using an established index measuring the level of health care system market orientation in each country,[3] and then weight the reference prices in those countries more akin to the U.S. system. This will value the prices from those countries more than others when calculating the upper payment limit. (Section 2).

Drug Pricing Data Acquisition

To obtain international and U.S. pricing data for the purpose of establishing reference prices, the bill requires drug manufacturers permitted by the Department of Business and Professional Regulation (DBPR) to report price data annually, as a permitting obligation. Starting October 1, 2026, the bill requires each prescription drug manufacturer permitholder and nonresident drug manufacturer permitholder to annually report the net prices paid or reimbursed for drugs and biological products in the outpatient setting, by all payers, in the reference price source countries identified by AHCA.

The bill allows manufacturers to include fully documented average payment amounts, weighted by utilization volume, in the annual report to AHCA. Utilization weights for each price will give a more accurate understanding of the market impact. The bill authorizes manufacturers to provide supplemental pricing data at any time throughout the year based on prices changes in a source country.

The bill requires DBPR to enforce manufacturer compliance with this requirement. DBPR must fine a noncompliant permitholder of $10,000 per day for the first 30 days. After 30 days, if the drug manufacturer remains

[3] An example of such an index is the FREOPP Market-Based International Index. *Supra* note 1.

noncompliant, the bill requires DBPR to suspend the manufacturer's permit. The bill requires DBPR to lift the suspension once the drug manufacturer complies. (Section 4).

Reference Price Calculations

The bill requires AHCA's contracted vendor to compare the international drug pricing data submitted by manufacturers with a publicly available, reliable, and consistent exchange rate source, so the prices are standardized by a common dominator across currencies. The vendor must then apply drug-by-drug adjustments to the prices to account for differences in utilization volume in each reference country, and to account for differences in economic weight (represented by national GDP).

After this analysis, the vendor must identify the lowest price paid, in any source country (after adjustment for volume and national GDP). Upon identifying the lowest price, AHCA with its vendor must establish that price as the reference price – if, when compared to U.S. prices, that price would result in savings for Florida patients and employers. The bill directs AHCA to prioritize non-competitively priced drugs with greatest price differences amongst the source countries listed on the MFN reference price index, such as brand-name and single-source drugs. For drugs that are competitively priced, for which a reference price would not advantage Floridians, the bill requires the vendor to inform AHCA which drugs and biologicals are competitively priced and what their respective reference prices would be if listed on the MFN reference price index.

AHCA's contracted vendor must reevaluate international reference prices annually. In addition, the vendor may reevaluate and update a specific reference price at any time based on a significant change in price documented by supplemental pricing data supplied by a permitholder. The bill requires the vendor to send AHCA reference prices by January 1 each. Then, within 10 days of receipt, AHCA must publish references prices online. (Section 2).

These lowest-cost reference prices become the upper payment limit set by the bill for insurers and retail pharmacy patients.

Upper Payment Limits

The bill establishes the international reference price set by AHCA and its contracted vendor as an upper payment limit applicable to Florida-licensed third-party payers and pharmacies, and to government coverage programs.

The requires commercial health insurers, health maintenance organizations (HMOs), Medicaid managed care plans, and the State Group Health Insurance Program to pay no more than the upper payment limits for prescription drugs and biological products. In other words, these payers must refer to a prescription drug or biological product's reference price on AHCA's MFN reference price index at the outpatient setting point-of-sale. (Sections 7 and 10). The bill applies upper payment limits to Medicaid coverage for prescription drug and biological products to the extent a reference price generates greater savings for Medicaid than the state supplemental rebate program[4] yields. (Section 7).

In addition, the bill also requires pharmacies serving cash-paying patients to treat reference prices for prescription drugs and biological products as upper payment limits. (Section 3).

The upper payment limit applies only to the reimbursement amount (or payment amount, in the case of a patient) for the drug itself; it does not apply to any dispensing fee or administration fee established under the terms of a pharmacy contract or retail policy. The upper payment limit only applies to the drug price line item in any outpatient reimbursement transaction. (Sections 7 and 10).

[4] 409.91196, F.S.

Cost-Reduction Pass-Through

Health plan payers (employers and individual coverage providers) will likely experience cost savings as a result of the bill's upper payment limit, assuming the reference price is below the insurer's net cost (with rebates). The bill requires commercial health insurers, and HMOs to pass on the savings generated by upper payment limits to their policyholders. Specifically, the bill requires health insurers to use the savings to cut premiums and cost sharing (such as deductibles and copays). As an accountability measure, the bill requires insurers to document anticipated savings and premium reductions in their rate filings, – beginning with the first-rate filing following the availability of reference prices. This requirement applies to the State Employee Group Health Insurance Program, as well. (Sections 7 and 10).

The bill also requires commercial health insurers, HMOs and the State Employee Group Health Insurance Program to assess the actuarial effect of Florida's MFN upper payment limit for each prescription drug and biological product that the insurer covers for each plan year. The bill requires insurers to submit a report on the assessed actuarial effect of MFN-based upper payment limits to the Office of Insurance Regulation (OIR) or AHCA (as applicable), by April 1 of each year, beginning with the April 1 following the first full plan year in which the upper payment limit applies. This will allow OIR and AHCA to better assess whether the payers are appropriately passing the savings from the MFN program on to consumers.

Implementation Reporting

The bill requires OIR and AHCA to submit a joint report, by January 1 annually, to the Governor, the President of the Senate, and the Speaker of the House of Representatives detailing the impact of Florida's MFN reference price index in the preceding year. The report must:

- compare savings realized under the model for referencing international prices to what prices would have been apart from the model;
- document any problems encountered;
- document any access barriers regarding prescription drugs and biological products;
- document how the domestic and international pharmaceutical markets respond to the Florida international reference price index; and
- monitor and evaluate how the Florida MFN reference price index affects:
    - both the Medicaid prescription drug program and Medicaid managed care plan beneficiaries' access to prescription drugs and biological products;
    - the quality of care experienced by Medicaid enrollees; and
    - the costs to Medicaid.

This annual reporting requirement begins with the first annual report due January 1, 2027, with the first year measuring the impact for calendar year 2026. (Section 7).

Statement of Important State Interest

The bill includes an express statement of important state interest. The bill finds that the state has an important state interest to establish a MFN reference price index for prescription drugs and biological products for five reasons:

1. Increasing medication adherence and reducing the likelihood that Floridians would choose to forgo, substitute, or ration prescribed medication and therapies due to high cost, by helping cost-burdened Floridians acquire prescribed medication and therapies at competitive, market-based prices.
2. Ensuring that Floridians do not have to spend more for the same quantity of a prescription drug than residents of other countries, by regulating, even-handedly and prospectively, in a historically regulated

industry, both resident and nonresident drug manufacturers with regard to international price transparency and international reference-based upper-payment limits.
3. Ensuring that Floridians are not at a competitive disadvantage compared to residents of other countries, by countering monopolistic and anticompetitive market conditions using international reference-based upper-payment limits regardless of the incidental effect that may be experienced if other states adopt similar legislation.
4. Maximizing the number of Floridians with commercial health plan coverage who can access competitive, market-based prices without interfering with nationally uniform plan administration.
5. Regulating state-licensed activity and establishing a competitive market without depriving drug manufacturers of reasonable opportunities to profit from their investments, by normalizing both the drug prices paid by Floridians with those the manufacturers accept in other countries and the profit they benefit from in those countries. (Section 13).

Pharmacy Benefit Managers

Prescription drug benefit plans – health insurers, self-insured employers, union health plans, and government purchasers – contract with pharmacy benefit managers (PBMs) to manage drug costs. PBMs establish pharmacy networks, pay claims, and negotiate drug manufacturer rebates, among other things. PBMs earn profits through a combination of revenues, including administrative fees charged to health plans, retention of drug rebates paid by pharmaceutical manufacturers, and fees charged to network pharmacies.

Contracts

The bill requires contracts between a PBM and pharmacy benefit plan to include terms which prohibit the PBM from using a formulary that forces the pharmacy to dispense an affiliated manufacturer's drug or biological product when a generic or biosimilar is available. (Section 5). This provision prevents a PBM from maintaining a formulary which requires plan beneficiaries to get their prescriptions filled only with drugs from an affiliated manufacturer. This provision does not impact a pharmacy's decision to choose whether to dispense a PBM-affiliated manufacturer's pharmaceutical or to dispense a non-affiliated manufacturer's medicine.

The bill requires contracts between a PBM and a participating pharmacy to include terms which establish an administrative appeal procedure such that a pharmacy may submit a consolidated appeal of all substantially similar claims. (Section 5). This provision is specific to contracts between PBMs and pharmacies and does not involve the state executive branch's Division of Administrative Hearings; consolidated appeals will promote administrative efficiencies for all parties involved in an internal maximum allowable cost appeal.

Unlawful Activity

The bill makes it unlawful for a PBM to prohibit or restrict a pharmacy or pharmacist from declining to dispense a prescription drug or biological product for less than the pharmacy or pharmacist's actual acquisition cost. (Section 6). This provision prevents a PBM from forcing a pharmacy to take a loss when dispensing a drug.

The bill also makes it unlawful for a PBM to reimburse a pharmacy or pharmacist less than the PBM reimburses an affiliated pharmacy or pharmacist, as those terms are defined in s. 626.8825, F.S. (Section 6). This provision prevents a PBM from leveraging the market power of its parent healthcare conglomerate over non-affiliated pharmacies.

OIR Rulemaking

The bill directs OIR to adopt rules to implement its PBM-related requirements by January 1, 2027. (Section 12).

Prescription Drug Formularies

A prescription drug formulary is a preferred list of medications that a health plan sponsor uses to control costs and utilization for plan beneficiaries. It dictates which drugs a health plan predetermines will be covered, and at what level, for reimbursement under the terms of its pharmacy benefit plan. Formularies distinguish between preferred or discouraged prescription drugs by dividing products into different tiers, designating different levels of patient out of pocket costs. Whenever drug manufacturers raise their prices, health plan sponsors can disincentivize the use of those drugs by changing their formularies, such as moving the drug to a higher tier, increasing out-of-pocket costs, adding prior authorization or step therapy requirements. Such formulary revisions can have negative effects on an individual's cost, efficacy of treatment, and overall compliance with their treatment plan.

Prescription Drug Formularies

The bill establishes mechanism to regulate mid-plan year formulary changes. Specifically, the bill prohibits commercial health insurers and HMOs from removing a drug or biological product from its covered drug list, reclassifying it to a more restrictive tier or to a higher cost-sharing tier, or increasing out of pocket expense for the drug or biological product during the plan year. This prohibition applies to drugs and biological products for which the insurer negotiates a net price with manufacturers that will apply to the entire plan year.

Notwithstanding this general prohibition, the bill authorizes insurers and HMOs to remove a drug or biological product from its formulary if the federal Food and Drug Administration (FDA) issues a clinical safety statement, if the manufacturer discontinues it, or if the drug or biological product becomes available over-the-counter. In addition, the bill authorizes insurers and HMOs to add drugs and biological products to their formularies during the plan year.

The frozen formulary mechanism does not apply to grandfathered health plans or to Medicaid managed care plans. The bill expressly preserves a pharmacist's authority to substitute generics or biosimilars. (Sections 8, 9, and 11). These provisions mitigate the sudden negative effect of mid-plan-year formulary revisions on an individual's cost, efficacy of treatment, and overall compliance with their treatment plan. Frozen formularies may bring price stability without restricting the power of drug manufacturers and health plan sponsors, through their PBMs, to negotiate drug prices for a plan year. The bill does not force the parties to negotiate prices for a plan year.

The bill provides an effective date of July 1, 2026. (Section 14).

RULEMAKING:

Current law authorizes DBPR to adopt rules to implement the Chapter 499, The Florida Drug and Cosmetic Act, pursuant to s. 499.05, F.S. The bill modifies a provision of law that is already under DBPR's rulemaking authority, thus allowing DBPR to make rules governing the reporting requirements for permitted prescription drug manufacturers and permitted non-resident prescription drug manufacturers to implement Section 4 of the bill.

Current law authorizes the Financial Services Commission (Commission) to adopt rules as necessary to implement Chapter 626 Part VII "Insurance Administrators" within the Florida Insurance Code,[5] pursuant to s. 626.8991, F.S. The bill expands this rulemaking authority to require the Commission to create rules governing PBM contract terms and regulating prohibited PBM business practices to implement Sections 5 and 6 of the bill.

Current law authorizes the Commission to adopt rules necessary to implement Chapter 627 Part II "The Insurance Contract", Chapter 627 Part VII "Group, Blanket, and Franchise Health Insurance Policies," and Chapter 641 Part I "Health Maintenance Organizations" within the Florida Insurance Code, pursuant to s. 624.308, F.S., s. 627.669(17), F.S., and s. 641.36, F.S., respectively. The bill modifies provisions of law within the Florida Insurance Code and with respect to HMOs that are already under the Commission's existing rulemaking authority, thus allowing the

[5] The Florida Insurance Code includes Chapters 624-632, 634, 635, 636, 641, 642, 648, and 651 of the Florida Statutes. s. 624.01, F.S.

Commission to make rules to governing commercial health insurers' reimbursement practices, reporting requirements, and prescription drug formulary practices to implement Sections 7, 8, 9, 10, and 11 of the act.

Current law authorizes the Board of Pharmacy (Board) to adopt rules to implement Chapter 465, the Florida Pharmacy Act, pursuant s. 465.005, F.S. The bill modifies a provision of law that is already under the Board's rulemaking authority, thus allowing the Board to make rules to governing a pharmacy's treatment of cash-paying customers to implement Section 3 of the bill.

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

The bill will have a significant negative fiscal impact on AHCA because AHCA will incur significant non-recurring start-up costs to implement the most-favored nation drug pricing program, and less significant, annual recurring costs to maintain program operations. AHCA anticipates a total fiscal impact of $1,631,582 in Fiscal Year 2026-2027, consisting of $1,500,000 in contractual services and $131,582 for one Pharmaceutical Program Manger FTE and related professional staff expenses. In subsequent years, AHCA projects a recurring need of $250,000 in contractual services to maintain the program, and the recurring cost of $131,582 for one Pharmaceutical Program Manager FTE and related professional staff expenses.[6]

In addition, the bill will have an indeterminate fiscal impact on AHCA, DBPR, and OIR relating to enforcement costs, which is absorbable within existing resources.

LOCAL GOVERNMENT:

The bill may have a positive fiscal impact on local governments that provide prescription drug coverage for employees due to cost savings in that benefit line.

PRIVATE SECTOR:

The bill may have a positive economic impact on HMOs, health insurers, employers, employees, and individual policyholders to the extent they experience savings due to reductions in drug costs and commensurate reductions in premiums and other forms of cost-sharing. The bill may have a negative economic impact on drug manufacturers because the bill sets an upper payment limit on the price of drugs that government-sponsored plans and commercially-sponsored plans may pay and that retail pharmacies may charge consumers.

The amount of potential savings from the program is unknown, and depends on several factors, including the speed and scale of drugs and biological products for which AHCA pursues establishing a reference price. Given the vast delta between international prices and prices in Florida, it is reasonable to anticipate significant savings, possibly in a range of $20 billion to $30 billion. Some payers not regulated by the State of Florida[7] are necessarily not included in the upper payment limit; this will limit potential savings. The following assumptions inform this gross estimate.

- CMS data on retail drug spending by all payers indicate all payers in Florida spent a combined $26.4 billion on retail prescription drugs in 2020, which represents about a 7.5% share of total U.S. retail prescription

[6] Agency for Health Care Administration, Agency Bill Analysis for HB 697(2026), pp. 6 (delivered Jan. 13, 2026) http://abar.laspbs.state.fl.us/ABAR/Attachment.aspx?ID=37295 (last visited Jan. 22, 2026).
[7] Specifically, large employer plans regulated by the federal government under the Employee Retiree Income Security Act (ERISA).

drug spending.[8] Applying Florida's 40-year average annual growth rate of 10.2% in drug spending, all payers in Florida spent about $42.5 billion on drugs in 2025.

- RAND Corporation data on country-by-country drug price comparisons indicate the average cost of brand-name and generic drugs combined in the U.S. is 227% of all other countries in the Organisation for Economic Co-operation and Development (OECD). For brand-name drugs only, the average markup in the U.S. is 422% of all other OECD countries.[9]
- Assuming that the bill's most-favored nation model reduces drug prices for all Floridians to 100% of the OECD average[10], then the bill reduces the 2025 retail prescription drug spending level to:
  - a floor of $10 billion, assuming that all retail prescription drug spending is for brand-name drugs (i.e., the 422% level); and
  - a ceiling of $18.7 billion, assuming that all retail prescription drug spending is a 50/50 mix of brand-name and generic drugs (i.e., the 277% level).
- Subtracting these floor and ceiling spending amounts from the $42.5 billion spent in 2025, the range of savings is between $23.8 billion and $32.4 billion in 2025 spending.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Pharmaceutical Spending

Total Health Care Spending in the United States

In 2023, the United States spent approximately $4.9 trillion, or 17.6% of gross domestic product, on various types of health care expenditures. U.S. health care spending grew 7.5.% in 2023, and per capita health care spending was $14,570 per person.[11] For 2023, the U.S. spent more per person on health care than comparable countries within the 38-member Organisation for Economic Co-operation and Development (OECD), an intergovernmental policy forum first formed to administer American and Canadian aid under the Marshall Plan for the reconstruction of Europe after World War II, of which the U.S. is a founding member.[12] The OECD converts CMS per capita spending as a measure of purchasing power parity (PPP) to reflect the actual buying power across currencies.[13] As the table below illustrates, the U.S. spent $13,818 per person (PPP) on health care in 2023, which is 2.5 times the average amount of the other OECD countries, which is $5,462 per person.[14]

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[8] Centers for Medicare and Medicaid Services, "National Health Expenditure Fact Sheet – Health Expenditures by State of Provider: summary tables (ZIP)," U.S. Department of Health and Human Services (last updated Jan. 14, 2026) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (last visited Jan. 22, 2026). At the bottom of the webpage, download "Health expenditures by state of provider: summary tables (ZIP). In the ZIP file, select the Excel Spreadsheet "Provider_all_tables". Once the file opens, locate "Table 8: Total All Payers State Estimates by State of Provider (1980 -2020) – Retail Prescription Drugs (Millions of Dollars)."

[9] Andrew Mulcahy, Daniel Schwam, and Susan Lovejoy, "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," The RAND Corporation, pp. 40 (Feb. 1, 2024) https://www.rand.org/pubs/research_reports/RRA788-3.html (last visited Jan. 22, 2026).

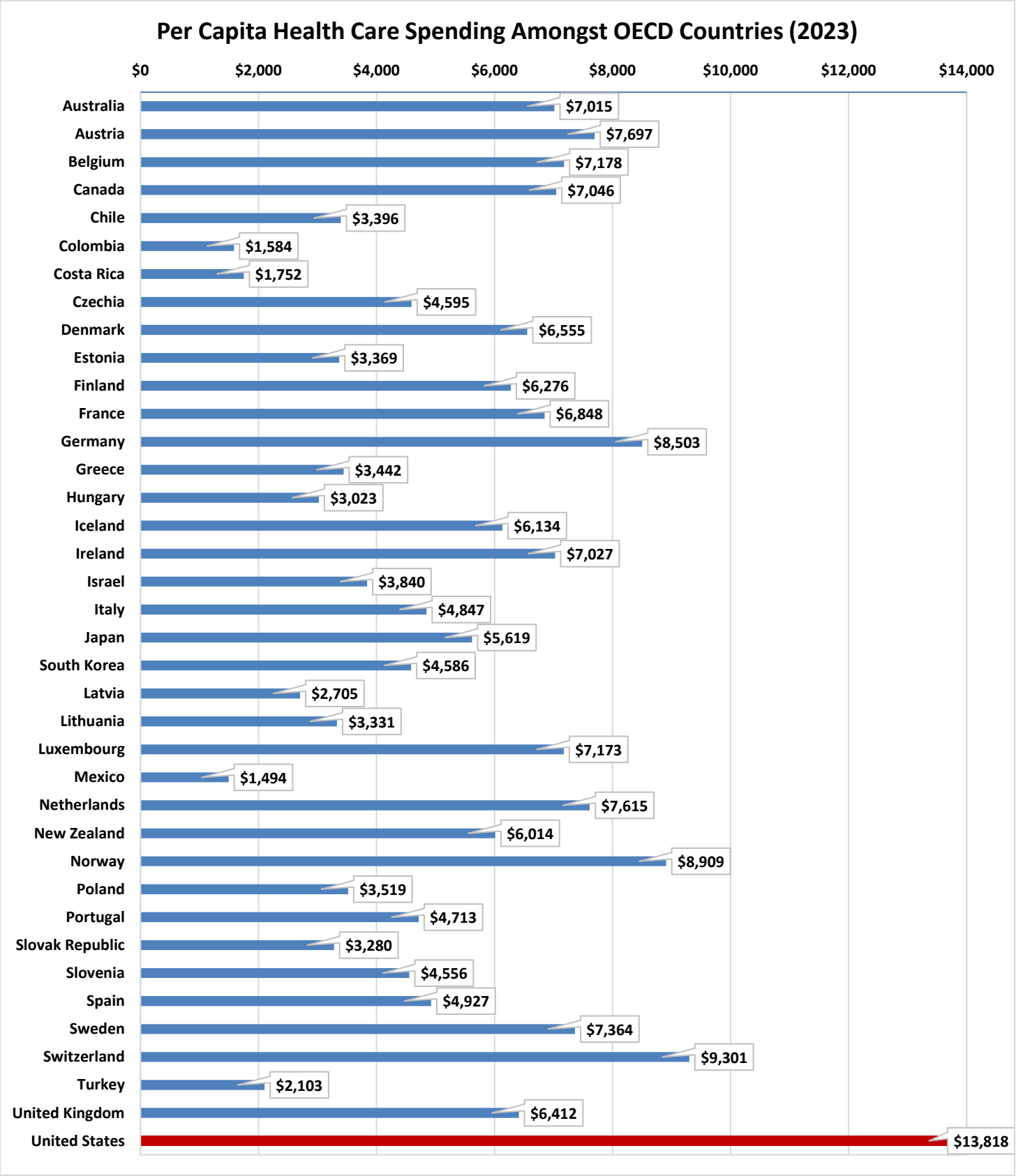
[10] Note, however, that the bill's policy of limiting the reference source country list to countries with more market-oriented health care systems may inflate the ultimate reference prices beyond this average.

