HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1431 International Drug Reference Pricing
SPONSOR(S): Fine and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 1750

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Health Innovation	13 Y, 2 N	DesRochers	Calamas
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 2021, retail prescription drugs accounted for 8.9% of U.S. health spending. Over the last six decades, the United States recorded an exponential increase in prescription drug spending per capita, adjusted for inflation. Drug spending per capita increase from $101 in 1960 to $1,147 in 2021. Increased drug spending per capita is attributable in large part to the high cost of drugs in the United States.

The most recent comprehensive study comparing U.S. drug prices to similarly situated countries in the Organisation for Economic Co-operation and Development reveals that U.S. drug prices were in the aggregate 256% more than drug prices in other OECD countries. U.S. prices for brand-name originator drugs were 344% of prices in other OECD countries. High prescription drug costs contribute to poor medication adherence which leads to adverse downstream effects on health care spending and health outcomes.

International reference pricing refers to the practice of using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark, or reference price, that informs price setting or price negotiation of the product in the home jurisdiction. In other words, reference pricing sets an upper payment limit for purchasers. Reference pricing is a cost-containment policy strategy to ensure the maximum price paid for a drug is not excessive priced relative to its price in other countries.

HB 1431 requires the Agency for Health Care Administration (AHCA) to establish an upper payment limit for prescription drug coverage based on an international reference for each prescribed drug. The upper payment limit applies to Medicaid, the State Group Insurance Program, health maintenance organizations, authorized insurers offering health insurance, and a pharmacy's prescription drug transactions with cash-paying patients.

The bill creates a reporting requirement for drug manufacturers. Starting October 1, 2025, the bill requires drug manufacturers permitted by Department of Business and Professional Regulation to annually provide AHCA international prescription drug pricing data.

The bill requires the Office of Insurance Regulation and AHCA to submit a joint report every year detailing the impact of international drug reference pricing. The first annual report is due January 1, 2026.

The bill obligates health insurers to reduce beneficiary premiums and co-pays to reflect savings generated by applying the drug reference price to the reimbursement rate. The bill requires health insurers to document beneficiaries' anticipated savings and premium reductions in rate filings.

The bill has a significant negative fiscal impact on AHCA and no fiscal impact on local government.

The bill provides an effective date of July 1, 2024.

FULL ANALYSIS

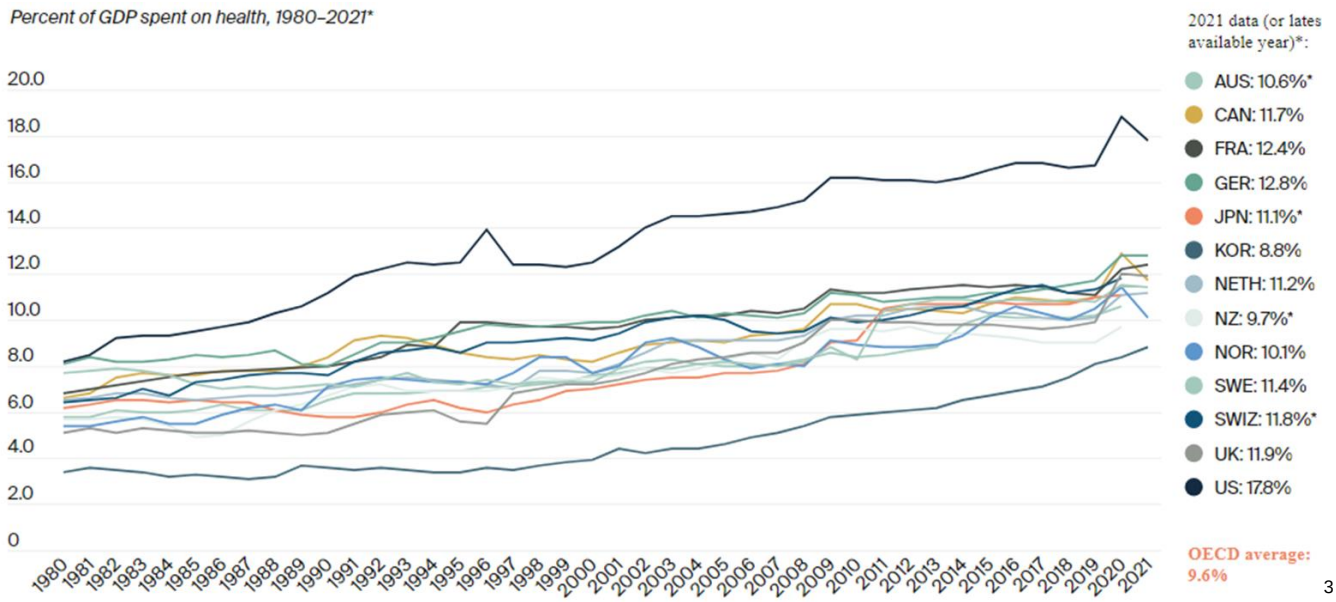
I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Spending in the United States