[11] Centers for Medicare and Medicaid Services, "National Health Expenditure Data – Historical," U.S. Department of Health and Human Services, (last updated Dec. 18, 2024) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical (last visited Jan. 22, 2026).

[12] OECD, "History" https://www.oecd.org/en/about/history.html (last visited Jan. 22, 2026); OECD, "Members and Partners," https://www.oecd.org/about/members-and-partners/ (last visited Jan. 22, 2026). The 38 OECD Member Countries are Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States.

[13] OECD, "Purchasing Power Parity (PPP)," https://www.oecd.org/en/data/indicators/purchasing-power-parities-ppp.html (last visited Jan. 22, 2026).

[14] OECD Data Explorer, "Health expenditure and financing," OECD, https://data-explorer.oecd.org/vis?df[ds]=DisseminateFinalDMZ&df[id]=DSD_SHA%40DF_SHA&df[ag]=OECD.ELS.HD&dq=TUR%2BESP%2BSVN%2BSVK%2BPRT%2BPOL%2BNOR%2BNZL%2BMEX%2BLUX%2BLTU%2BLVA%2BKOR%2BITA%2BISR%2BIRL%2BISL%2BHUN%2BGRC%2BFIN%2BEST%2BDNK%2BCZE%2BCRI%2BCOL%2BCHL%2BU.S.A%2BGBR%2BCHE%2BSWE%2BNLD%2BJPN%2BDEU%2BFRA%2BCAN



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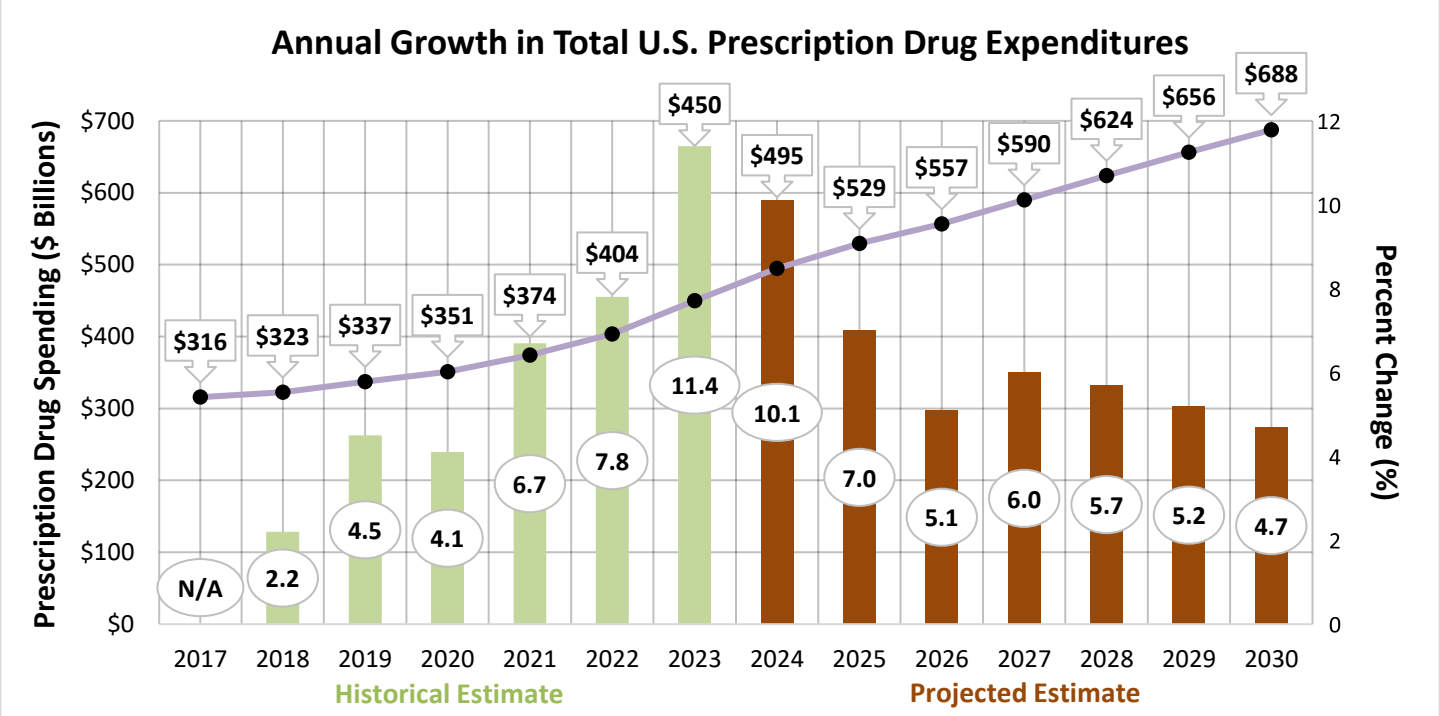
Although the United States spends on average 2.5 times per capita more on healthcare than other OECD countries, the United States generally performs worse than its peers on multiple health outcome indicators. For example, the average life expectancy in the United States is 4.1 years shorter than the comparable country average.[15]

Trends in Pharmaceutical Spending

For 2025, CMS projects total U.S. health spending will hit $5.6 trillion, with retail prescription drugs alone accounting for $529.4 billion at $1,557 per person. CMS also projects consumers will cover 11.4% of retail prescription drug spending out-of-pocket and insurance will cover the remaining 87.6%.[16]

The graph below depicts historical and projected estimates for annual growth in total prescription drug expenditures. CMS finds that 2023 will be the high watermark in terms of annual percentage growth, at 11.4%, before slowing in subsequent years.[17]



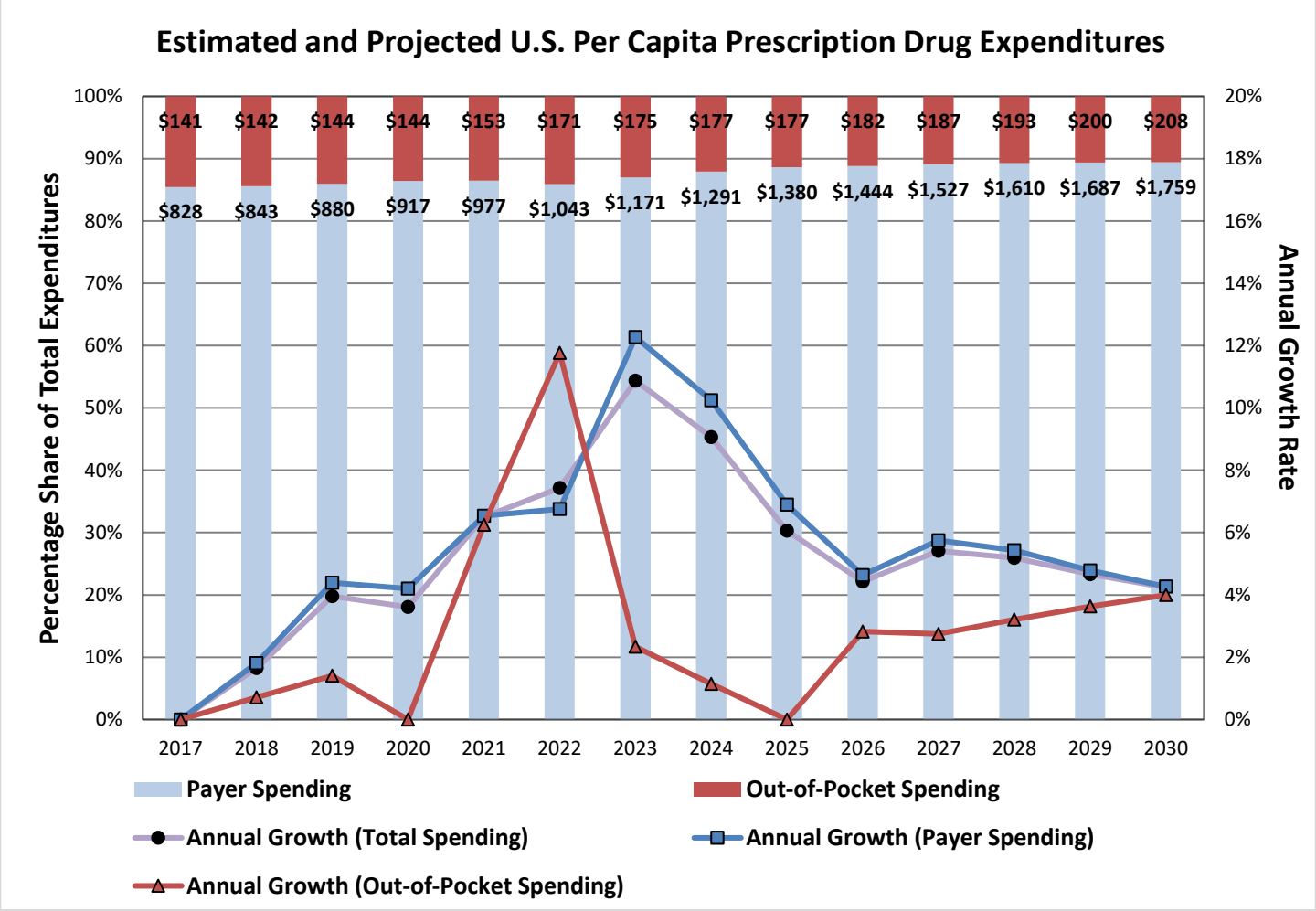
While the graph shows that the annual percentage growth in total prescription drug expenditures is on a downward trend, CMS projects total spending on prescription drugs will continue to increase from $449.7 billion

[15] An apples-to-apples comparison of international health systems is complicated by the fact that long-term measures like life expectancy are not only reflective of an individual country's health system, but also of differences in socioeconomic conditions and population behaviors that are largely outside the domain of the health system. Imani Telesford, Emma Wagner, and Cynthia Cox, "How does the quality of the U.S. health system compare to other countries?" *Peterson-KFF Health System Tracker* (Oct. 6, 2025) https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/ (last visited Jan. 22, 2026).

[16] The 87.6% remaining share includes private insurance at 40.6%, Medicare at 33.2%, Medicaid at 10.7%, and the remaining 4.1% from other government sources. Centers for Medicare and Medicaid Services, "National Health Expenditure Projections – Tables (ZIP) - Table 11 Prescription Drug Expenditures" (last modified Jun. 25, 2025) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected (last visited Jan. 22, 2026); *See* Matt McGough, Imani Telesford, Aubrey Winger, Lynne Cotter, and Cynthia Cox, "How much is health spending expected to grow?" *Peterson-KFF Health System Tracker*, (Aug. 4, 2025) https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow/ (last visited Jan. 22, 2026).

[17] CMS records the annual growth in total prescription drug expenditures as a "Historical Estimate from Calendar Years 2017-2023" and as a "Projected Estimate from Calendar Years 2024-2030". Centers for Medicare and Medicaid Services, "National Health Expenditure Projections – Tables (ZIP) - Table 11 Prescription Drug Expenditures" (last modified Jun. 25, 2025) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected (last visited Jan. 22, 2026).

in 2023 to $556.6 billion in 2025 and eventually to $687.5 billion by 2030. Also, on a per capita basis, the annual growth rate in prescription drug expenditures sharply escalated for both payers and out-of-pockets with the onset of the COVID-19 pandemic, as the chart below illustrates.[18]



While CMS projects the annual growth rate will stabilize for both payer and out-of-pocket cohorts in the back half of the decade, health plans continue to accrue a larger share of total prescription drug spending without a decrease in out-of-pocket spending. In 2026, CMS projects per capita prescription drug spending will reach $1,444 for insurer/plan payers and $182 for consumers out-of-pocket by 2026.

U.S. Pharmaceutical Prices Compared to OECD Countries

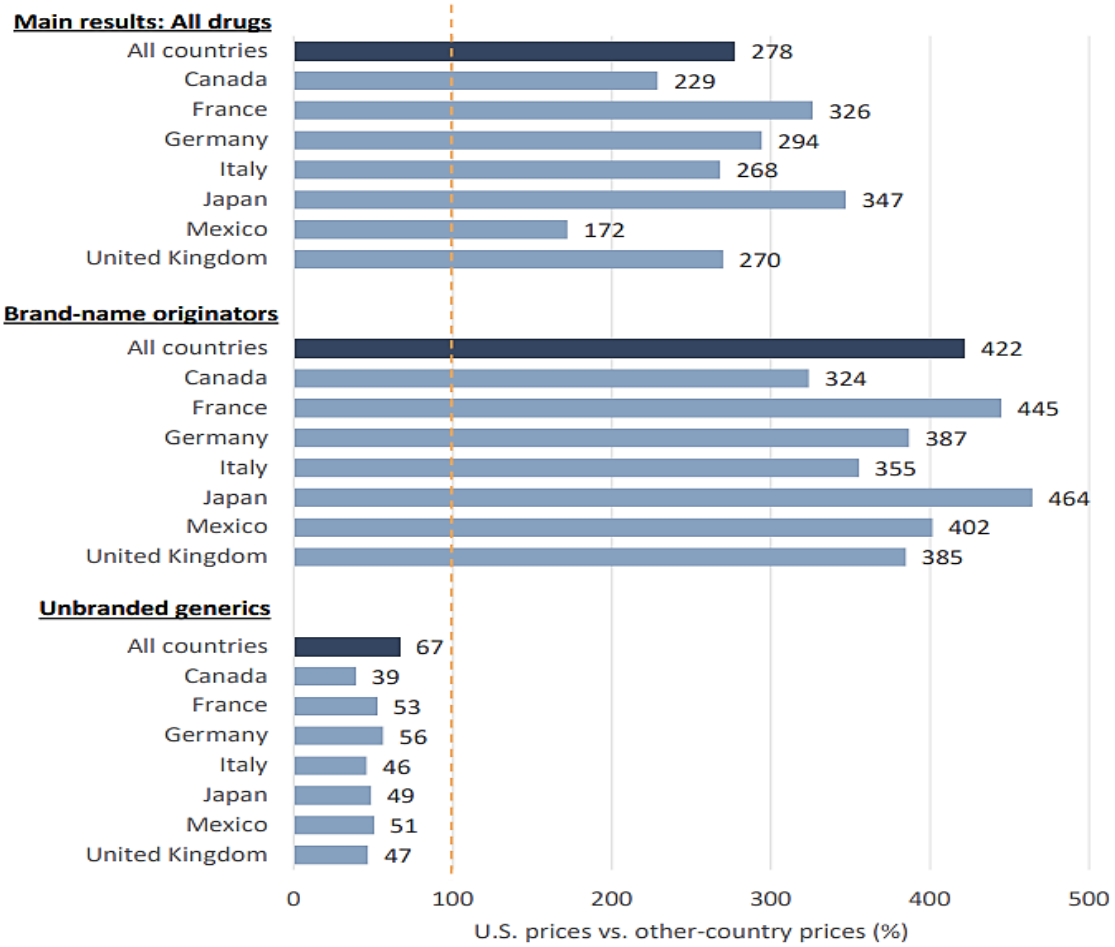
According to the RAND Corporation (RAND), with the exception of unbranded generic drugs, U.S. gross drug prices[19] exceed those in OECD countries in nearly every category.[20] RAND finds that overall, 2022 U.S. drug prices

[18] *Supra*, FN 8.

[19] RAND's comparative analysis used manufacturer gross prices instead of net prices (i.e., the prices realized by manufacturers after any discounts are applied) because net prices are often kept confidential and not released by pharmaceutical companies. RAND relied on a commercially-licensable data source that records volume and spending at the manufacturer list price for nearly all OECD countries and drugs. Although RAND applied sensitivity analyses to estimate relative differences between manufacturer gross prices and net prices, the U.S. prices remained substantially higher than prices in other OECD countries but with a smaller difference. *Id.* at ix, 4.

[20] Andrew Mulcahy, Daniel Schwam, and Susan Lovejoy, "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," The RAND Corporation, pp. vii-viii, 8, and 13 (Feb. 1, 2024) https://www.rand.org/pubs/research_reports/RRA788-3.html (last visited Jan. 22, 2026). Authors analyzed IQVIA MIDAS sales and volume data for calendar year 2022. Comparison countries were 33 select OECD member countries at the time of the study. In 2022, the 33 other OECD Member Countries that RAND analyzed were Australia, Austria,

were 278 percent higher than those in other OECD countries. This is an increase from 2018 where U.S. drug prices were 256 percent of the average OECD price.[21] Regarding brand name originator drugs, U.S. brand name drug prices were 422 percent of the OECD brand name price in 2022. This is an increase from 2018 when they were 344 percent higher.[22] The greatest difference in price noted was for the top 60 drugs by U.S. sales, which were 504% of OECD drug prices for the same drugs.[23] In the graphic below, the vertical dotted line represents the drug price in the other OECD countries or a specific country, as listed, and the horizontal bar represents the U.S. drug price in comparison to specified reference point; either all the OECD countries or a specific one.



Belgium, Canada, Chile, Colombia, Czechia, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and United Kingdom. Costa Rica did not have OECD membership at the time, and data was not available for the OECD countries of Denmark, Iceland, and Israel. Authors compared the top 60 drugs by U.S. Sales at the active ingredient level. The U.S Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation contracted RAND for this study.

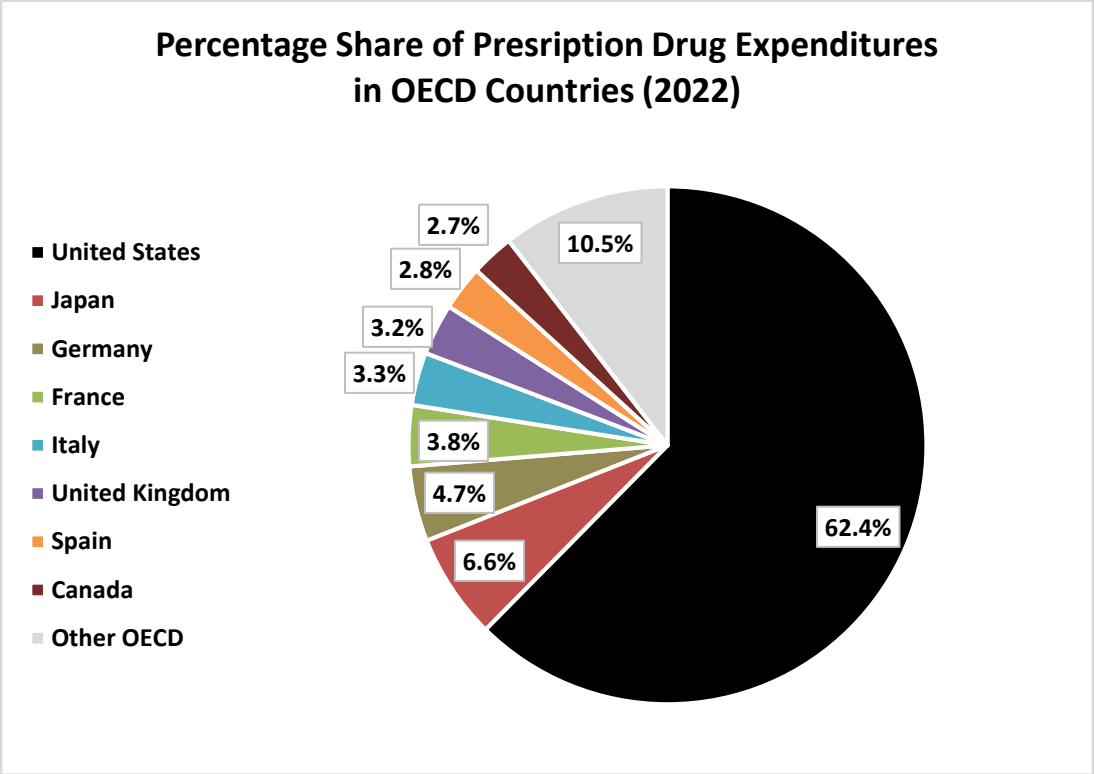
[21] The 2021 version of the RAND report used 2018 data. Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, Alejandro U. Becerra-Ornelas, "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies," The RAND Corporation, pp. xiv (Jan. 28, 2021), https://www.rand.org/pubs/research_reports/RR2956.html (last visited Jan. 22, 2026). Authors analyzed IQVIA MIDAS sales and volume data for calendar year 2018. Comparison countries were 32 select OECD member countries at the time of the study. Authors compared the top 60 drugs by U.S. Sales at the active ingredient level.

[22] Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, Alejandro U. Becerra-Ornelas, "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies," The RAND Corporation. p. xiv (Jan. 28, 2021), https://www.rand.org/pubs/research_reports/RR2956.html (last visited Jan. 22, 2026).

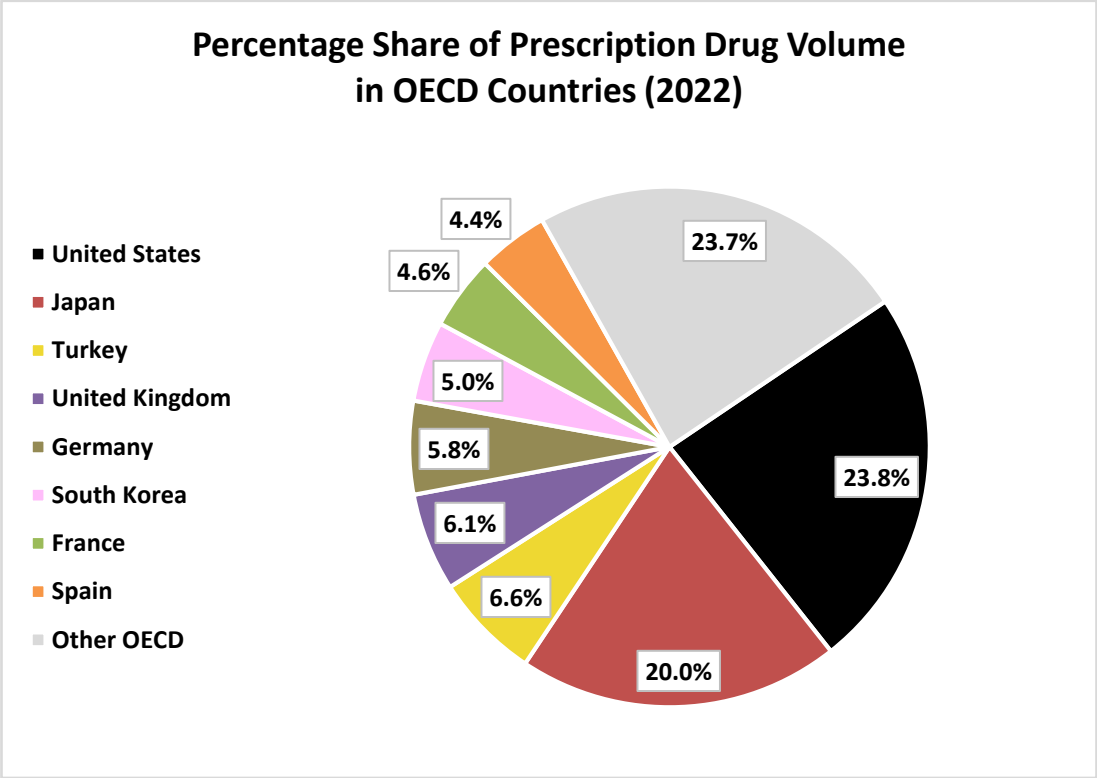
[23] Andrew Mulcahy, Daniel Schwam, and Susan Lovejoy, "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," The RAND Corporation, pp. vii-viii, 8, and 13 (Feb. 1, 2024) https://www.rand.org/pubs/research_reports/RRA788-3.html (last visited Jan. 22, 2026). Other countries' prices were set to 100, represented by the vertical orange dotted line on the bar graph. Table B.1. on pp. 40 records the country-by-country breakdown for drug price indexes concerning brand-name originator drugs, unbranded generics, and biologics.

RAND observes France and Japan generally have the lowest prices amongst the non-U.S. OECD countries for all drugs and for all brand-name originator, biologics, and nonbiological drugs separately. Canada, Germany, and the United Kingdom tend to have higher prices amongst the other OECD countries across each subset of drug.[24]

As the twin pie charts below illustrate, the United States accounted for 62.4% of prescription drug expenditures across all OECD countries in 2022, but only 23.8% of volume.[25] In 2022, the United States had an 87% share of expenditures, and a 7% share of volume, for brand-name originator drugs across all OECD countries. For unbranded generic drugs, the United States had an 8% share of expenditures and a 90% share of volume.[26]



[24] *Id.*
[25] *Id.* at 9-10.
[26] *Id.* at 12.



The United States' share of total prescription drug costs far exceeds its utilization of the global prescription drug supply. In 2022, the United States population was 333.27 million which represents 24.1% of the total OECD country population of 1.38 billion. For comparison, Japan's population was just 37.4% of the United States population and 9% of total OECD country population but Japan accounted for the second-most in both prescription drug expenditures at 6.6% and a 20.0% share of volume. Germany's population was just 25% of the United States population and 6% of total OECD country population but Germany came in third in prescription drug expenditures at 4.7% and fifth in share of volume at 5.8%.[27]

U.S. Pharmaceutical Pricing Dynamics

Some pinpoint the 1990s as the era when the relationship between higher drug spending per capita and higher drug prices manifested for the first time. Signature characteristics of the 1990s drug market include the rapid growth of brand-name drugs, increased advertising to physicians and consumers,[28] and the FDA's pivot to a user-

[27] *Id.* at 11. OECD, "Population," https://www.oecd.org/en/data/indicators/population.html (last visited Jan. 22, 2026).
[28] Drug manufacturers advertise to encourage consumers to ask their doctors for specific medications. Aaron S. Kesselheim, *High Drug Prices in the U.S.: What We Can Learn from Other Countries (and Some U.S. States)*, Testimony to the United States Senate Committee on Health, Education, Labor, and Pensions, pp. 2 (Mar. 23, 2021) https://www.help.senate.gov/imo/media/doc/Kesselheim1.pdf (last visited Jan. 22, 2026). At the time of testimony, Aaron Kesselheim was a Professor of Medicine at Harvard Medical School and the Director of Program on Regulation, Therapeutics, and Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Department of Medicine at Brigham and Women's Hospital. *See* United States General Accounting Office, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising has Limitations," GAO-03-177, pp. 3 (Oct. 2002) https://www.gao.gov/assets/gao-03-177.pdf (last visited Jan. 22, 2026).

fee model to expedite new drug approvals.[29] In addition, Medicare, Medicaid, and the Children's Health Insurance Program expanded coverage to prescription drugs.[30]

While a critical mass of prescription drug patents expired[31] throughout the mid-2000s, temporarily scaling back per capita spending, new therapeutic biological products contributed to a per capita spending resurgence in the mid-2010s. This era introduced precision medicine stemming from the completion of the human genome project. Precision medicine means drugs made for smaller populations to match specific genetic characteristics – making drugs more effective and creating a greater dependence on these drugs.[32]

Other factors that contribute to high drug prices in the United States include:

- Pharmaceutical market consolidation;[33]
- Lack of drug price negotiation by Medicare (until recently);[34]
- New medicine launches at record-high prices;[35]
- Delayed introduction of cheaper generic alternatives because drug manufacturers found ways to extend regulatory exclusivities;[36]
- Pharmacy benefit managers;[37] and
- Lack of price transparency.[38]

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[29] C. Michael White, *Why is the FDA Funded in Part by the Companies it Regulates?* UConn Today (May 21, 2021) https://today.uconn.edu/2021/05/why-is-the-fda-funded-in-part-by-the-companies-it-regulates-2/ (last visited Jan. 22, 2026). At the time of publication, C. Michael White was the Department Head & Distinguished Profession of Pharmacy Practice at the University of Connecticut School of Pharmacy. *See* United States General Accounting Office, "FDA Drug Approval: Application Review Times Largely Reflect Agency Goals," GAO-20-244, pp. 4-5 (Mar. 2020) https://www.gao.gov/assets/gao-20-244.pdf (last visited Jan. 22, 2026).

[30] Austin Frakt, *Something Happened to U.S. Drug Costs in the 1990s*, The New York Times (Nov. 12, 2018) https://www.nytimes.com/2018/11/12/upshot/why-prescription-drug-spending-higher-in-the-us.html (last visited Jan. 22, 2026). At the time of publication, Austin Frakt was a Senior Research Scientist in the Department of Health Policy and Management at Harvard T.H. Chan School of Public Health.

[31] Patents endorse the drug manufacturer's sole right to sell and profit off their inventions and market exclusivities prevent generic and biosimilar competitors from entering the drug manufacturer's market for a period of time. Therefore, drug manufacturers producing drugs under patent or exclusivity protection have pricing power. Dicken, John, *Prescription Drug Spending*, The United States Government Accountability Office https://www.gao.gov/prescription-drug-spending (last visited Jan. 22, 2026).

[32] The Cleveland Clinic, "Precision Medicine," (last updated Sept. 28, 2023) https://my.clevelandclinic.org/health/articles/precision-medicine (last visited Jan. 22, 2026).

[33] *See* Robin Feldman, Brent D. Fulton, Jamie R. Godwin, Richard M. Scheffler, *Challenges with Defining Pharmaceutical Markets and Potential Remedies to Screen for Industry Consolidation*, 47 J. Health Pol. Pol'y & L. 583 (2022). https://repository.uclawsf.edu/cgi/viewcontent.cgi?article=2922&context=faculty_scholarship (last visited Jan. 22, 2026).

[34] Evan D. Gumas, Paige Huffman, Irene Papanicolas, and Reginald D. Williams III, *How Prices for the First 10 Drugs Up for U.S. Medicare Price Negotiations Compare Internationally*, The Commonwealth Fund (Jan. 4, 2024) https://www.commonwealthfund.org/publications/2024/jan/how-prices-first-10-drugs-medicare-negotiations-compare-internationally (last visited Jan. 22, 2026); *See* Centers for Medicare & Medicaid Services, *Medicare Drug Price Negotiation*, U.S. Department of Health and Human Services (last updated Jan. 5, 2024) https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation (last visited Jan. 22, 2026).

[35] Deena Beasley, "Prices for new U.S. Drugs doubled in 4 years as focus on rare disease grows," *Reuters* (May 25, 2025) https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22/ (last visited Jan. 22, 2026).

[36] Delay tactics to extend the life of a brand-name patent include paying generic manufacturers to not enter the market, changing formulations, strengthening doses, and expanding FDA-approved uses for the brand-name drug. Kristi Martin, "How Drugmakers Use the Patent Process to Keep Prices High," *The Commonwealth Fund* (Jan. 22, 2026) https://www.commonwealthfund.org/publications/explainer/2025/nov/how-drugmakers-use-patent-process-keep-prices-high (last visited Jan. 22, 2026).

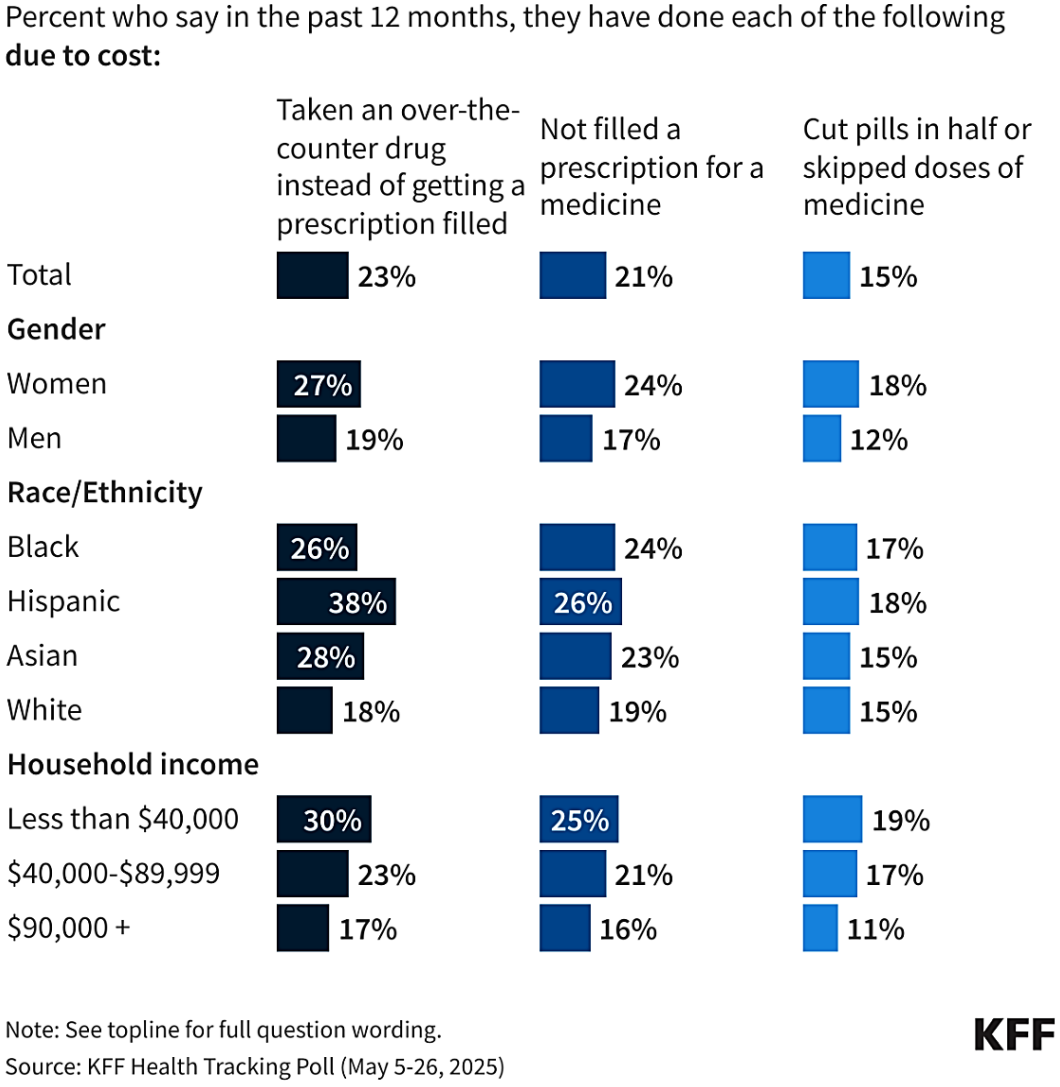
[37] Pharmacy benefit managers are intermediary companies that manage prescription drug benefits on behalf of pharmacy benefit plans or programs (health insurers, Medicare Part D drug plans, large employers, state health plans, and other payers). Federal Trade Commission, "FTC Releases Second Interim Staff Report on Prescription Drug Middlemen," (Jan. 14, 2025) https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen (last visited Jan. 22, 2026).

[38] *Id.*

More recently, the reversal of the annual percentage change in prescription drug spending may be attributable to two key provisions of the Inflation Reduction Act of 2022 (IRA), which affect how much certain drugs will cost under Medicare going forward. The IRA establishes negotiated drug pricing for certain drugs covered by Medicare Part B and Part D and caps beneficiary out-of-pocket spending on Medicare Part D prescription drugs at $2,000.[39]

U.S. Pharmaceutical Prices and Medication Nonadherence

The high cost of prescription drugs in the United States forces many people to cut back on their medications. According to May 2025 public opinion polling conducted by KFF, 21% did not fill a prescription due to cost concerns, 23% took an over-the-counter drug as a substitute due to cost concerns, and 15% cut pills in half or skipped doses of medicine due to cost at least once within the preceding 12 months.[40]



[39] Inflation Reduction Act, P.L. 117-169 (Aug. 16, 2022), 136 Stat. 1818, Title I, Subtitle B, Part 1, Sec. 11001. *See* Delaney Tevis, Matt McGough, Juliette Cubanski, and Cynthia Cox, "How Medicare negotiated drug prices compare to other countries," *Peterson-KFF Health System Tracker*, (Dec. 19, 2024) https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/ (last visited Jan. 22, 2026).

[40] Grace Sparks, Lunna Lopes, Alex Montero, Marley Presiado, and Liz Hamel, "Americans' Challenges with Health Care Costs," *KFF* (Jul. 11, 2025) https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/ (last visited Jan. 22, 2026). Methodology: May 5-26, 2025, online and telephone survey among a nationally representative sample of 2,539 U.S. adults. Margin of sampling error within the accepted ± 3 percentage points. KFF, "Topline: KFF Health Tracking Poll May 2025," KFF, (Jun. 2025) https://files.kff.org/attachment/kff-topline-health-tracking-poll-june-2025.pdf (last visited Jan. 22, 2026).

Of the 2,539 respondents polled by KFF, 89% reported being covered by health insurance and 61% reported taking at least one prescription medicine.[41] High prescription drug costs contribute to poor medication adherence which may lead to adverse health outcome effects and increased health care spending.[42]

Pharmaceutical Regulation

Patents and Market Exclusivity Periods

The United States Constitution gives Congress the power to enact laws relating to intellectual property.[43] Two forms of intellectual property rights incentivize the development of, and affect the pricing of, prescription drugs and biologics.[44] First, the United States Patent and Trademark Office (USPTO) may grant patents to drug manufacturers, which give the exclusive right to make and sell their novel drug. Second, in addition to the drug manufacturer's patent, the Food and Drug Administration (FDA) may grant market exclusivities, which means the FDA will not approve applications for a generic or biosimilar form of the drug until the exclusivity period expires.[45]

A new drug patent from the USPTO is good for 20 years,[46] and once the FDA approves the drug or licenses it for marketing, a drug manufacturer can sell the new drug without any competition from generics or biosimilars for an exclusive period. A number of empirical studies within the past ten years found drug manufacturers receive between 12 and 15 years on average to sell their brand-name drugs without generic or biosimilar competition.[47] Meanwhile, a recent analysis of 236 drugs covered by Medicare Part D and Medicaid which were 1) sold commercially for at least 10 years and 2) cost the government at least $10 million in 2019 found that some drug manufacturers exercise monopolistic power for longer terms, as the dual tables below show. Note that primary monopoly time and second monopoly time are distinct time periods that run consecutively, not concurrently.[48]

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[41] *Id*.

[42] Julie Lauffenburger, Renee A. Barlev, Eniola Olatunji, Gregory Brill, and Niteesh Choudhry, *Costs of Prescription Drugs for Children and Parental Adherence to Long-Term Medications*, PubMed Central, National Library of Medicine (Oct. 6, 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10580109/ (last visited Jan. 22, 2026). An international group of academic researchers recently identified 43 systematic reviews between 2014-2024 studying the impact of medication nonadherence on clinical and economic outcomes throughout the world, which includes over 410 original studies on clinical outcomes and 174 original studies on economic outcomes. "Maria Achterbosch, Milay Aksoy, George Obeng, David Ameyaw, Tamás Ágh, Job van Boven, "Clinical and economic consequences of medication nonadherence: a review of systematic reviews," *Frontiers in Pharmacology* (Jun. 25, 2025) https://pmc.ncbi.nlm.nih.gov/articles/PMC12237677/ (last visited Jan. 22, 2026).

[43] "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Art I. § 8, cl. 8, U.S. Const.

[44] Jim Hahn, Kevin Hickey, Suzanne Kirchhoff, and Hannah-Alise Rogers, "Selected Issues in Pharmaceutical Drug Pricing," *Congressional Research Service* (Mar. 1, 2023) https://crsreports.congress.gov/product/pdf/IF/IF12272 (last visited Jan. 22, 2026).

[45] Kevin Hickey and Erin Ward, "Drug Prices: The Role of Patents and Regulatory Exclusivities," *Congressional Research Service* (updated Jan. 30, 2024) https://crsreports.congress.gov/product/pdf/R/R46679 (last visited Jan. 22, 2026).

[46] 35 U.S.C. §§ 154(a)(2). The Patent Act authorizes the USPTO to extend a patent term to account for delays in obtaining USPTO and, or FDA approval prior to the commercialization of the drug or biological product. 35 U.S.C. §§ 154(b)(1), 156(a).

[47] Kevin Hickey and Erin Ward, "Drug Prices: The Role of Patents and Regulatory Exclusivities," *Congressional Research Service*, pp. 22-23 (updated Jan. 30, 2024) https://crsreports.congress.gov/product/pdf/R/R46679 (last visited Jan. 22, 2026). *See* 35 U.S.C. §§ 271(a).

[48] Robin Feldman, "Patent Term Extensions and the Last Man Standing," 42 Yale L. & Pol'y Rev. 1 (Fall 2023) https://yalelawandpolicy.org/sites/default/files/YLPR/feldman_patent_term_extensions_ylpr_2023.pdf (last visited Jan. 22, 2026). At the time of publication, Robin Feldman was the Arthur J. Goldberg Distinguished Professor of Law, the Albert Abramson Distinguished Professor of Law Chair, and Director of the Center for Innovation at University of California San Francisco College of the Law. https://www.uclawsf.edu/people/robin-feldman/ Feldman's scholarly research analysis tracked the prevalence of patent term extensions, measured their average duration, and calculated the average time drugs are on the market prior to their core patents expiring. Feldman cross-checked CMS spending datasets and USPTO datasets. Feldman excluded rebate spending in determining the $10 million threshold of government spending.