In 2021, the United States spent 17.8% of gross domestic product (GDP) on health care, nearly twice as much as the average country in the Organisation for Economic Co-operation and Development ("OECD")[1] which is 9.6%.[2]



[3]

Total health spending in the United States for 2021 reached $4.3 trillion.[4] Despite enormous health care spending, health outcomes in the United States are poor compared to other similarly situated countries in the international community.[5] Regrettably, the United States has the lowest life expectancy at birth, the highest death rates for avoidable or treatable conditions, the highest maternal and infant mortality, and among the highest suicide rates.[6]

The COVID-19 pandemic, recent broad-based inflation trends in the economy, and health sector employment trends complicate future spending projections.[7] However, as health care utilization returns to pre-pandemic levels, the average annual health care spending per person projection signals an

[1] OECD. https://www.oecd.org/about/members-and-partners/ (last visited Dec. 11, 2023). 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.

[2] Munira Z. Gunja, Evan D. Gumas, Reginald D. William II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, The Commonwealth Fund (Jan. 31, 2023) https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 (last visited Dec. 5, 2023).

[3] OECD Health Statistics 2022 uses 2020 data. The chart reflects current expenditures on health for all functions by all providers for all financing schemes. Data points reflect share of GDP. OECD average reflects the average of 38 OECD member countries, including ones not shown here.

[4] Imani Telesford, Shameek Rakshit, Matthew McGough, Emma Wager, and Krutika Amin, *How has U.S. spending on healthcare changed over time?* Peterson-KFF Health System Tracker (Feb. 7, 2023) https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/ (last visited Dec. 8, 2023).

[5] *Id.*

[6] *Id.*

[7] Matthew McGough, Meghan Salaga, Cynthia Cox, and Krutika Amin, *How much is health spending expected to grow?* Peterson-KFF Health System Tracker (Oct. 11, 2023) https://www.healthsystemtracker.org/chart-collection/how-much-is-health-spending-expected-to-grow/ (last visited Dec. 5, 2023).

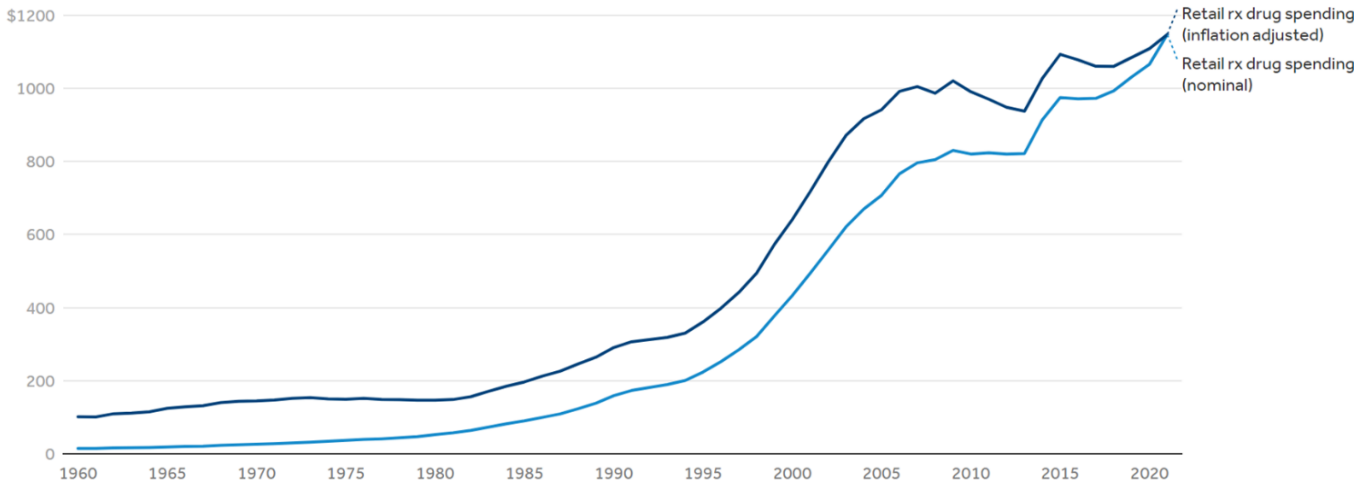
increase from 3.9% per capita during 2014 to 2019 to 4.8% per capita from 2022 to 2031.[8] Already, the average amount spent on health per person in the United states was $12,914 in 2021 – which dramatically exceeds both the OECD average ($6,125 per person) and the next closest OECD country, Germany ($7,383 per person).[9] For 2023 and beyond, health care spending may outpace overall economic growth and eventually hit 19.6% GDP by 2031.[10]