	Type of Monopoly Time					
	Primary Monopoly (Core Patent[49])[50]			Secondary Monopoly (Add-Ons)[51]		
Data Metric	**Total**	**Average Time**	**Maximum Time**	**Subtotal of Total**	**Average Time**	**Maximum Time**
Drugs with Identifiable Core Patents	236	13.5 yrs	23.7 yrs	176	7.2 yrs	16.4 yrs
Subset: Drugs with Core Patent Extensions	139	11.3 yrs	14.0 yrs	126	7.8 yrs	16.8 yrs
Subset: Drugs without Core Patent Extensions	97	17.1 yrs	27.4 yrs	50	5.5 yrs	13.3 yrs

Total Monopoly Time (Core Patent + Add-ons)		
Data Metric	**Average Time**	**Maximum Time**
Drugs with Identifiable Core Patents	18.9 yrs	27.5 yrs
Subset: Drugs with Core Patent Extensions	18.4 yrs	26.2 yrs
Subset: Drugs without Core Patent Extensions	19.7 yrs	30.3 yrs

This study found that drug manufacturers use a mix of USPTO non-core patent protections and FDA regulatory exclusivities (i.e., this mix is the secondary monopoly) to extend the total monopoly time for particular drugs or biological products beyond the expiration of the core patents (i.e., the primary monopoly).[52]

However, once the drug manufacturer's patent term and regulatory exclusivities expire, other manufacturers may begin competing with generics or biosimilar products.[53] If the market functions properly, this will lower their own prices.[54]

In 2007, the U.S. Court of Appeals for the Federal Circuit[55] acknowledged "[t]hese two objectives – to reward innovators with higher profits and to keep prices reasonable for consumers – are in dialectic tension."[56] The Court observed "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods."[57] At the same time, the Federal Circuit cautioned "state law must yield to congressional enactments if it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[58]

[49] Feldman explains that identifiable core patents protect the initial chemical or biologic invention, such as the active ingredient. *Id*. at pp. 4.
[50] Feldman explains that the primary monopoly interval is the time period between the FDA's approval date of the drug manufacturer's new drug application and the expiration date of the core patent plus any patent term extensions on the core patent itself. *Id*. at pp. 6, 21.
[51] Feldman explains that the second monopoly interval begins after the primary monopoly period expires and ends when the drug's last-expiring protection, whether a USPTO secondary patent protection or an FDA regulatory exclusivity protection, ends. *Id*. at pp. 21.
[52] *Id*. at 6. The study also noted that a vast majority of the drugs associated with new patents are for existing drugs and not for new drugs coming on the market. *Id* at 4-5.
[53] *See Biotechnology Industry Organization v. District of Columbia,* 496 F.3d 1362, 1373 (Fed. Cir. 2007).
[54] *Id*.
[55] The U.S. Court of Appeals for the Federal Circuit has exclusive jurisdiction over appeals of federal district court decisions relating to patents and appeals of decisions made by the Patent Trial and Appeal Board of the United States Patent and Trademark Office. 28 U.S.C § 1295(a)(1), (4).
[56] *Biotechnology Industry Organization*, 496 Fed. at 1373.
[57] *Id.* at 1372. The federal patent statute still does not expressly prohibit states from regulating the price of patented goods (current through Dec. 20, 2023).
[58] *Id*., citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Drug Manufacturers

State Permits

A drug manufacturer who manufactures[59] or distributes[60] prescription drugs in Florida must obtain a prescription drug manufacturer permit from the Department of Business and Professional Regulation (DBPR).[61] The permitted prescription drug manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.[62] The table below reflects the number of active drug manufacturer permits issued by DBPR; a virtual permit is for a manufacturer which holds the rights and possesses FDA approval to manufacture a drug but outsources drug manufacturing and shipping.[63]

Permit Type	Permit Sub-Type	Permits by Sub-Type	Total Active Permits (as of 12/29/25)
Resident Prescription Drug Manufacturer	Virtual[64]	23	115
	Non-virtual	92	
Nonresident Prescription Drug Manufacturer	Virtual[65]	272	969
	Non-virtual	697	
Total			1,084

Trade Secret Protection

The Florida Uniform Trade Secrets Act grants trade secret protection to information that derives independent economic value because that information is closely guarded to maintain its secrecy, not generally known, and not readily ascertainable to others who can obtain economic value from its disclosure or use.[66]

Trade secrets held by a state agency are confidential and exempt from constitutional and statutory public records access requirements. In other words, since trade secrets are exempt from public disclosure requirements, but are also deemed confidential, current law prohibits an agency from disclosing trade secrets even if it chose to waive the exemption. Current law authorizes state agencies to share trade secret information with other state agencies, if within the scope of the other agency's official duties.[67] Current law holds state agency contractors to the same

[59] Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug. s. 499.003(28), F.S.
[60] Drug distribution includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs. S. 499.003(16), F.S.
[61] S. 499.01(1), F.S. DBPR regulates drug manufacturers, which are entities holding an FDA New Drug Application or Abbreviated New Drug Application for a drug or a Biologics License issued under the federal Public Health Service Act for a biologic. A drug manufacturer can also be the person who manufactured the drug or biologic if they lack an approved application or license, a co-licensed partner, or an affiliate. S. 499.003(29), F.S.
[62] S. 499.01(2)(a), F.S.
[63] Email from Sam Kerce, Chief of Staff, Department of Business and Professional Regulation on December 29, 2025, on file with the Health and Human Services Committee.
[64] DBPR requires a resident prescription drug manufacturer which manufactures and distributes a prescription in or into Florida, but does not engage in the physical possession of any prescription drug, to obtain a virtual permit. Rule 61N-2.0141, F.A.C.
[65] DBPR requires a nonresident prescription drug manufacturer which manufactures and distributes a prescription drug into Florida, but does not engage in the physical possession of any prescription drug, to obtain a virtual permit. Rule 61N-2.0111, F.A.C.
[66] S. 688.002(4), F.S. When someone knowingly acquires a trade secret by improper means, or has reason to know that a trade secret was improperly acquired, they misappropriate the trade secret. A person can also commit trade secret misappropriation when they disclosure or use a proprietor's trade secret without the proprietor's express or implied consent. A proprietor combats actual or threatened trade secret misappropriation with an action in court for injunctive relief and damages. s. 688.002(2), F.S., s. 688.003, F.S., s. 688.004, F.S.
[67] S. 119.0715, F.S.

standard through the duration of the contract term and following completion of the contract if the contractor does not transfer the records to the state agency.[68]

Current law authorizes DBPR agents and agents from the Department of Law Enforcement to inspect, monitor, and investigate any DBPR permitted establishment which includes, among other things, the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.[69] Permitted establishments have the opportunity to claim and designate trade secret information in the event of such regulatory enforcement activity.[70]

Certain pricing information qualifies for trade secret protection. For example, current law treats Medicaid supplemental rebate amounts and percentages, and manufacturer prices, as confidential and exempt from the public disclosure requirements. This trade secret protection extends to the portions of AHCA's Pharmaceutical and Therapeutics Committee meetings during discussion of supplemental rebate information.[71]

Price Increase Reporting Requirements

In 2023, Florida established a price increase reporting requirement for all prescription drug manufacturer and nonresident prescription drug manufacturer permitholders, as a condition of permitting.[72] Permitholders must notify DBPR of a drug price increase on the date the increase becomes effective. [73] This applies to prescription drugs with a wholesale acquisition cost (WAC)[74] of at least $100 for a course of therapy before the effective date of an increase and to increases greater than 15 percent or more of WAC during the preceding 12 months or any cumulative increase of 30 percent or more of WAC in the previous three calendar years.[75] By April 1 of each year, each drug manufacturer must submit an annual report to DBPR of all increases and cumulative increases on a DBPR form.[76] This means permitholders who increase their drug prices submit specific reports during the year and an annual aggregate report.

Pharmacies

A pharmacy must obtain a permit from the Department of Health (DOH) to operate in Florida, and as of December, 21, 2025, there were 10,821 permitted pharmacies in the state.[77] The Board of Pharmacy regulates pharmacies and issues six different classes of pharmacy permits.[78]

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[68] S. 119.0701(2)(b), F.S.
[69] S. 409.051, F.S.
[70] Rule 61N-1.021(3), F.A.C.
[71] S. 409.91196, F.S.
[72] Ch. 2023-29, Laws of Fla; s. 499.012(16), F.S. *See* Division of Drugs, Devices, and Comestics, "Apply for a License: Drug Price Increase Reporting," The Department of Business and Professional Regulation, https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/apply/#drug-price-increase-reporting (last visited Jan. 22, 2026).
[73] S. 499.026(2), F.S
[74] "Wholesale acquisition cost" means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data. s. 499.026(1)(e), F.S.
[75] To calculate the 30 percent threshold, it must be based on the WAC in effect at the end of the 3-year period compared to the WAC at the beginning of the 3-year period. S. 499.026(1), F.S.
[76] S. 499.026(3), F.S.
[77] Division of Medical Quality Assurance, "License Verification," Department of Health, https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders (last visited Jan. 22, 2026). In the "Profession" row, select "Pharmacy" and in the "License Status" row, select "Practicing statuses only", and click "Search" for inquiry results.
[78] A pharmacy can receive a permit as a community pharmacy, institutional pharmacy, internet pharmacy, nonresident sterile compounding pharmacy, nuclear pharmacy, or special pharmacy. In addition, an actively permitted pharmacy may acquire a special sterile compounding permit to engage in sterile compounding. s. 499.003, F.S. Florida Board of Pharmacy, "Pharmacy Permit," Department of Health, https://floridaspharmacy.gov/pharmacy-permit/ (last visited Jan. 22, 2026).

As a condition of participation in the Florida Medicaid program or the pharmaceutical expense assistance program,[79] current law requires a pharmacy to charge Medicare-card carrying Florida residents a price no greater than the cost of ingredients equal to the average wholesale price minus 9 percent, and a dispensing fee of $4.50. AHCA publishes average wholesale prices for at least the 200 most frequently dispensed drugs on its MyFloridaRX Prescription Drug Price Locator webpage which gives consumers price transparency of prescription drug costs at pharmacies all across Florida's counties.[80]

Health Care Coverage in Florida

Government Sponsors

Florida Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The Agency for Health Care Administration (AHCA) is responsible for administering the Medicaid Program, licensing and regulating health facilities, and providing health care quality and price information to Floridians.[81] The Department of Children and Families makes Medicaid eligibility determinations.[82] For November 2025, Florida Medicaid recorded a monthly enrollment total of 3,997,975 people, with 72.5% enrolled in managed care plans, 27.3% enrolled in fee-for-service plans, and 0.1% enrolled in the Program of All-Inclusive Care for the Elderly (PACE).[83, 84]

The structure of each state's Medicaid program varies, but what states must pay for is largely determined by the federal government, as a condition of receiving federal funds.[85] The federal government also sets the minimum mandatory benefits to be covered in every state's Medicaid program.[86] Under federal Medicaid law, prescription drug coverage is an optional benefit states may choose to cover; Florida Medicaid covers prescription drugs.[87]

Manufacturer Rebates

The Medicaid Drug Rebate Program (MDRP) is a federally negotiated rebate program that helps State Medicaid agencies obtain rebates from drug manufacturers in return for outpatient coverage of the manufacturer's brand-name drugs. The rebate amount is the sum of a basic rebate[88] plus an inflation rebate.[89]

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[79] AHCA provides, subject to availability, pharmaceutical expense assistance to individuals diagnosed with cancer or individuals who have received organ transplants who were medically needy recipients prior to 2006. Specifically, AHCA pays the Medicare Part B prescription drug coinsurance and deductibles for eligible Part B covered drugs on behalf of program enrollees. s. 402.81, F.S.

[80] S. 409.9066, F.S. As an alternative discount, a pharmacy may elect to instead provide or accept a private voluntary discount prescription program for state residents who are Medicare beneficiaries. Heath Care Transparency, "MyFloridaRX Prescription Drug Price Locator," Agency for Health Care Administration https://prescription.healthfinder.fl.gov/ (last visited Jan. 22, 2026).

[81] Office of Program Policy Analysis and Government Accountability, *Agency for Health Care Administration*, https://oppaga.fl.gov/ProgramSummary/ProgramDetail?programNumber=5048 (last visited Jan. 22, 2026).

[82] S. 409.902, F.S.

[83] The Program of All-Inclusive Care for the Elderly (PACE) is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility. Medicaid, PACE, https://www.medicare.gov/health-drug-plans/health-plans/your-coverage-options/other-medicare-health-plans/PACE (last visited Jan. 22, 2026).

[84] Florida Agency for Health Care Administration, Current Comprehensive Medicaid Managed Care Enrollment Reports, (Nov. 2025) https://ahca.myflorida.com/medicaid/medicaid-finance-and-analytics/medicaid-data-analytics/medicaid-monthly-enrollment-report (last visited Jan. 22, 2026). Select the "Medicaid" tab on the lower toolbar of the Excel Spreadsheet.

[85] Title 42 U.S.C. §§ 1396-1396w -5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725).

[86] S. 409.905, F.S. Florida Medicaid Managed Care sets a minimum benefit package that build on top of the federal minimum benefits package. S. 409.973, F.S.

[87] S. 409.973(1)(x), F.S.

[88] The basic rebate is the greater of 23.1% of the average manufacturer price or the average manufacturer price minus the Medicaid best price. The Medicaid best price is the manufacturer's net price for a drug and is inclusive of all applicable discounts, rebates, or other transactions that adjust prices.

[89] The inflation rebate is an amount that offsets the increase in a manufacturer's gross price for a drug above inflation.

In addition to federally negotiated rebates, Florida Medicaid also negotiates for state-only manufacturer rebates, also known as state supplemental rebates. Current law specifies the threshold amount of supplemental rebates at 14% of the average manufacturer's price on the last day of the quarter. In addition, current law authorizes Florida Medicaid to require generic drug manufacturers to provide a minimum rebate of 15.1% of the average manufacturer price for the generic drug. There is no upper limit on the supplemental rebate amount.[90]

Prescription Drug Coverage and Utilization Management

AHCA administers a prescription-drug spending-control program for Florida Medicaid which includes the use of a preferred drug list (PDL) and various utilization management techniques. The PDL is recommended by gubernatorially appointed Pharmaceutical and Therapeutics (P&T) Committee, which considers which drugs are medically appropriate, cost-effective therapeutic drugs for Medicaid enrollees. The P&T Committee also makes recommendations regarding the use of prior authorization. Current law requires the PDL to include at least two drugs in each therapeutic class, if feasible. AHCA requires prior authorization for Medicaid-covered prescription drugs not on the PDL.[91]

Medicaid managed care plans must follow the AHCA prescription drug coverage and utilization management requirements and use the preferred drug list, and may not establish their own preferred drug list. The plans establish the pharmacy networks, and may limit the size of pharmacy networks based on need, competitive bidding, price negotiations, credentialing, or similar criteria.[92]

Commercial Plan Sponsors

Commercial Health Insurers

The Office of Insurance Regulation (OIR) reports that the individual health insurance market in Florida covers about 3.6 million people, and another 2.1 million receive coverage through the group health insurance market. Total premiums for the commercial market exceeded $38.5 billion in 2023 with approximately $24.4 billion in the individual market and $14.0 billion in the group market.[93]

The Florida Health Insurance Advisory Board (FHIAB) advises OIR, AHCA, the Department of Financial Services, other executive departments, and the Legislature on health insurance issues. As of year-end 2023, FHIAB reports that health insurance coverage by market segment consisted of:

- Individual Coverage – 3,631,873 covered lives, an increase of 25.2% from 2022.
- Small Group (1-50 members) – 400,164 covered lives, a decrease of 4.8% from 2022.
- Large Group (51+ members) – 1,789,341 covered lives, an increase of 32.4% from 2022.
- Total Market – 5,821,378 covered lives, an increase of 24.6% from 2022.[94]

[90] S. 409.912(5)(a), F.S. AHCA may negotiate an amount lower than 14% of the average manufacturer price if the federal and/or supplemental rebate equal or exceeds 29%.
[91] Ss. 409.912; 409.912(5)(a); 409.91195; 409.91196, F.S.
[92] *Id*.
[93] Florida Health Insurance Advisory Board, *2024 Florida Health Insurance Market Report*, Florida Office of Insurance Regulation (adopted Feb. 11, 2025) https://floir.com/docs-sf/default-source/life-and-health/health-insurance-advisory-board-reports/fhiab-2024-market-report---final-(approved-2-11-25).pdf?sfvrsn=7dfc4a52_3 (last visited Jan. 22, 2026).
[94] *Id*.

Prescription Drug Spending Reports

In 2020, Congress enacted legislation that requires commercial health insurers to report frequently dispensed, high-spend[95] prescription drug spending for each plan year to HHS, the Department of Labor, and the Department of Treasury. In addition, commercial health insurers must also report how prescription drug rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers impact beneficiary premiums.[96] The 2020 law also requires HHS to biannually publish a report on prescription drug reimbursement under commercial health plans, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage. HHS must exclude confidential and trade secret information from reports; current law instructs HHS to aggregate its biannual pharmacy benefits and drug cost report so that it does not publicize information about a specific plan or drug.[97]

In November 2024, HHS reported commercial health insurers paid 38% of total retail drug spending in 2022, which HHS states is by far the largest source of prescription drug coverage for Americans. In Florida, HHS reported that gross spending by commercial health insurers[98] for prescription drugs was approximately $10.3 million in 2020 and $11.5 million in 2021, with net-to-gross spending ratios of 0.79 (2020) and 0.77 (2021), ratios which are both equivalent to national averages. This means for every $100 initially spent on prescription drugs at gross prices, between $21-23 is later returned to commercial health insurers in the form of rebates and other discounts, for net spending at $77-79. HHS also reports that, nationwide between 2020 and 2021, spending at the net drug price level grew at a slower rate than spending at the gross drug price level; however, both net and gross spending grew faster than increases in drug volume.[99]

Health Maintenance Organizations

A health maintenance organization (HMO) offers cost-sensitive health insurance plans geared towards preventative health care and characterized by strict in-network, referral-based care coordination, with exceptions for emergencies, managed by the plan beneficiary's designated primary care physician.[100] HMOs must have an OIR-issued certificate of authority and an AHCA-issued Health Care Provider Certificate to operate in Florida.[101] Once an HMO is issued a certificate, the HMO may enter into contracts in Florida to provide an agreed-upon set of

[95] Specifically, current law requires commercial health insurers to report: the 50 brand-name prescription drugs most frequently dispensed by pharmacies for claims paid by the plan or coverage, and the total number of paid claims for each drug; the 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each drug; and the 50 prescription drugs with the greatest increase in plan or coverage expenditures year-over-year, and for each drug, the change in amounts expended by the plan or coverage spending for each drug.

[96] This includes the amounts paid for each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration from drug manufacturers during the plan year.

[97] Consolidated Appropriations Act of 2021, P.L. 116-260 (Dec. 27, 2020), 134 Stat. 2918, Division BB, Title II, Sec. 204; 42 U.S.C. § 300gg-120.

[98] The market segments included in the HHS commercial health insurer analysis were self-funded plans (small and large employers), group market plans (small and large), individual market plans, student market plans, and the Federal Employees Health Benefit Program plans.

[99] However, the study did not weigh in on whether the ratios are driven by relatively high gross prices, relatively low net prices, or both. Office of the Assistant Secretary for Planning and Evaluation, "Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans: Report Required by the Consolidated Appropriations Act of 2021," U.S. Department of Health and Human Services, (Nov. 2024) https://aspe.hhs.gov/sites/default/files/documents/91cec91387cd81ca1db5ba5cc5916a19/nsa-drug-pricing-rtc.pdf (last visited Jan. 22, 2026). *See also* Andrew W. Mulcahy, Preethi Rao, Lindsey Patterson, Annetta Zhou, Jonathan Levin, Rachel Reid, Sarah Junghee Kang, Zetianyu Wang, Susan Lovejoy, "Prescription Drug Prices, Rebates, and Insurance Premiums," *The RAND Corporation*, (Nov. 2024) https://aspe.hhs.gov/sites/default/files/documents/953a9848a82b0652b15313359747f60b/prescription-drug-prices-rebates-insurance-premiums.pdf (last visited Jan. 22, 2026).

[100] *See* Chief Financial Officer, "Health Insurance and Health Maintenance Organizations: a guide for consumers" Department of Financial Services, (Jul. 2025) https://myfloridacfo.com/docs-sf/consumer-services-libraries/consumerservices-documents/understanding-coverage/consumer-guides/health-insurance-guide.pdf?sfvrsn=5546b2b_4 (last visited Jan. 22, 2026).

[101] S. 641.21(1), F.S.

comprehensive health care services, including drugs, to subscribers in exchange for a prepaid per capita sum or a prepaid aggregate fixed sum.[102] As of December 19, 2025, OIR reports there are 56 HMOs.[103]

State Employee Group Insurance Program

The State Employee Group Insurance Program (SGI Program) is governed by ch. 110, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees, and includes health, life, dental, vision, disability, and other supplemental insurance benefits. The SGI program covers over 360,000 state employees, dependents, and retirees. The SGI Program typically makes benefits changes on a plan year basis, January 1 through December 31.

As part of the SGI Program, DMS is required to maintain the State Employee Prescription Drug Program (Prescription Drug Plan).[104] DMS contracts with Optum Rx, a pharmacy benefit manager, to administer the Prescription Drug Plan.[105] For Fiscal Year 2024-2025, DSGI estimates that the State Employee Group Insurance Program spent $1.22 billion on prescription drug claims for covered beneficiaries and an additional $5.1 million on pharmacy benefit manager claims administration.[106]

Pharmacy Benefit Managers

To manage drug costs, a health plan sponsor typically contracts a pharmacy benefit manager (PBM) to build their prescription drug benefit package. As a contracted professional service, the PBM develops the health plan's prescription drug formulary and organizes a network of pharmacies where plan beneficiaries can pick up their prescriptions at reduced prices. A PBM who contracts to administer prescription drug benefits in Florida on behalf of a health plan sponsor must be licensed as an insurance administrator by obtaining a certificate of authority from OIR.[107] A certificate of authority issued to a PBM remains valid, unless OIR suspends or revokes the certificate, so long as the PBM conducts business in Florida.[108] As of December 19, 2025, OIR regulates 72 PBMs.[109]

As an insurance administrator, a PBM acts in a fiduciary capacity[110] on behalf of the health plan sponsor,[111] and negotiates directly with drug manufacturers and pharmacies interested in selling their drugs and pharmacist services, respectively, to the health plan's beneficiaries. PBMs can manage utilization of a prescription drug and its overall cost by making the drug's out-of-pocket cost higher or lower. As a result, the placement of prescription drugs on a formulary can affect utilization of a drug. Through negotiations, PBMs secure reduced drug prices or arrange rebate deals with drug manufacturers and drug manufacturers receive a steady volume of beneficiary demand for their drugs. The inclusion of a pharmacy within a health plan's pharmacy network can increase

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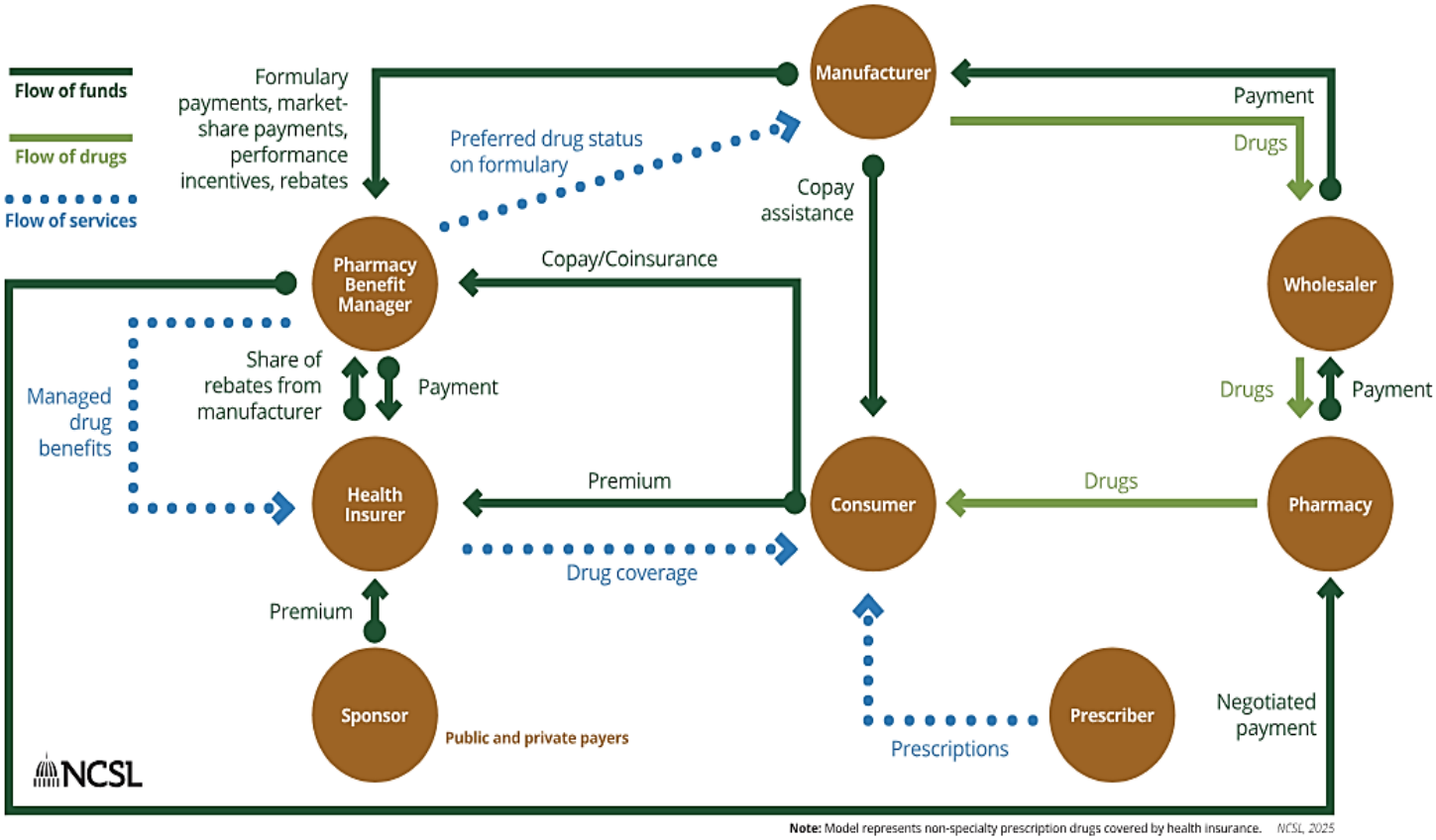
[102] Ss. 641.19(4), 641.31(1), F.S.
[103] Office of Insurance Regulation, "Active Company Search," https://companysearch.floir.gov/ (last visited Jan. 22, 2026). For the "Company Type" row, select "Health Maintenance Organization (HMO)" and click "Search" for inquiry results.
[104] S. 110.12315, F.S.
[105] Department of Management Services, *myFlorida, Prescription Drug Plan*, https://www.mybenefits.myflorida.com/myhealth/prescription_drug_plan (last visited Jan. 22, 2026).
[106] DSGI estimates that the state preferred provider organization plans spent $644.3 million on prescription drug claims plus another $2.7 million on PBM administration, the state health maintenance plans spent $570.7 million on prescription drug claims plus another $2.4 million on PBM administration, and the Medicare Advantage prescription drug plans spent $9.6 million. Division of State Group Insurance, "State Employees' Group Health Self-Insurance Trust Fund: Report on Financial Outlook for the Fiscal Years Ending June 30, 2025 through June 30, 2030," Department of Management Services, Ex. III: Financial Outlook by Fiscal Year, pp. 9 (Aug. 11, 2025) https://www.edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf (last visited Jan. 22, 2026).
[107] S. 626.8805(1), F.S. If a PBM lacks a valid certificate of authority to act as an administrator, the PBM is subject to a fine of $10,000 per violation per day.
[108] S. 626.8805(6), F.S.
[109] Office of Insurance Regulation, "Active Company Search," https://companysearch.floir.gov/ (last visited Jan. 22, 2026). For the "Company Type" row, select "Pharmacy Benefit Manager" and click "Search" for inquiry results.
[110] Fiduciary representation contemplates a legally cognizable relationship of trust where an intermediary figure advances the interests of a principal for the primary and direct benefit of the principal's designated beneficiary.
[111] S. 626.883, F.S.

customer volume for that pharmacy. Through negotiations, PBMs gain favorable reimbursement rates with pharmacies. In return, in-network pharmacies enjoy a steady volume of beneficiary demand for their services.

The prescription drug supply chain is a complex machine where PBMs directly or indirectly influence most individualized transactions amongst industry participants, as the infographic below illustrates.[112]



In recent years, state governments have focused on PBMs for several reasons, including their business practices, market consolidation, and lack of transparency, all of which factor into concerns that PBMs themselves have played a role in increasing drug prices, even as they work to manage pharmacy benefits and costs for insurers.[113]

Contracts

Current law sets many parameters on PBM contracts with health plan sponsors and pharmacies, including requiring or prohibiting certain terms and conditions.

With respect to its contractual agreements with health plan sponsors, PBMs must incorporate the following terms and conditions, pursuant to s. 626.8825(2), F.S.:

- Use a pass-through pricing model[114] without applying financial clawbacks, reconciliation offsets, or offsets to adjudicated claims.

[112] "Prescription Drug Supply Chain," *National Conference of State Legislatures* (updated Jan. 22, 2026) https://www.ncsl.org/health/prescription-drug-supply-chain (last visited Jan. 22, 2026).
[113] Meredith Freed, Julliette Cubanski, and Elizabeth Williams, "What to Know About Pharmacy Benefit Managers (PBMs) and Federal Efforts at Regulation," *KFF* (Dec. 18, 2025) https://www.kff.org/other-health/what-to-know-about-pharmacy-benefit-managers-pbms-and-federal-efforts-at-regulation/ (last visited Jan. 22, 2026).
[114] A pass-through pricing model is where the health plan sponsor pays the PBM for covered outpatient drugs which are 1) equivalent to the payments the PBM makes to a dispensing pharmacy or provider for such drugs, including any contracted professional dispensing fee

- Prohibit spread pricing.[115]
- Use accounting measures to ensure a health plan sponsor's payment for services rendered to the PBM is allocated pursuant to the terms of the contract.
- Pass 100% of manufacturer rebates to offset plan beneficiary cost-sharing obligations and premium amounts, provided the contract delegates rebate negotiation to the PBM.[116]
- Include federally complaint pharmacy network adequacy requirements.
- Prohibit conditioning a pharmacy's participation in one pharmacy network upon its participation in another pharmacy network.
- Prohibit penalizing a pharmacy from exercising its prerogative not to participate in a specific pharmacy network.
- Prohibit requiring that in-network pharmacies meet accreditation standards inconsistent with or more stringent than federal and state requirements for licensure as a pharmacy (except specialty networks).
- Provide a 60-day continuity-of-care period concerning drug formulary changes, during which plan beneficiaries may access covered drugs on the formulary at the current price.

With respect to its contractual agreements with pharmacies, PBMs must incorporate the following terms and conditions, pursuant to s. 626.8825(3), F.S.

- Provide detailed remittance information that helps pharmacies identify the appropriate reimbursement schedule at the time of claim adjudication and ensure that claim level payment adjustments comply with nationally standardized protocols.
- Use nationally standardized reconciliation protocol for any effective rate guarantee.
- Prohibit financial clawbacks, reconciliations offsets, or offsets to adjudicated claims.
- Prohibit PBM from charging, withholding, or recouping direct or indirect remuneration fees, dispensing fees, or brand name or generic rate adjustments through reconciliation.[117]
- Prohibit PBM from charging, withholding, or recouping amounts related to discounts, multiple network reconciliation offsets, adjudication transaction fees, and any other instance when a free may be recouped from a pharmacy.[118]
- Prohibit PBM from unilaterally changing the terms of any participation contract.
- Allow pharmacy to offer mail or delivery services if plan beneficiary generally opts in to such services or specifically requests such services.
- Allow pharmacy to charge a shipping and handling fee if pharmacy discloses the amount to the plan beneficiary as well as the possibility of not being reimbursed for those fees.
- Provide upon a pharmacy's request a list of health plan sponsors in which the pharmacy is part of the network.[119]

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between the PBM and in-network pharmacies, and which are 2) passed through in their entirety by the health plan sponsor or by the PBM to the pharmacy or provider that dispenses the drugs, and the payments are made in a manner that is not offset by any reconciliation. S. 626.8825(1)(p), F.S.

[115] Spread pricing occurs when a PBM charges a health plan sponsor a different amount for pharmacist services than the amount the PBM reimburses a pharmacy for the same pharmacist services. s. 626.8825(1)(w), F.S.

[116] The manufacturer rebate pass-through payment does not apply to PBM contracts involving Medicaid managed care plans.

[117] This prohibition does not apply to recoupments returned to Medicaid or the State Group Insurance Program. This prohibition also does not apply to PBM incentive payments to network pharmacies for meeting or exceeding quality metrics. This prohibition also does not apply to recoupment due to erroneous claims, fraud, waste, or abuse. This prohibition also does not apply to a claim adjudicated in error, a maximum allowable cost appeal pricing adjustment, or an adjustment made as part of a pharmacy audit.

[118] *Id.*

[119] The PBM must communicate list updates to the pharmacy within 7 days, and the PBM cannot restrict the pharmacy from publicly disclosing the list.

Maximum Allowable Cost and Reimbursement Appeals

Current law requires a PBM's contractual agreement with a pharmacy to provide a reasonable administrative appeal procedure that allows a pharmacy to appeal the PBM's maximum allowable cost pricing information and the corresponding reimbursement for a specific drug that the pharmacy argues is below its acquisition cost. Every 90 days, OIR-regulated PBMs must report to OIR the total number of appeals received and denied for each specific drug in the preceding 90-day period and supply its explanations or reasonings for each denial.[120]

Unlawful Activity

OIR also takes enforcement action against PBMs that commit the following unlawful business activities, pursuant to s. 626.8827, F.S.:

- Prohibiting, restricting, or penalizing a pharmacy from disclosing to any person:
  - The nature of treatment, risks, or alternatives.
  - The availability of alternate treatment, consultations, or tests.
  - The decision of, or the process used by, utilization reviewers to authorize or deny pharmacist services or benefits.
  - Information on financial incentives and structures used by the health plan sponsor.
  - Information that may reduce the costs of pharmacist services.
  - Whether the cost-sharing obligation exceeds the retail price for a covered prescription drug and the availability of a more affordable alternative drug.
  - Other information the pharmacy deems appropriate to disclose.
- Prohibiting, restricting, or penalizing a pharmacy from disclosing confidential proprietary information to certain state agencies,[121] provided that the pharmacy marks such information as confidential or requests confidential treatment for any oral communication of such information.
- Communicating at the point-of-sale, or otherwise require, a cost-sharing obligation for the plan beneficiary in an amount that exceeds the lesser of:
  - The applicable cost-sharing amount under the applicable pharmacy benefits plan or program; or
  - The usual and customary price[122] of the pharmacist services.
- Transferring or sharing records relative to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose other than the limited purposes of facilitating pharmacy reimbursement, formulary compliance, or utilization review on behalf of the applicable pharmacy benefits plan or program.
- Failing to make any payment due to a pharmacy for an adjudicated claim with a date of service before the effective date of a pharmacy's termination from a pharmacy benefit network.[123]
- Terminating the contract of, penalize, or disadvantage a pharmacy that lawfully discloses information about PBM practices, exercises statutorily reserved prerogatives, or shares its contractual agreement with OIR pursuant to a compliant or query.
- Failing to pay a pharmacy for any pharmacy benefit claim, provided that the health plan sponsor delegates the obligation of payment to the PBM.
- Failing to comply with contractual requirements as specified in 626.8825(2), F.S.

As an OIR-regulated entity, PBMs must cooperate with biennial examinations and ad hoc investigations, make available certain documents and records, and comply with recordkeeping requirements. OIR must impose an

[120] S. 626.8825(3)(h), F.S.
[121] These state agencies include OIR, AHCA, the Department of Management Services, law enforcement, or state and federal governmental officials.
[122] The usual and customary price means the amount charged to cash customers for a pharmacist service exclusive of sales tax or other amounts claimed. s. 626.8825, F.S.
[123] However, a PBM may withhold payment because of fraud on the part of the pharmacy or when other law requires.

administrative fine of $5,000 for each contractual violation and, or each unlawful activity discovered; a PBM's failure to pay is grounds for the denial, suspension, or revocation of its certificate of authority.[124] OIR has approximately 38 ongoing PBM investigations, as of September 2025.[125]

Vertical Integration

Vertical integration describes a form of marketplace consolidation where different lines of business affiliate under a parent conglomerate to maximize administrative efficiencies, bring emerging markets to scale, and streamline the customer's user experience. A noteworthy example of vertical integration in the technology sector is Amazon's expansion into the grocery business (Whole Foods), primary care (One Medical), entertainment (Metro-Goldwyn-Mayer), home automation (Ring), and pharmacy (PillPack), amongst other lines of business. In contrast to vertical integration, horizontal integration occurs when business rivals within the same line of business acquire or merge with each other to exercise greater market share over remaining competitors. A timely example of horizontal integration is the present merger & acquisition fight in the entertainment sector between Netflix and Paramount for Warner Bros. Discovery.

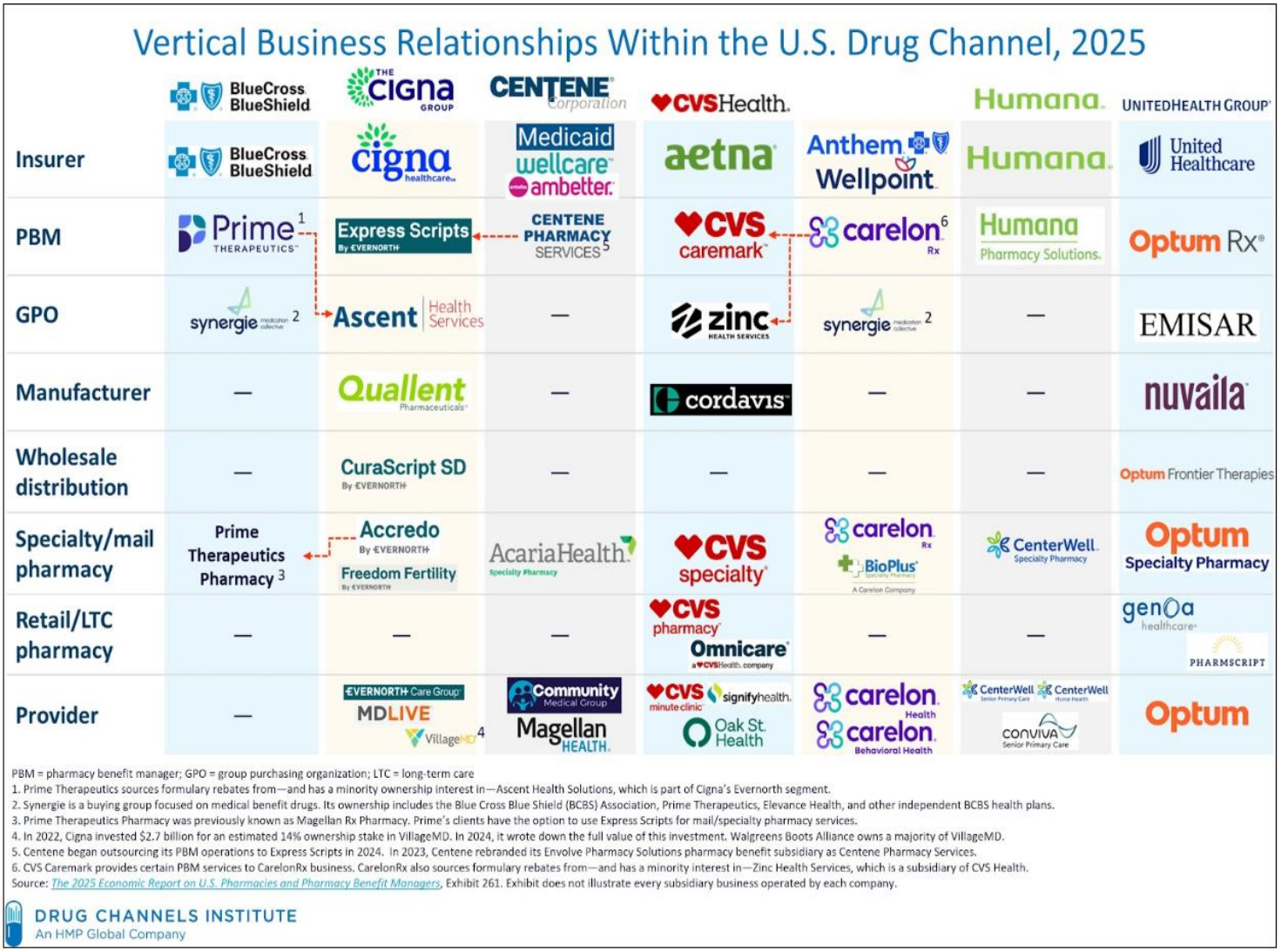
Vertical integration of the healthcare sector reflects a recent shift towards risk-based contracting amongst payers and providers, where a parent healthcare conglomerate builds a vertically integrated network of different lines of business (e.g., insurance, PBM, primary care, pharmacy, etc.) to distribute acute financial risks for individual business segments across the entire healthcare delivery supply chain. While vertical mergers may create pro-competitive administrative efficiencies, they also create anticompetitive effects.[126]

Current law requires PBMs to disclose to OIR any ownership interests or affiliations of any kind with:

- Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the PBM provides administrative services; and
- Any pharmacy which, either directly or indirectly, through one or more intermediaries:
    - Has an investment or ownership interest in an OIR-regulated PBM;
    - Share common ownership with an OIR-regulated PBM; or
    - Has an investor or a holder of an ownership interest which is an OIR-regulated PBM.[127]

Any such ownership interest or affiliation with an insurance company or pharmacy means the PBM is vertically integrated with a parent healthcare conglomerate, alongside its affiliated insurance company and affiliated pharmacies. As the below infographic illustrates, a handful of parent healthcare conglomerates control the prescription drug supply chain in the United States, which includes manufacturing, distribution, prescription drug coverage and reimbursement, PBMs, prescribing providers, and pharmacy fulfillment.[128]

[124] S. 626.8828, F.S.
[125] Email from Seth Stubbs, Director of Legislative & Cabinet Affairs, Office of Insurance Regulation, on September 19, 2025. On file with the Health & Human Services Committee.
[126] *See* Kevin Hahm and Brian Miller, "A Framework for Evaluating Vertical Integration Among Payers and Providers," *American Bar Association*, 39 Fall Antitrust 45 (Fall 2024) https://www.americanbar.org/content/dam/aba/publications/antitrust/magazine/2024/vol-39-issue-1/framework-evaluating-vertical-integration.pdf (last visited Jan. 22, 2026).
[127] S. 626.8814, F.S. A PBM must also formally report any change ownership interests or affiliations to OIR within 60 days after the change occurs.
[128] Drug Channels Institute, "Drug Channels: Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers" (Apr. 2025) https://www.drugchannels.net/2025/04/mapping-vertical-integration-of.html (last visited Jan. 22, 2026).



For 2024, nearly 80% of all equivalent prescription claims were processed by three PBMs: the CVS Caremark business of CVS Health, the Express Scripts business of Cigna, and the Optum Rx business of UnitedHealth Group. Five of the six largest PBMs are now owned by organizations that also own a health insurer.[129]

In 2025, the FTC analyzed 51 specialty generic drugs[130] dispensed from 2017 to 2022 for members of commercial health plans and Medicare Part D prescription drug plans managed by CVS Caremark, Express Scripts, and Optum Rx as a part of its ongoing study of the PBM industry. The FTC found that these three PBMs marked up numerous specialty generic drugs by hundreds and thousands of precent, with the majority of the most highly marked up drugs dispensed by the PBM's own affiliated pharmacies. The FTC believes this dispensing pattern indicates that these PBMs may be steering highly profitable prescriptions to their own affiliated pharmacies. The FTC also found that CVS Caremark, Express Scripts, and Optum Rx reimbursed their affiliated pharmacies at a higher rate than they paid unaffiliated pharmacies on nearly every specialty generic drug examined. Collectively, these companies

[129] Adam Fein, "The Top Pharmacy Benefit Mangers of 2024: Market Share and Key Industry Developments," *The Drug Channels Institute* (Mar. 31, 2025) https://www.drugchannels.net/2025/03/the-top-pharmacy-benefit-managers-of.html (last visited Jan. 22, 2026).
[130] Historically, specialty drugs necessitated special handing and administration. The FTC asserts this is not necessarily the case anymore and that there is no standard definition. Instead, the FTC states specialty drugs are characterized by a variety of factors, including their high cost.

generated more than $7.3 billion in revenue from dispensing drugs in excess of the drugs' estimated acquisition costs plus an additional $1.4 billion from spread pricing. [131]

In the same analysis, the FTC observed that these specialty generic drug dispensing practices account for 12% of aggregated operating income in 2021 as reported by the parent healthcare conglomerates' business segments.[132]

Prescription Drug Formularies

A prescription drug formulary is a list of prescription drugs covered by a health plan. It dictates which drugs will be covered, and at what level, of reimbursement. Formularies distinguish between preferred or discouraged prescription drugs by dividing products into different tiers, designating different levels of patient out of pocket costs for each tier. A formulary may cover both generic and brand name prescription drugs. Formulary selection involves both clinical and financial considerations.

Typically, PBMs employ Pharmacy and Therapeutics committees to assess and recommend formulary placement for individual drugs. These committees are typically comprised of clinicians, pharmacists, medical professionals, legal experts, and administrators. Formularies generally have two to five tiers. For example, a five-tier formulary includes generic, preferred brand, non-preferred brand, preferred specialty drugs and non-preferred specialty drug tiers.

Tier placement determines the amount a patient pays out of pocket for a prescription medication at the point-of-sale, typically as coinsurance or copays. The varying out-of-pocket costs of a plan's formulary provide incentives for plan beneficiaries to obtain prescriptions that are included on the formulary, especially those on lower-cost tiers, to reduce or eliminate their out-of-pocket costs.[133]

Mid-Year Formulary Changes

Current law authorizes changes to a health plan sponsor's prescription drug formulary during the plan year. When the health plan sponsor's PBM adds or removes a drug from the list, or reclassifies a drug into a different tier, current law requires the health plan sponsor and PBM to provide a 60-day continuity-of-care period. This means that for 60 days following the notice of revision to plan beneficiaries, the formulary must continue to honor the preexisting out-of-pocket cost of the drug for plan beneficiaries. However, the 60-day continuity-of-care period does not apply in cases where:

- The FDA approved the covered prescription drug for over-the-counter purchase in the commercial market;
- The manufacturer discontinued selling the covered prescription drug in the commercial market; or
- Federal authorities subjected the covered prescription drug to an involuntary recall and the drug is no longer available on the commercial market.[134]

[131] Federal Trade Commission, "FTC Releases Second Interim Staff Report on Prescription Drug Middlemen," (Jan. 14, 2025) https://www.ftc.gov/news-events/news/press-releases/2025/01/ftc-releases-second-interim-staff-report-prescription-drug-middlemen (last visited Jan. 22, 2026).
[132] *Id.*
[133] Maggie Aime, Charlene Rhinehart, and Joshua Murdock, "A Guide to Medication Formularies: Understanding Your Prescription Medication Coverage," *GoodRx* (updated Jul. 16, 2025) https://www.goodrx.com/insurance/health-insurance/medication-formulary (last visited Jan. 22, 2026).
[134] S. 626.8825(2)(h), F.S.

Drug Pricing Reform

Medicare Drug Spending

The federal Medicare program, administered by the Centers for Medicare and Medicaid Services (CMS), pays for covered health care services of qualified beneficiaries, including prescription drugs.[135] With the latest data available through September 2025, the CMS Medicare Enrollment Dashboard records the following Medicare enrollment counts.[136]

Geographic Area	Medicare Enrollment	Medicare Drug Plan Enrollment
United States	69,355,656	56,239,766
Florida	5,226,732	4,328,388

Drug Price Negotiation Program

The Inflation Reduction Act (IRA) requires the U.S. Department of Health and Human Services (HHS) to negotiate prices for Medicare Part B[137] drugs and Medicare Part D[138] drugs.[139] To this end, CMS selects a small number of covered single-source brand-name drugs or biologics without generic or biosimilar competitors that have the highest total Part D and Part B spending.[140] Medicare Part D and Part B drug spending is highly concentrated among a relatively small share of covered drugs, mainly those without generic or biosimilar competitors.[141]

Each year, CMS determines which Qualifying Single Source Drugs (QSSD) are eligible for the Medicare Drug Price Negotiation Program.[142] CMS must consider drug-specific information[143] submitted by drug manufacturers and clinical benefit information[144] submitted by the public (e.g., consumer and patient organizations, researchers,

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[135] Kevin Hickey, Hannah-Alise Rogers, and Suzanne Kirchhoff, *Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Reponses and Potential Effects*, Congressional Research Service (Dec. 8, 2023) p. 1, https://crsreports.congress.gov/product/pdf/R/R47872 (last visited Jan. 22, 2026).

[136] Centers for Medicare and Medicaid Services, Medicare Enrollment Dashboard, U.S. Department of Health and Human Services, (last updated Sept. 2025) https://data.cms.gov/tools/medicare-enrollment-dashboard (last visited Jan. 22, 2026). Find "Enrollment Count 12-Month Trend: All Areas" under the "Grid" option.

[137] Medicare reimburses providers for physician-administered drugs in an outpatient setting under Part B based on a formula set at 106% of the average sales price (ASP), which is the average price to all non-federal purchasers, inclusive of rebates (other than rebates paid under the Medicaid program. 42 U.S.C. § 1395w-3a(b). 42 U.S.C. § 1395u(o)(1). Drugs administered during Medicare-covered inpatient stays are typically included in diagnosis-related group bundled payments to facilities under Medicare Part A. Medicare Part A drugs are not eligible for price negotiation.

[138] Medicare contracts with private plan sponsors to provide a prescription drug benefit under Part D. 42 U.S.C. § 1395w-112(b).

[139] The IRA carves out limited drug price negotiation authority from the Part D non-interference clause, which prohibits HHS from interfering with drug pricing negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors and prohibits HHS from requiring a specific drug formulary and from instituting a price structure for Part D reimbursement. 42 U.S.C. § 1320f(a). 42 U.S.C. § 1395w-111(i). 42 U.S.C. § 1395w-104(b)(3)(l).

[140] 42 U.S.C. § 1320f-1.

[141] Juliette Cubanski, Tricia Neuman, and Meredith Freed, "Explaining the Prescription Drug Provisions in the Inflation Reduction Act," *KFF* (Jun. 24, 2023) https://www.kff.org/medicare/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/ (last visited Jan. 22, 2026).

[142] CMS excludes drugs with available generic or biosimilar equivalents, small-molecule drugs that are less than 9 years removed from their FDA-approval or license date, biologic products that are less than 13 years removed from their FDA-approval or license data, small biotech drugs (until 2029), drugs with Medicare spending of less than $200 million in 2021 (and indexed for inflation), orphan drugs, and all plasma-derived biological products. 42 U.S.C. 1320f-1(e). IRA delays biologic drug negotiation by up to two years if a biosimilar product is likely to enter the market within that time. 42 U.S.C. § 1320f-1(f).

[143] Drug-specific information includes research and development (R&D) costs, costs of production and distribution, prior federal financial support for R&D, information on pending and approved patent applications, and U.S. sales and market data.

[144] Clinical benefit information includes the extent to which the selected drug represents a therapeutic advance compared to existing alternatives, FDA-approved prescribing information and therapeutic alternatives, comparative effectiveness and therapeutic alternatives for

health providers, and other drug companies).[145] CMS decides what proprietary information submitted by drug manufacturers must be kept confidential.[146] Once CMS publishes the list of QSSDs up for price negotiation, CMS negotiates the maximum fair price (i.e., upper payment limit)[147] for each QSSD based on IRA criteria.[148] The IRA imposes an excise tax on drug companies that do not comply with the Medicare negotiation process, starting at 65% of a product's sales in the U.S. and increasing 10 percentage points per quarter to a maximum of 95%.[149] CMS finalizes negotiated prices by contractual agreement with drug manufacturers,[150] and the price agreement for a selected QSSD lasts until the drug no longer qualifies as a QSSD under the Medicare Drug Price Negotiation Program.[151] However, the maximum fair price for a QSSD increases each year during the term of the agreement to adjust for inflation;[152] also, prices may be renegotiated during the term of the agreement.[153]

In August 2024, CMS published negotiated drug prices for 10 Part D drugs which were selected for the first round of price negotiation. Negotiated prices take effect at the start of calendar year 2026. These 10 drugs account for $56.2 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drugs costs, during calendar year 2023. The chart below itemizes cost, enrollee utilization, and negotiated prices for these 10 drugs and itemizes the drugs in descending order by total gross cost.[154]

specific populations (such as people with disabilities, older adults, people with terminal illness, and children), and whether the selected drug addresses an unmet medical need.

[145] 42 U.S.C. § 1320f-3(e).

[146] 42 U.S.C. § 1320f-2(c).

[147] The Medicare maximum fair price is the lower of either the QSSD's 1) enrollment-weighted negotiated price for the covered drug under Part D or the average sales price or wholesale acquisition cost for the covered drug under Part B or 2) the percentage of the QSSD's average non-federal average manufacturer's price. The cap for the non-federal average manufacturer's price is:

- 75% for small-molecule drugs and vaccines more than 9 years but less than 12 years beyond FDA approval or licensure.
- 65% for drugs between 12 and 16 years beyond FDA approval or licensure.
- 40% for drugs more than 16 years beyond FDA approval or licensure. 42 U.S.C. § 1320f-3(c). 42 U.S.C. § 1395w-3a(b)(4).

[148] CMS must consider the manufacturer's research and development costs (including the extent to which the manufacturer has recouped these costs); the current unit costs of production and distribution; any federal financial support for novel therapeutic discovery and development related to the drug; data on pending and approved patent applications, exclusivities, and certain other applications and approvals; market data and revenue and sales volume data in the U.S.; and evidence about alternative treatments. 42 U.S.C. § 1320f-2(a)(4), 42 U.S.C. § 1320f-3(b)(2), (e).

[149] Alternatively, manufacturers may withdraw all of their drugs from coverage under Medicare and Medicaid. The IRA authorizes HHS to impose a civil penalty (equal to 10 times the difference between the manufacturer's price charge and Medicare's maximum fair price) on a manufacturer that refuses to offer the negotiated price to Medicare beneficiaries or to outpatient providers. Inflation Reduction Act, P.L. 117-169 (Aug. 16, 2022), 136 Stat. 1818, Title I, Subtitle B, Part 1, Sec. 11003. 26 U.S.C. § 5000d.

[150] 42 U.S.C. § 1320f-2(a).

[151] 42 U.S.C. § 1320f-2(b).

[152] 42 U.S.C. § 1320f-4(b).

[153] 42 U.S.C. § 1320f-3(f).

[154] Centers for Medicare and Medicaid, "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026," U.S. Department of Health and Human Services, (Aug. 15, 2024) https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf (last visited Jan. 22, 2026).

Medicare Part D Drug Price Negotiations: Round One							
Drug Name		Manufacturer	Total Gross Costs CY 2023	# Patients Using Drug CY 2023	List Price (30-day supply) CY 2023	Negotiated Price (30-day supply) CY 2026	Discount (%)
1.	Eliquis	Bristol Myers Squibb; Pfizer	$18.2B	3,928,000	$521.00	$231.00	56%
2.	Jardiance	Boehringer Ingelheim; Eli Lilly	$8.8B	1,883,000	$573.00	$197.00	66%
3.	Xarelto	Bayer AG	$6.3B	1,324,000	$517.00	$197.00	62%
4.	Farxiga	AstraZeneca	$4.3B	994,000	$556.00	$178.50	68%
5.	Januvia	Merck	$4.0B	843,000	$527.00	$113.00	79%
6.	Entresto	Novartis	$3.4B	664,000	$628.00	$295.00	53%
7.	Enbrel	Amgen	$2.9B	48,000	$7,106.00	$2,355.00	67%
8.	Stelara	Janseen	$2.9B	23,000	$13,836.00	$4,695.00	66%
9.	Fiasp; NovoLog	Novo Nordisk	$2.6B	785,000	$495.00	$119.00	76%
10.	Imbruvica	AbbVie	$2.3B	17,000	$14,934.00	$9,319.00	38%

In December 2024, KFF specifically analyzed the negotiated drug prices for Medicare Part D enrollees against the OECD countries of Australia, Austria, Belgium, Canada, France, Germany, Japan, Netherlands, Sweden, Switzerland, and the United Kingdom and found the Medicare prices remain higher than the average price for the same drugs aggregated from those OECD countries. KFF identified an array of factors that may contribute to the pricing contrast between Medicare and the other comparable countries, such as differences in patent law and market exclusivity periods for single-source brand name drugs, the degree of government participation in drug price setting amongst all payers, and differences in implementation of value-based pricing strategies.[155]

In November 2025, CMS published negotiated drug prices for 15 Part D drugs widely used to treat cancer and other serious chronic conditions. This second round of negotiated prices take effect at the start of calendar year 2027. These 15 drugs account for $40.7 billion in total Part D gross covered prescription drug costs utilized by 5.3 million Medicare Part D enrollees from November 2023 and October 2024. The chart below itemizes cost, utilization, and negotiated prices for these 15 drugs and itemizes the drugs in descending order by total gross cost.[156]

[155] Delaney Tevis, Matt McGough, Juliette Cubanski, and Cynthia Cox, "How Medicare negotiated drug prices compare to other countries," Peterson-KFF Health System Tracker (Dec. 19, 2024) https://www.healthsystemtracker.org/brief/how-medicare-negotiated-drug-prices-compare-to-other-countries/ (last visited Jan. 22, 2026). Note: The 11-country subset of 38 member OECD is comprised of Australia, Austria, Belgium, Canada, France, Germany, Japan, Netherlands, Sweden, Switzerland, and the United Kingdom. KFF notes the price of Januvia was unavailable in Austria and Xarelto was unavailable in Belgium. KFF converted prices to $U.S.D using exchange rates as of June 30, 2024 and rounded to the nearest dollar. KFF notes that the OECD country average is not weighted to population or utilization of the drug. Medicare is prohibited from using a standardized measure called Quality Adjusted Life Years (QALYs) to assess cost-effectiveness, while countries like the United Kingdom, Sweden, Australia, and the Netherlands incorporate QALYs when pricing drugs. Medicare does not use drug prices in other countries as a benchmark in the process of arriving at negotiated prices.

[156] Centers for Medicare and Medicaid, "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027," U.S. Department of Heath and Human Services, (Nov. 25, 2025) https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf (last visited Jan. 22, 2026). Juliette Cubanski, "FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program, KFF (Jan. 23, 2025) https://www.kff.org/medicare/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/?entry=table-of-contents-how-many-and-which-types-of-drugs-qualified-for-price-negotiation-for-2027 (last visited Jan. 22, 2026).

Medicare Part D Drug Price Negotiations: Round Two							
Drug		Manufacturer	Total Gross Costs CY 2023	# Patients Using Drug CY 2023	List Price (30-day supply) CY 2023	Negotiated Price (30-day supply) CY 2026	Discount (%)
1.	Ozempic; Rybelsus; Wegovy	Novo Nordisk	$14.4B	2,287,000	$959	$274	71%
2.	Trelegy Ellipta	GlaxoSmithKline	$5.1B	1,252,000	$654	$175	73%
3.	Xtandi	Pfizer	$3.1B	35,000	$13,480	$7,004	48%
4.	Pomalyst	Bristol Myers Squibb	$2.0B	14,000	$21,744	$8,650	60%
5.	Ibrance	Pfizer	$1.9B	16,000	$15,741	$7,871	50%
6.	Ofev	Boehringer Ingelheim	$1.9B	24,000	$12,622	$6,350	50%
7.	Linzess	Ironwood	$1.9B	627,000	$539	$136	75%
8.	Calquence	AstraZeneca	$1.6B	15,000	$14,228	$8,600	40%
9.	Austedo; Austedo XR	Teva	$1.5B	26,000	$6,623	$4,093	38%
10.	Breo Ellipta	GlaxoSmithKline	$1.4B	634,000	$397	$67	83%
11.	Tradjenta	Boehringer Ingelheim	$1.1B	278,000	$488	$78	84%
12.	Xifaxan	Salix	$1.1B	104,000	$2,696	$1,000	63%
13.	Vraylar	Gedeon Richter	$1.0B	116,000	$1,376	$770	44%
14.	Janumet; Janumet XR	Hybio	$1.0B	243,000	$526	$80	85%
15.	Otezla	Amgen	$0.9B	31,000	$4,722	$1,650	65%

In 2026, CMS must select and negotiate prices for 15 more high-spend QSSDs from amongst the Medicare Part B and Part D program formularies, with implementation of maximum fair prices for plan year 2028. In 2027 and beyond, CMS must select and negotiate prices for 20 more high-spend QSSDs from amongst the Medicare Part B and Part D program formularies, with implementation of maximum fair prices scheduled two years from the selection date.[157]

The IRA expressly bars administrative and judicial review of drug selection determinations, unit or dosage size determinations, maximum fair price determinations, and renegotiation-eligible drugs.[158] However, drug manufacturers have challenged the Medicare Drug Price Negotiation Program in least ten different federal lawsuits since 2023,[159] and two U.S. Circuit Court of Appeals (Second and Third) issued opinions on the merits in 2025 that favor the program.[160]

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[157] 42 U.S.C. § 1320f-1.
[158] 42 U.S.C. § 1320f-7.
[159] AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Janssen Pharmaceuticals, Merck, Novartis, Novo Nordisk, Pharmaceutical Research and Manufacturers of America, Teva Pharmaceuticals, and the U.S. Chamber of Commerce are lead plaintiffs in separate cases. O'Neill Institute for National and Global Health Law, "Health Care Litigation Tracker: Medicare Drug Price Negotiation," *Georgetown University*, https://litigationtracker.law.georgetown.edu/issues/medicare-drug-price-negotiation/ (last visited Jan. 22, 2026).
[160] *Boehringer Ingelheim Pharm. v. U.S. Dep't of Health and Human Services*, 150 F.4th 76 (2d Cir. 2025) (holding that drug manufacturer participation in the Medicare Drug Price Negotiation Program is voluntary, and its voluntary nature means the program does not effect an unlawful taking, a deprivation of property interests, or a compulsion of speech; holding that the Medicare Drug Price Negotiation Program is designed to promote a legitimate government purpose [i.e., controlling Medicare spending] and does not regulate conduct outside the scope of Medicare and Medicaid; holding that the Inflation Reduction Act expressly exempts manufacturer agreements from notice-and-comment procedural requirements under the Administrative Procedures Act); *AstraZeneca Pharmaceuticals LP v. Secretary, U.S. Dep't of Health and Human Services*, 137 F.4th 116 (3d Cir. 2025) (holding that the Medicare Drug Price Negotiation Program does not infringe drug manufacturer's property right [i.e., patent rights] because patent law does not confer a right to sell or a right to sell at a particular price; holding that the Inflation Reduction Act's bar on judicial review is permissible because the program only sets prices for drugs that CMS pays

Out-of-Pocket Cap

Medicare Part D provides catastrophic coverage for high out-of-pocket drug costs.[161] The IRA caps a Part D beneficiary's out-of-pocket spending for covered prescription drugs at $2,000 for plan year 2025. For 2026 and beyond, the cap increases by the annual percentage increase in average per capita spending for covered Part D drugs and by accounting for inflation.[162] HHS projects 11 million Part D enrollees will reach the $2,000 out-of-pocket cap in 2025 and save $600 each.[163]

International Reference Pricing Models

Concept

In the United States, the best-known reference price index is the U.S. Department of Labor's Bureau of Statistics' Consumer Price Index (CPI). Generally, a price index like the CPI compares differences in prices for a basket of goods over time or across markets. The rationale behind price indices is that a comparison of prices is most meaningful when they isolate price variances by holding other variables like drug volume and mix constant. This approach is transferrable for price comparisons of prescription drugs amongst countries.[164]

The international referencing of drug prices refers to the practice of a government observing the price of drug amongst various jurisdictions (i.e., source countries) to derive a benchmark, or reference price in the home jurisdiction. The government uses the reference price, usually the lowest price paid for a drug amongst the source countries, to establish upper payment limits for purchasers. The government references international prices as a cost-containment policy strategy to ensure the maximum price paid for a drug is competitively priced relative to its price in other countries.[165]

The precise impact of any model for referencing international prices depends on the variables chosen during the decision point phase. These variables include the selection of population groups, the regulated point-of-sale transaction, drugs, countries, the formula to calculate price, the frequency of price revisions, the granularity of prices and quantity, the data sources, remedies for noncompliance, and ensuring benefits accrue to patients.

for when it reimburses Medicare Part D plan sponsors and because the program does not cover private market transactions; holding that drug manufacturer does not have standing to pursue procedural claims under the Administrative Procedure Act). *See* Andrew Twinamastsiko, "A Tale of Three Decisions: Courts Continue to Reject Challenges to Medicare Negotiation," *Health Affairs* (Aug. 20, 2025) https://www.healthaffairs.org/content/forefront/tale-three-decisions-courts-continue-reject-challenges-medicare-negotiation (last visited Jan. 22, 2026).

[161] 42 U.S.C. § 1395w-102(b)(4).

[162] Inflation Reduction Act, P.L. 117-169 (Aug. 16, 2022), 136 Stat. 1818, Title I, Subtitle B, Part 3, Sec. 11201 -11202. 42 U.S.C. § 1395w-102(b)(4)(B), (6), (7).

[163] Office of the Assistant Secretary for Planning and Evaluation, "Inflation Reduction Act Research Series: Projecting the Impact of the $2,000 Part D out-of-Pocket Cap for Medicare Part D Enrollees with High Prescription Drug Spending," U.S. Department of Health and Human Services (Jan. 13, 2025) https://aspe.hhs.gov/reports/impact-ira-2000-cap (last visited Jan. 22, 2026).

[164] Andrew Mulcahy, Daniel Schwam, and Susan Lovejoy, "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," *The RAND Corporation*, pp. 5 (Feb. 1, 2024) https://www.rand.org/pubs/research_reports/RRA788-3.html (last visited Jan. 22, 2026).

[165] Dominic Voehler, Benjamin Koethe, Patricia Synnott, and Daniel Ollendorf, "The impact of external reference pricing on pharmaceutical costs and market dynamics", *Center for the Evaluation of Value and Risk in Health, Tufts Medical Center*, p.1, (Mar. 18, 2023) https://cevr.tuftsmedicalcenter.org/publications/the-impact-of-external-reference-pricing-on-pharmaceutical-costs-and-market-dynamics (last visited Jan. 22, 2026). Rachel Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, The National Academy for State Health Policy (Aug. 10, 2020) https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/ (last visited Jan. 22, 2026).

While the technical aspects of referencing international prices vary by country, the practice is widespread; over 75 markets across the Asia-Pacific, Europe, Latin America, and the Middle East-North Africa reference international drug prices to calculate medicine prices within their own markets.[166]

In 2023, a Tufts Medical Center research team (Tufts) ran a comparative analysis of drug launch timing, drug launch price, and prices changes for 100 drugs[167] over an eleven-year period between 66 countries with some form of prescription drug reference pricing models against 10 other countries without such models. Tufts observes the utility of prescription drug reference pricing may relate to its use as a price management tool rather than a launch price negotiation tool because it found countries with reference pricing experience greater reductions in list price annually than other countries without reference pricing.[168] If the United States adopted a prescription drug reference pricing model, Tufts cautions that drug manufacturers may pivot to preserve current prices in the United States by delaying drug launches in other countries, by exiting the lowest-price markets for established drugs, and by increasing drug launch prices in the United States.[169]

For countries that adopt prescription drug reference pricing models, savings appear greatest in nations where price revisions are frequent, the number of countries referenced is high, the lowest-price countries are weighted more heavily in calculations, and exchange-rate fluctuations are closely monitored.[170]

Federal Most Favored Nation Models

The 2020 Proposal: Most Favored Nation Drug Pricing for Medicare Part B Covered Drugs

In 2020, a presidential executive order directed CMS to develop a new Medicare rate methodology, called most favored nation (MFN) pricing, where Medicare would pay no more for certain covered high-cost prescription drugs and biological products than the lowest price paid, after adjusting for volume and differences in national gross domestic product (GDP), in a similarly situated OECD member country.[171]

When CMS published the implementing interim rule later in 2020,[172] CMS explained the goal of the Medicare MFN model was to rein in unsustainable growth in Medicare Part B spending for the 50 single source drugs and biologicals that encompass a high percentage of Medicare Part B spending.[173] The interim rule did not address Medicare Part D drug spending.

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[166] Alex Watt, "International Reference Pricing (IRP) 2024: A year in review," *Pharmaceutical Technology*, (Mar. 20, 2025) https://www.pharmaceutical-technology.com/analyst-comment/international-reference-pricing-irp-2024/?cf-view (last visited Jan. 22, 2026).

[167] Tufts selected 100 brand name drugs without significant competition that were associated with annual Medicare or Medicaid spending per beneficiary greater than $10,000.

[168] Tufts observed that prescription drug reference pricing is probably not a launch price negotiation tool because countries with reference pricing experienced drug launch delays and average drug launch prices did not differ between countries with reference pricing and countries without reference pricing.

[169] Dominic Voehler, Benjamin Koethe, Patricia Synnott, and Daniel Ollendorf, "The impact of external reference pricing on pharmaceutical costs and market dynamics," *Center for the Evaluation of Value and Risk in Health, Tufts Medical Center*, (Mar. 18, 2023) https://cevr.tuftsmedicalcenter.org/publications/the-impact-of-external-reference-pricing-on-pharmaceutical-costs-and-market-dynamics (last visited Jan. 22, 2026).

[170] Daniel Ollendorf, Patricia Synott, and Peter Neumann, "External Reference Pricing: The Drug-Pricing Reform America Needs?" *The Commonwealth Fund* (May 27, 2021) https://www.commonwealthfund.org/publications/issue-briefs/2021/may/external-reference-pricing-drug-pricing-reform-america-needs (last visited Jan. 22, 2026).

[171] United States, Presidential Documents, "Executive Order 13948 of September 13, 2020: Lowering Drug Prices by Putting America First," 85 Fed. Reg. 59649 (Sept. 23, 2020) https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-21129.pdf (last visited Jan. 22, 2026). The OECD countries comprise a set of countries that share with the U.S. both democratic principles and a commitment to market-based economies.

[172] Most Favored Nation (MFN) Model, 85 Fed. Reg. 76180 (Nov. 27, 2020) https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26037.pdf (last visited Jan. 22, 2026).

[173] *Id.* at 76180-76181.

To this end, the Medicare MFN model would target the following point-of-sale transaction: when providers and suppliers who participate in the Medicare program submit a separately payable claim for a physician-administered drug on the MFN model drug list in the hospital out-patient setting, the price of that transaction serves as the reference price.[174] CMS proposed benchmarking this reference price to the lowest per capita GDP-adjusted price of similarly situated OECD member countries (other than the U.S.).[175]

To identify those countries, CMS developed an eligibility threshold of a least 60% of the U.S. GDP per capita, updated quarterly.[176] For the first quarter of 2021, the CMS interim rule reported that the first basket group yielded 22 qualifying OECD member countries.[177]

The CMS interim rule anticipated significant savings using the MFN model over a 7-year period (2021-2027). The CMS Office of the Actuary reported savings in the amount of $64.4 billion in Medicare Fee-For-Service benefits, $49.6 billion in Medicare Advantage payments, $9.9 billion in Medicaid dual-eligible beneficiary spending, and $28.5 billion for beneficiaries.[178] The HHS Office of the Assistant Secretary for Planning and Evaluation projected savings in the amount of $87.7 billion for the federal government, state governments, and beneficiaries.[179]

However, CMS never implemented the Medicare MFN model. A legal challenge to the interim rule on procedural grounds was successful, and the court enjoined the rule. CMS did not resolve the procedural problem and stopped the rule's advancement.[180]

The 2025 Proposal: Most Favored Nation Drug Pricing for Direct-to-Consumer and Government Payers

Most-Favored-Nation Executive Order

In May 2025, the White House expressed a policy to end "global freeloading" by other developed countries with respect to low-cost prescription drugs and biological products because it found Americans subsidize those lower costs and face overcharges for the same products in the United States. The White House declared Americans must have access to MFN prices for these pharmaceuticals.

To this end, the "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" executive order directed HHS to 1) communicate MFN price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations and 2) facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the MFN price.[181] HHS subsequently announced that the MFN target price is the lowest price in an OECD country with a GDP per capita of at least 60%

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[174] *Id*. at 76181, 76187.
[175] This reference price methodology counteracts the current Medicare average sales price + 6% commission payments that tend to incentivize the procurement/prescription of drugs with higher ASPs.
[176] CMS chose the CIA World Factbook over the World Bank and the International Monetary Fund as its GDP per capita data source because the CIA World Factbook is a U.S.-issued report containing the most recent estimate of GDP per capita based on purchasing power parity for a country as well as historical data.
[177] These 22 qualifying OECD countries were Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom.
[178] For modeling purposes, CMS used a federal government license to IQVIA's proprietary MIDAS data set. MIDAS data contains monthly estimates of drugs sales and volume from audits of drug transactions in different countries and distribution channels (e.g., retail pharmacies and hospitals).
[179] *Id*.
[180] CMS revoked their interim rule on December 29, 2021 following a nationwide preliminary injunction to enjoin enforcement of the MFN model in *California Life Sciences Association v. Center for Medicare and Medicaid*, 2020 WL 7690650 *1 (N.D. Cal. Dec. 28, 2020). ("The motion for a preliminary injunction is granted based on the government's failure to complete the notice and comment procedures by the Administrative Procedures Act"). Most Favored Nation (MFN) Model, 86 Fed. Reg. 73986 (Dec. 29, 2021).
[181] United States, Presidential Documents, "Executive Order 14297 of May 12, 2025: Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients." 90 Fed. Reg. 20749 (May 15, 2025) https://www.govinfo.gov/content/pkg/FR-2025-05-15/pdf/2025-08876.pdf (last visited Jan. 22, 2026).

of the U.S. GDP per capita, with the expectation that drug manufacturers commit to align U.S. pricing for all brand products across all markets that lack generic or biosimilar competition.[182]

The executive order also warned drug manufacturers that the executive branch would pursue any number of six possible enforcement actions if the executive branch believed significant progress towards MFN pricing was not being delivered, which includes:

- A notice of proposed rulemaking by HHS to impose MFN pricing;
- A certification by HHS to Congress which declares the Section 804(j) prescription drug importation program poses no additional risk to public health and safety and would result in significant reductions to the cost of prescription drugs. Upon certification, the FDA would describe circumstances under which it would consistently grant waivers to import prescription drugs on a case-by-case basis from developed nations with low-cost prescription drugs;
- The initiation of enforcement action by the Attorney General and the Federal Trade Commission for any acts of anticompetitive behavior by pharmaceutical manufacturers, as identified pursuant to a joint-agency report;[183]
- The initiation of all necessary action by the Department of Commerce, amongst other agencies, regarding the export of pharmaceutical drugs or precursor material which the executive branch believes may be fueling global price discrimination;
- FDA scrutiny to potentially modify or revoke approvals granted for drugs, for those drugs it believes may be unsafe, ineffective, or improperly market; and
- Interagency coordination with the White House to address global freeloading and price discrimination against American patients.

In addition, the executive order also instructed the Department of Commerce and the U.S. Trade Representative to take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair U.S. national security and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries.[184] This mandate appears to promote the executive branch's overall efforts to leverage tariff policy against foreign countries to improve the domestic economy and national security.[185] This means the executive branch could extract MFN pricing concessions from drug manufacturers by applying pharmaceutical-related tariff policy towards them, or exempting them from the same.

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[182] U.S. Department of Health and Human Services, "HHS, CMS Set Most-Favored-Nation Pricing Targets to End Global Freeloading on American Patients," (May 20, 2025) https://www.hhs.gov/press-room/cms-mfn-lower-us-drug-prices.html (last visited Jan. 22, 2026).
[183] *See* United States, Presidential Documents, "Executive Order 14273 of April 15, 2025: Lowering Drug Prices by Once Again Putting Americans First", Sec. 13, 90 Fed. Reg. 16441 (Apr. 15, 2025) https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf (last visited Jan. 22, 2026).
[184] United States, Presidential Documents, "Executive Order 14297 of May 12, 2025: Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients." 90 Fed. Reg. 20749 (May 15, 2025) https://www.govinfo.gov/content/pkg/FR-2025-05-15/pdf/2025-08876.pdf (last visited Jan. 22, 2026).
[185] *See* United States, Presidential Documents, "Executive Order 14257 of April 2, 2025: Regulating Imports with a Reciprocal Tariff to Rectify Trade Practices That Contribute to Large and Persistent Annual United States Goods Trade Deficits," 90 Fed. Reg. 15041 (Apr. 2, 2025) https://www.govinfo.gov/content/pkg/FR-2025-04-07/pdf/2025-06063.pdf (last visited Jan. 22, 2026); United States, President Documents, "Memorandum of February 13, 2025: Reciprocal Trade and Tariffs," 90 Fed. Reg. 9837 (Feb. 13, 2025) https://www.govinfo.gov/content/pkg/FR-2025-02-19/pdf/2025-02872.pdf (last visited Jan. 22, 2026).

Voluntary Negotiation Period

Starting in July 2025, the White House entered a voluntary negotiation period with 17 major drug manufacturers[186] to guarantee MFN prices for their medicines in the United States.[187] Through the end of 2025, the White House negotiated deals with the vast majority of these drug manufacturers for MFN pricing in the direct-to-consumer market and for the Medicare program; in addition, drug manufacturers guarantee that state Medicaid programs will have access to the same MFN drug prices. It is important to note that these deals appear to cover only select primary care drugs, not the entire lineup of the drug manufacturers' pharmaceuticals. Many details of these deals remain confidential, including the MFN methodology employed in this context.

The White House will publish MFN prices for these drug manufacturers' drugs on a new price transparency website, "TrumpRx,"[188] which is expected to launch in January 2026. In addition, TrumpRx will be a portal connecting the public with the websites of select pharmaceutical companies that will sell certain prescription drugs at the negotiated MFN prices. Both uninsured and cash-paying customers may purchase directly from the pharmaceutical companies, provided they upload a doctor's prescription for verification.[189] For context, the Florida Department of Health records that 2,520,660 million Floridians aged 0-64 are uninsured, which represents 13.4% of Florida's 2023 population.[190]

The table below records MFN drug pricing deals in the order in which they were reached.

[186] The President published individual letters to 17 drug manufacturers: AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, EMD Serono, Genentech, GSK, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, and Sanofi.
[187] The White House, "Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs," (Jul 31, 2025) https://www.whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-announces-actions-to-get-americans-the-best-prices-in-the-world-for-prescription-drugs/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Trump says he asked 17 drugmakers to take steps to cut U.S. prices within 60 days," *CNBC*, https://www.cnbc.com/2025/07/31/trump-drug-prices-eli-lilly.html (Jul. 31, 2025) (last visited Jan. 22, 2026).
[188] The White House, "TrumpRx," https://trumprx.gov/ (last visited Jan. 22, 2026). The National Design Studio, established within the Executive Office of the President pursuant to executive order, built the digital infrastructure of TrumpRx. *See* National Design Studio, "Posts," https://ndstudio.gov/posts (last visited Jan. 22, 2026); see United States, Presidential Documents, "Executive Order 14338 of August 21, 2025: Improving Our Nation Through Better Design." 90 Fed. Reg. 41759 (Aug. 21, 2025) https://www.govinfo.gov/content/pkg/FR-2025-08-26/pdf/2025-16396.pdf (last visited Jan. 22, 2026).
[189] David Mills, "TrumpRx to Lower Cost of GLP-1s, but Experts Say Overall Savings are Minimal," *Healthline Media* (Nov. 13, 2025) https://www.healthline.com/health-news/trump-rx-lower-costs-glp-1s-prescription-drugs (last visited Jan. 22, 2026).
[190] Division of Public Statistics and Performance Management, "FLHealthCHARTS: Population Uninsured (Aged 0-64 Years)" Department of Health https://www.flhealthcharts.gov/ChartsDashboards/rdPage.aspx?rdReport=NonVitalIndNoGrpCounts.TenYrsRpt&cid=8733 (last visited Jan. 22, 2026); Jennifer Tolbert, Sammy Cervantes, Clea Bell, and Anthony Damico, "Key Facts about the Uninsured Population," KFF, Figure 6: Uninsured Rates Among Population Ages 0-64 by State, 2023, (Dec. 18, 2024) https://www.kff.org/uninsured/key-facts-about-the-uninsured-population/ (last visited Jan. 22, 2026).

2025 Direct-to-Consumer Most-Favored-Nation Drug Pricing Deals					
#	**Manufacturer**	**Drug Example**	**Direct-to-Consumer Discount (%)**	**New Investment in U.S. R&D and Manufacturing**	**Tariff Exemption Grace Period for Investment**
1.	Pfizer (Sept. 2025)[191]	Abrilada	60%	$70 Billion	3 Years
		Duavee	85%		
		Eucrisa	80%		
		Tovias	85%		
		Xeljanz	40%		
		Zazvpret	50%		
2.	AstraZeneca (Oct. 2025)[192]	Breztri Aerosphere	98%	$50 Billion	3 Years
		Airsupra	96%		
3.	EMD Serono (Oct. 2025)[193]	Gonal-f, Ovidrel, Cetrotide	84%	Yes; Not Disclosed	Yes; Not Disclosed
4.	Eli Lilly (Nov. 2025)	Emgality	60%	$27 Billion	Yes; Not Disclosed
		Orforglipron	69%		
		Trulicity	60%		
		Zepbound	69%		
5.	Novo Nordisk (Nov. 2025)[194]	Ozempic	65%	$10 Billion	Yes; Not Disclosed
		Wegovy	74%		
6.	Amgen (Dec. 2025)	Repatha	58%	A share of $150 Billion	3 Years
7.	Bristol Myers Squibb (Dec. 2025)	Reyataz	85%	A share of $150 Billion	3 Years
8.	Boehringer Ingelheim (Dec. 2025)	Jentadeuto	89%	A share of $150 Billion	3 Years
9.	Genentech (Dec. 2025)	Xofluza	70%	A share of $150 Billion	3 Years
10.	Gilead Sciences (Dec. 2025)	Epclusa	90%	A share of $150 Billion	3 Years
11.	GlaxoSmithKline (Dec. 2025)	Advair Diskus 500/50	66%	A share of $150 Billion	3 Years
12.	Merck (Dec. 2025)	Januvia	69%	A share of $150 Billion	3 Years
13.	Novartis (Dec. 2025)	Mayzent	88%	A share of $150 Billion	3 Years

[191] Pfizer said it will offer a large share of its primary care treatments and certain specialty branded drugs at discounts of 50% on average and up to 85%. The White House, "Fact Sheet: President Donald J. Trump Announces First Deal to Bring Most-Favored-Nation Pricing to American Patients," (Sept. 30, 2025) https://www.whitehouse.gov/fact-sheets/2025/09/fact-sheet-president-donald-j-trump-announces-first-deal-to-bring-most-favored-nation-pricing-to-american-patients/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Trump, Pfizer agree to lower U.S. drug prices, exempt company from pharma tariffs," *CNBC* (Sept. 30, 2025) https://www.cnbc.com/2025/09/30/trump-pfizer-drug-price-agreement.html (last visited Jan. 22, 2026).

[192] The White House, "Fact Sheet: President Donald J. Trump Announces Second Deal to Bring Most-Favored-Nation Pricing to American Patients," (Oct. 10, 2025) https://www.whitehouse.gov/fact-sheets/2025/10/fact-sheet-president-donald-j-trump-announces-second-deal-to-bring-most-favored-nation-pricing-to-american-patients/ (last visited Jan. 22, 2026); Jacob Pramuk, "Trump reaches deal with AstraZeneca to lower U.S. drug prices," *CNBC* (Oct. 10, 2025) https://www.cnbc.com/2025/10/10/trump-astrazeneca-drug-pricing-deal.html (last visited Jan. 22, 2026).

[193] The White House, "Fact Sheet: President Donald J. Trump Announces Actions to Lower Costs and Expand Access to In Vitro Fertilization (IVF) and High-Quality Fertility Care," (Oct. 16, 2025) https://www.whitehouse.gov/fact-sheets/2025/10/fact-sheet-president-donald-j-trump-announces-actions-to-lower-costs-and-expand-access-to-in-vitro-fertilization-ivf-and-high-quality-fertility-care/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Trump announces efforts to expand access to IVF drugs," *CNBC* (Oct. 16, 2025) https://www.cnbc.com/2025/10/16/trump-announces-efforts-to-expand-access-to-ivf-drugs.html (last visited Jan. 22, 2026); EMD Serano, "EMD Serano Announces Agreement with U.S. Government to Expand Access to IVF Therapies," (Oct. 16, 2025) https://www.emdgroup.com/en/news/fertility-announcement-16-10-2025.html (last visited Jan. 22, 2026).

[194] The White House, "Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients," (Nov. 6, 2025) https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Trump announces deals with Eli Lilly, Novo Nordisk to slash weight loss drug prices, offer some Medicare coverage," *CNBC* (Nov. 6, 2025) https://www.cnbc.com/2025/11/06/trump-eli-lilly-novo-nordisk-deal-obesity-drug-prices.html (last visited Jan. 22, 2026).

2025 Direct-to-Consumer Most-Favored-Nation Drug Pricing Deals					
#	**Manufacturer**	**Drug Example**	**Direct-to-Consumer Discount (%)**	**New Investment in U.S. R&D and Manufacturing**	**Tariff Exemption Grace Period for Investment**
14.	Sanofi (Dec. 2025)[195]	Plavix	97%	A share of $150 Billion	3 Years
15.	AbbVie (Jan. 2026)[196]	Alphagan Combigan Humira Synthroid	Not Disclosed	$100 Billion	3 Years
16.	Johnson & Johnson (Jan. 2026)[197]	Not Disclosed	Not Disclosed	$55 Billion	Yes; Not Disclosed
17.	Regeneron (Expected Soon)	TBA	TBA	TBA	TBA

As a part of the Eli Lilly and Novo Nordisk deal in November 2025, Medicare also negotiated prices of Ozempic, Wegovy, Mounjaro, and Zepbound for its beneficiaries, which will be $245 each. State Medicaid programs will also have access to these medications at the $245 price point.[198]

As the table above documents, these drug manufacturers benefit from a pharmaceutical-specific tariff exemption in return for guaranteeing most-favored-nation drug prices and for investing heavily in research and development in the U.S. However, in November 2025, the Supreme Court of the United States heard oral arguments in *Learning Resources v. Trump*, which relates to the scope of the executive branch's authority to establish and enforce certain tariff policies without an express delegation of authority from Congress.[199] The Supreme Court's forthcoming decision may bolster or detrimentally affect these direct-to-consumer most-favored-nation deals.

Medicaid Most-Favored-Nation Pricing Developments: The GENEROUS Model

In April 2025, the White House formalized an intent to ensure drug manufacturers pay accurate Medicaid drug rebates consistent with the Medicaid Drug Rebate Program (MDRP). To this end, the White House directed the

[195] The White House, "Fact Sheet: President Donald J. Trump Announces Largest Developments to Date in Bringing Most-Favored-Nation Pricing to American Patients," (Dec. 19, 2025) https://www.whitehouse.gov/fact-sheets/2025/12/fact-sheet-president-donald-j-trump-announces-largest-developments-to-date-in-bringing-most-favored-nation-pricing-to-american-patients/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Nine of the largest pharm companies ink deals with Trump to lower drug prices," *CNBC* (Dec. 19, 2025) https://www.cnbc.com/2025/12/19/nine-pharma-companies-ink-deals-with-trump-to-lower-drug-prices.html (last visited Jan. 22, 2026).

[196] AbbVie, "Press Release: AbbVie and Trump Administration Reach Agreement to Improve Access and Affordability for Americans," *AbbVie* (Jan 12, 2026) https://news.abbvie.com/2026-01-12-AbbVie-and-Trump-Administration-Reach-Agreement-to-Improve-Access-and-Affordability-for-Americans (last visited Jan. 22, 2026).

[197] Johnson & Johnson, "Press Release: Johnson & Johnson Reaches Agreement with U.S. Government to Improve Access to Medicines and Lower Costs for Millions of Americans; Delivers on U.S. Manufacturing and Innovation Investments," Johnson & Johnson (Jan. 8, 2026) https://www.jnj.com/media-center/press-releases/johnson-johnson-reaches-agreement-with-u-s-government-to-improve-access-to-medicines-and-lower-costs-for-millions-of-americans-delivers-on-u-s-manufacturing-and-innovation-investments (last visited Jan. 22, 2026).

[198] The White House, "Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients," (Nov. 6, 2025) https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients/ (last visited Jan. 22, 2026); Annika Kim Constantino, "Trump announces deals with Eli Lilly, Novo Nordisk to slash weight loss drug prices, offer some Medicare coverage," *CNBC* (Nov. 6, 2025) https://www.cnbc.com/2025/11/06/trump-eli-lilly-novo-nordisk-deal-obesity-drug-prices.html (last visited Jan. 22, 2026).

[199] *See* consolidated appeals in *Trump v. V.O.S. Selections*, Doc. 25-250 / *Learning Resources, Inc. v. Trump* (Tariffs), 24-1287; Amy Howe, "Trump's tariffs to receive Supreme Court scrutiny," *SCOTUS.blog* (Oct. 30, 2025), https://www.scotusblog.com/2025/10/trumps-tariffs-face-supreme-court-scrutiny/ (last visited Jan. 22, 2026); Supreme Court of the United States, "Oral Argument – Audio: *Learning Resources, Inc. v. Trump, President of U.S.* (Date Argued Nov. 5, 2025) https://www.supremecourt.gov/oral_arguments/audio/2025/24-1287 (last visited Jan. 22, 2026).

several executive branch offices to promote innovation in Medicaid drug payment methodologies, link payments for drugs to the valued obtained, and to support states' efforts in managing their drug spending.[200]

In November 2025, the CMS Innovation Center announced it was ready to test a new payment model, called the GENEROUS Model, in which MDRP-participating drug manufacturers provide supplemental rebates to state Medicaid programs that result in MFN international pricing for manufacturers' covered outpatient drugs. As a volunteer-driven model, CMS asks drug manufacturers and interested states for help in testing the model over the course of a five-year trial period, which it intends to launch in January 2026. However, as part of the direct-to-consumer drug pricing deals between select drug manufacturers and the White House, those drug manufacturers will participate in the GENEROUS Model to ensure state Medicaid programs receive MFN prices on covered outpatient drugs.

The GENEROUS Model will reference manufacturer drug prices amongst the non-U.S. G7 countries (Canada, France, Germany, Italy, Japan, and the United Kingdom) plus Denmark and Switzerland. The GENEROUS Model calculates the most-favored-nation price for each covered outpatient drug by identifying the second lowest country-specific manufacturer-reported net price, after deducting rebates, discounts, and other price concessions. This raw net price will be adjusted by gross domestic product per capita using a purchasing power parity model, with the outcome yielding the Model's Guaranteed Net Unit Price (GNUP). The Model will plug the GNUP amount into a formula which produces the state supplemental rebate amount for a covered outpatient drug. States participating in the model would not be able to negotiate any further supplemental rebates for covered outpatient drugs for which the state is accessing the MFN.

For interested states, CMS says the GENEROUS Model may alleviate the trouble experienced by some states to pursue supplemental rebate agreements for high-cost brand name drugs where there may be few or no supplemental rebates available from drug manufacturers. This model may also facilitate savings to states due to greater rebates for Medicaid covered outpatient drugs and long-term reductions in health expenditures. [201]

Medicare Most-Favored-Nation Pricing Developments: The GLOBE Model and The GUARD Model

In April 2025, the White House formalized an intent to reduce the prices of high-cost drugs for seniors. To this end, the White House directed HHS to develop and implement a rulemaking plan and select for testing a payment model to improve the ability of Medicare program to obtain better value for high-cost prescription drugs and biological products covered by Medicare, including those not subject to the Medicare Drug Price Negotiation Program.[202]

In December 2025, the CMS Innovation Center noticed rulemaking proposals to link Medicare drug payments to international benchmarks for Part B and Part D drugs, an effort aimed at lowering costs and improving

[200] United States, Presidential Documents, "Executive Order 14273 of April 15, 2025: Lowering Drug Prices by Once Again Putting Americans First", Sec. 6, 90 Fed. Reg. 16441 (Apr. 15, 2025) https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf (last visited Jan. 22, 2026).

[201] Section 1115A allows CMS to test innovative healthcare payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program spending while maintaining or improving the quality of beneficiaries' care. Centers for Medicare and Medicaid Services, "GENEROUS Model (GENErating cost Reductions fOr U.S. Medicaid Model): Request for Applications from Applicable Manufacturers, Version 1.2" U.S. Department of Health and Human Services, (Last Modified Dec. 23,, 2025) https://www.cms.gov/files/document/generous-rfa.pdf (last visited Jan. 22, 2026).

[202] United States, Presidential Documents, "Executive Order 14273 of April 15, 2025: Lowering Drug Prices by Once Again Putting Americans First", Sec. 4, 90 Fed. Reg. 16441 (Apr. 15, 2025) https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf (last visited Jan. 22, 2026).

affordability for beneficiaries.[203] Both the GLOBE Model (for Part B)[204] and GUARD models (for Part D) [205] will reference manufacturer drug prices amongst OECD countries with a CIA-estimated real GDP per capita of at least 60% of U.S. real GDP per capita and a CIA-estimated annual real GDP of at least $400 billion (U.S. dollars). CMS says this criterion yields 19 reference countries: Australia, Austria, Belgium, Canada, Czechia, Denmark, France, Germany, Ireland, Israel, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.[206]

The GLOBE Model calculates MFN prices for a subset of Part B drugs and biological products without generic or biosimilar competition that cost Medicare Part B fee-for-service more than $100 million within a 12-month period and that are classified within select therapeutic categories, including oncology, rheumatology, immunology, ophthalmology, and endocrinology.[207]

The GUARD Model calculates MFN prices for a subset of Part D drugs and biological products without generic or biosimilar competition that costs Medicare Part D at least $69 million (adjusted annually for inflation) within a 12-month period, and that are classified within specific therapeutic classes, including analgesics, anticonvulsants, antidepressants, antimigraine agents, antineoplastics, antipsychotics, antivirals, bipolar agents, blood glucose regulators, cardiovascular agents, central nervous system agents, gastrointestinal agents, genetic or enzyme or protein disorder treatments, immunological agents, metabolic bone disease agents, ophthalmic agents, and respiratory tract/pulmonary agents.[208]

To calculate federal rebate amounts for each covered drug under both GLOBE and GUARD, CMS will first determine the international benchmark price of a drug,[209] and then incorporate that benchmark price into a separate formula. The GLOBE and GUARD rebate amount must not be less than the rebate amount determined under the existing Part B or Part D inflation rebate program,[210] respectively. CMS will calculate benchmark prices by referencing drug manufacturer-reported international drug pricing data pursuant to a voluntary data agreement or proprietary global pharmaceutical pricing data sources.[211]

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[203] Section 1115A allows CMS to test innovative healthcare payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program spending while maintaining or improving the quality of beneficiaries' care.

[204] The Global Benchmark for Efficient Drug Pricing (GLOBE) Model focuses on physician-administered drugs in a clinical inpatient setting, such as cancer therapies or drugs used to treat autoimmune conditions and arthritis. The GLOBE is a 5-year model running between October 1, 2026 through 2031, with rebate invoicing and reconciliation continuing through 2033. Centers for Medicare and Medicaid Services, "GLOBE (Global Benchmark for Efficient Drug Pricing) Model: Notice of Proposed Rulemaking" U.S. Department of Health and Human Services (Dec. 19, 2025) https://www.cms.gov/priorities/innovation/innovation-models/globe (last visited Jan. 22, 2026).

[205] The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model focuses on health practitioner-prescribed drugs in the outpatient setting. The GUARD is a 5-year model running between January 2027 through December 31, 2031, with rebate invoicing and reconciliation continuing through 2033. Centers for Medicare and Medicaid Services, "GUARD (Guarding U.S. Medicare Against Rising Drug Costs) Model: Notice of Proposed Rulemaking" U.S. Department of Health and Human Services (Dec. 19, 2025) https://www.cms.gov/priorities/innovation/innovation-models/guard (last visited Jan. 22, 2026).

[206] United States, Centers for Medicare & Medicaid Services, "Notice of Proposed Rulemaking: Global Benchmark for Efficient Drug Pricing (GLOBE) Model," 90 Fed. Reg. 60244 (Dec. 23, 2025) https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23702.pdf (last visited Jan. 22, 2026); United States, Centers for Medicare & Medicaid Services, "Notice of Proposed Rulemaking: Guarding U.S. Medicare Against Rising Drugs Costs (GUARD) Model," 90 Fed. Reg. 60338 (Dec. 23, 2025) https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23705.pdf (last visited Jan. 22, 2026).

[207] CMS found that the majority of Medicare Part B Fee-For-Service spending was concentrated on these select drugs for 2024, where the top 50 drug spending was $45 billion. GLOBE excludes Part B drugs for which a maximum fair price under the Medicare Drug Price Negotiation Program is in effect, which will not occur until plan year 2029.

[208] GUARD excludes drugs that are subject to a negotiated most-favored-nation price because of the Medicare Drug Price Negotiation Program.

[209] The benchmark price will be the greater of a price that 1) reflects GDP purchasing power parity (PPP) adjusted lowest country-level price among a set of reference countries at a baseline using existing data sources (called Method I) or 2) reflects volume-weighted average of the GDP PPP adjusted manufacturer's net pricing for sales amongst reference countries (called Method II).

[210] The Inflation Reduction Act of 2022 established the Medicare inflation rebate program, which requires drug manufacturers to pay a rebate to Medicare if they raise their price for certain drugs faster than the rate of inflation over a 12-month period. Inflation Reduction Act, P.L. 117-169 (Aug. 16, 2022), 136 Stat. 1818, Title I, Subtitle B, Part 2, Sec. 11101-11102. 42 U.S.C. §§ 1395w-3a, 1395w-114b.

[211] CMS will consider licensing IQVIA MIDAS, GlobalData Pharmaceutical Prices, and Eversana NAVLIN's Price & Access databases.

CMS estimates GLOBE may result in overall savings of $11.9 billion in Medicare Part B net spending[212] and GUARD may result in overall savings of $14.1 billion in Medicare Part D net spending.[213]

National Academy for State Health Policy Model

The National Academy for State Health Policy (NASHP) state-based international referencing pricing model (NASHP Model) regulates the in-state purchase of drugs by setting the maximum price at which a payer is willing to provide reimbursement. This approach may enable a state to create upper payment limits on the basis of an international reference price without limiting the price a manufacturer can charge for a product.[214]

The NASHP Model offers guidance on selecting the basket group of countries, the target drugs, enforcement remedies, and methods to share savings with beneficiaries:

- The basket group of countries should feature countries with comparable GDPs or similar economic conditions and countries with existing and accessible data sources containing price information.
- There are numerous options for selecting target drugs, including all drugs, the most costly drugs, the drugs of particular public interest, or the drugs whose prices exceed a specified amount for a particular time frame.
- Civil penalties could be enacted to enforce compliance, and noncompliance could also be deemed an unfair trade practice.
- The payers should pass along savings to beneficiaries through their premiums and copays.[215]

The NASHP Model anticipates a state's pursuit of a Medicaid waiver. The Social Security Act authorizes the HHS Secretary to waive Medicaid requirements when a state requests permission to conduct experimental, pilot, or demonstration projects, that in the judgment of the HHS Secretary, are likely to assist in promoting the objectives of the Medicaid program. A 1115 waiver could allow states to establish drug payments that vary from the federally-managed rebate system and any state supplemental rebate program.[216]

If the NASHP Model were applied to Medicaid, NASHP cautions states regarding the federal policy on the manufacturer's best price obligation: if one state's internationally benchmarked price is less than other states' Medicaid drug prices, the drug manufacturer must offer the internationally benchmarked price in every state where they do business with Medicaid. Under this policy, the federal rebate mechanism ensures Medicaid always gets the lowest price available for brand-name drugs. Generic drugs are not bound by the best price obligation. To avoid triggering the manufacturer's best price obligation in other states, the NASHP Model promotes a state supplement rebate agreement since state supplemental agreements are not subject to the best price obligation.[217]

For commercial insurers and consumer retail purchasers, NASHP addresses the point-of-sale transaction by targeting the insurer's payment rate for drugs. The NASHP Model empowers a purchaser or payer to decline reimbursement for the drug in question that exceeds the maximum benchmarked price – whether the purchase is from the manufacturer or the wholesaler – even for physician-administered drugs. The state may obligate private

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[212] United States, Centers for Medicare & Medicaid Services, "Notice of Proposed Rulemaking: Global Benchmark for Efficient Drug Pricing (GLOBE) Model," 90 Fed. Reg. 60244 (Dec. 23, 2025) https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23702.pdf (last visited Jan. 22, 2026).

[213] United States, Centers for Medicare & Medicaid Services, "Notice of Proposed Rulemaking: Guarding U.S. Medicare Against Rising Drugs Costs (GUARD) Model," 90 Fed. Reg. 60338 (Dec. 23, 2025) https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23705.pdf (last visited Jan. 22, 2026).

[214] Rachel Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, The National Academy for State Health Policy (Aug. 10, 2020) https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/ (last visited Jan. 22, 2026).

[215] *Id.*

[216] *Id.*

[217] *Id*. *See* 42 U.S.C. 1396r-8(b)(3)(A)(i)(II), (c)(1)(C)(i).

purchasers and payers to participate on behalf of the state's residents. For a risk-averse approach, the NASHP Model recommends an ERISA[218] plan opt-in provision to avoid federal preemption issues.[219]

The acquisition of relevant international pricing information is necessary for a payer or regulator to set the benchmark price.[220] While the NASHP Model suggests any reporting and disclosure requirements could be legally and administratively costly, a state could alternatively purchase a license to a commercial database[221] that records international sales and volume or use publicly available data from other countries.[222] These sources probably use drug manufacturer gross prices for drugs because net prices (that is, the prices ultimately paid for drugs after negotiated rebates and other discounts are applied) are not publicly available in most markets.[223] However, gross pricing data is an inflated measure for reference pricing because the gross price is the manufacturer's list price before rebates and other negotiated discounts. To overcome this issue, some researchers take the additional step of adjusting prices downward based on an approximation of these discounts.[224]

Furthermore, the NASHP cautions that some international pricing information is unavailable due to trade secret protections.[225]

Market-Based International Index Model

Across the world, market-based healthcare systems consist of a multi-payer system of universal health insurance financed jointly by employers and employees through payroll deductions. In contrast, single-payer systems of universal healthcare mean the government either unilaterally provides and finances healthcare as a service through taxes or runs a health insurance system financed by taxes and delegates day-to-day administration to private-sector providers.

The Market-Based International Index Model (MBII) is a reference pricing model proposed by the Foundation for Research on Equal Opportunity (FREOPP). The MBII Model benchmarks reimbursement rates according to a weighted, two-tier formula focused on thirteen market-based health care systems.

- Tier 1: The Netherlands, Singapore, Switzerland, and Denmark. Drug prices are weighted at 60% of the overall MBII benchmark because these four countries are among the most market-oriented health care systems in the industrialized world.
- Tier 2: Austria, Belgium, the Czech Republic, France, Germany, Ireland, Japan, Portugal, and Slovakia. Drug prices are weighted at 40% of the overall MBII benchmark because these nine countries have a mix of private and public health insurance like the United States.

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[218] The Employee Retirement Income Security Act (ERISA) is a comprehensive economic plan of federal regulation governing private employee benefit plans. ERISA preempts state law with an impermissible connection to or an impermissible reference to ERISA regulated plans. Bryan Adkins, Alexander Pepper, and Jay Sykes, *Federal Preemption: A Legal Primer*, Congressional Research Service, pp. 7-8 (updated May 18, 2023) https://crsreports.congress.gov/product/pdf/R/R45825 (last visited Jan. 22, 2026).

[219] The NASHP Model acknowledges that the regulated transaction could alternatively be the manufacturer-pharmacy point-of-sale or the wholesale distributor-pharmacy point of sale.

[220] Rachel Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, The National Academy for State Health Policy (Aug. 10, 2020) https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/ (last visited Jan. 22, 2026).

[221] RAND Corp. and the CMS Interim Rule utilized IQVIA's MIDAS commercial database. The Center for the Evaluation of Value and Risk in Health at Tufts Medical Center utilized EVERSANA's NAVLIN commercial database (formerly known as Pricentric ONE).

[222] E.g., the United Kingdom's National Health Service (NHS) Prescription Services produces the Drug Tariff on a monthly basis to show reimbursement amounts to pharmacy contractors. NHS Business Services Authority, *Drug Tariff*, https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff (last visited Jan. 22, 2026).

[223] Andrew Mulcahy, Daniel Schwam, and Susan Lovejoy, "International Prescription Drug Price Comparisons: Estimates Using 2022 Data," The RAND Corporation, pp. ix (Feb. 1, 2024) https://www.rand.org/pubs/research_reports/RRA788-3.html (last visited Jan. 22, 2026).

[224] *Id.*

[225] Rachel Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs*, The National Academy for State Health Policy (Aug. 10, 2020) https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/ (last visited Jan. 22, 2026).

- Exclusions: Jurisdictions with government-run health care systems and drug price controls with little to no role for private insurance or market-based pricing.

If the benchmark price exceeds consumer inflation, the MBII caps the growth of prices at the ratio of inflation. The MBII Model authors suggest it accounts for costly, artificial market dynamics in the United States such as off-patent biologic drug pricing and biologic drugs regulatory exclusivities. The MBII Model acknowledges the necessity of standardized pricing data. In addition, the authors of MBII suggest further refinement by weighing the MBII benchmark by national prescription volume or equally weighing countries.[226]

RECENT LEGISLATION:

YEAR	BILL #/SUBJECT	HOU.S.E/*SENATE* SPONSOR(S)	OTHER INFORMATION
2025	HB 5015 - State Group Insurance	Lopez, V.	The Governor vetoed the bill on June 30, 2025.
2023	CS/CS/SB 1550 - Prescription Drugs	Chaney/ *Brodeur*	Became law July 1, 2023.

OTHER RESOURCES:

Central Intelligence Agency: The World Factbook (Field Listing – Real GDP per capita)
Florida House of Representatives: Speaker's Office Press Release – Florida House Unveils Florida's New Frontier in Healthcare (12/09/2025)
Presidential Documents: Executive Order 14297 of May 12, 2025 – Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients

BILL HISTORY

COMMITTEE REFERENCE	ACTION	DATE	STAFF DIRECTOR/ POLICY CHIEF	ANALYSIS PREPARED BY
Health Care Facilities & Systems Subcommittee	15 Y, 1 N	1/21/2026	Lloyd	DesRochers
Budget Committee	27 Y, 2 N	1/27/2026	Pridgeon	Smith
Health & Human Services Committee				

[226] Avik Roy, "What Medicare Can Learn From Other Countries on Drug Pricing: Market-based policies from countries like Denmark and Singapore can make medicines more affordable in the U.S.," *The Foundation for Research on Equal Opportunity*, (Jan. 11, 2019) https://freopp.org/whitepapers/what-medicare-can-learn-from-other-countries-on-drug-pricing/ (last visited Jan. 22, 2026).