Pharmaceutical Spending

U.S. Pharmaceutical Spending

In 2021, retail prescription drugs accounted for 8.9% of U.S. health spending.[11] Over the last six decades, the United States recorded an exponential increase in prescription drug spending per capita, adjusted for inflation.[12] As the graph below indicates, prescription drug spending per capita increased from $101 in 1960 to $1,147 in 2021.[13]

Nominal and inflation-adjusted per capita spending on retail prescription drugs, 1960-2021



Some pinpoint the 1990s as the era when the relationship between high drug spending per capita and high 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,[14] and the FDA's pivot to a user-fee model to expedite new drug approvals.[15] In addition, Medicare, Medicaid, and the Children's Health Insurance Program expanded coverage to prescription drugs.[16]

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[8] *Id*.
[9] Matthew McGough, Imani Telesford, Shameek Rakshit, Emma Wager, Krutika Amin, and Cynthia Cox, *How does health spending in the U.S. compare to other countries?* Peterson-KFF Health System Tracker (Feb. 9, 2023) https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/ (last visited Dec. 8, 2023).
[10] *Supra*, FN 7.
[11] Emma Wager, Imani Telesford, Cynthia Cox, and Krutika Amin, *What are the recent and forecasted trends in prescription drug spending?* Peterson-KFF Health System Tracker (Sept. 15, 2023) https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/ (last visited Dec. 5, 2023).
[12] *Supra*, FN 7.
[13] *Supra*, FN 11.
[14] Drug manufacturers advertise to encourage consumers to ask their doctors for specific medications. Aaron S. Kesselheim, *High Drug Prices in the US: What We Can Learn from Other Countries (and Some US States)*, Testimony to the United States Senate Committee on Health, Education, Labor, and Pensions (Mar. 23, 2021) https://www.help.senate.gov/imo/media/doc/Kesselheim1.pdf (last visited Jan. 15, 2024). Aaron Kesselheim is 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.
[15] 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. 15, 2024). C. Michael White is the Department Head & Distinguished Profession of Pharmacy Practice at the University of Connecticut School of Pharmacy.
[16] 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. 15, 2024). Austin Frakt is a Senior Research Scientist in the Department of Health Policy and Management at Harvard T.H. Chan School of Public Health.

While a critical mass of prescription drug patents expired[17] throughout the mid-2000s, temporarily scaling back per capita spending, new biologic drugs directed 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.[18]

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

- Pharmaceutical market consolidation;[19]
- Until recently, Medicare did not negotiate drugs prices.[20]
- New medicine launches at record-high prices;[21]
- Increases in unit cost or dosage cost;[22]
- Delayed introduction of cheaper generic alternatives because drug manufacturers found ways to extend regulatory exclusivities;[23]
- Pharmacy benefit managers[24] and other intermediaries between drug manufacturers and consumers, [25]
- Lack of price transparency.[26]

U.S. Pharmaceutical Spending Compared to Other Countries

For all drugs, U.S. prices were 256% of prices in other OECD countries. U.S. prices for brand-name originator drugs were 344% of prices in other OECD countries. With the exception of unbranded generics, the magnitude of the difference between prices in the United States and those in other OECD countries was substantial. The bar graph below compares U.S. prices with OECD member countries. [27]

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[17] 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 Dec. 11, 2023).

[18] *Supra*, FN 15; Steven Schwartz, Millie Mo, Jinesh John, Ryan Chandanais, and Stephanie LaPointe, *Precision Medicine and the Pharmacist's Role as a Trusted Counselor in Specialty Pharmacy*, Pharmacy Times (May 19, 2020) https://www.pharmacytimes.com/view/precision-medicine-and-the-pharmacists-role-as-a-trusted-counselor-in-specialty-pharmacy (Jan. 15, 2024).

[19] *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. 15, 2024).

[20] 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. 15, 2024); 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. 15, 2024).

[21] Deena Beasley, *Focus: Newly launched U.S. drugs head toward record-high prices in 2022*, Reuters (Aug. 16, 2022) https://www.reuters.com/business/healthcare-pharmaceuticals/newly-launched-us-drugs-head-toward-record-high-prices-2022-2022-08-15/ (last visited Dec. 11, 2023).

[22] American Academy of Actuaries, *Prescription Drug Spending in the U.S. Health Care System*, Issue Brief (Mar. 2018), available at: http://www.actuary.org/files/publications/PrescriptionDrugs.030718.pdf (last visited Dec. 11, 2023).

[23] *Id*. 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.

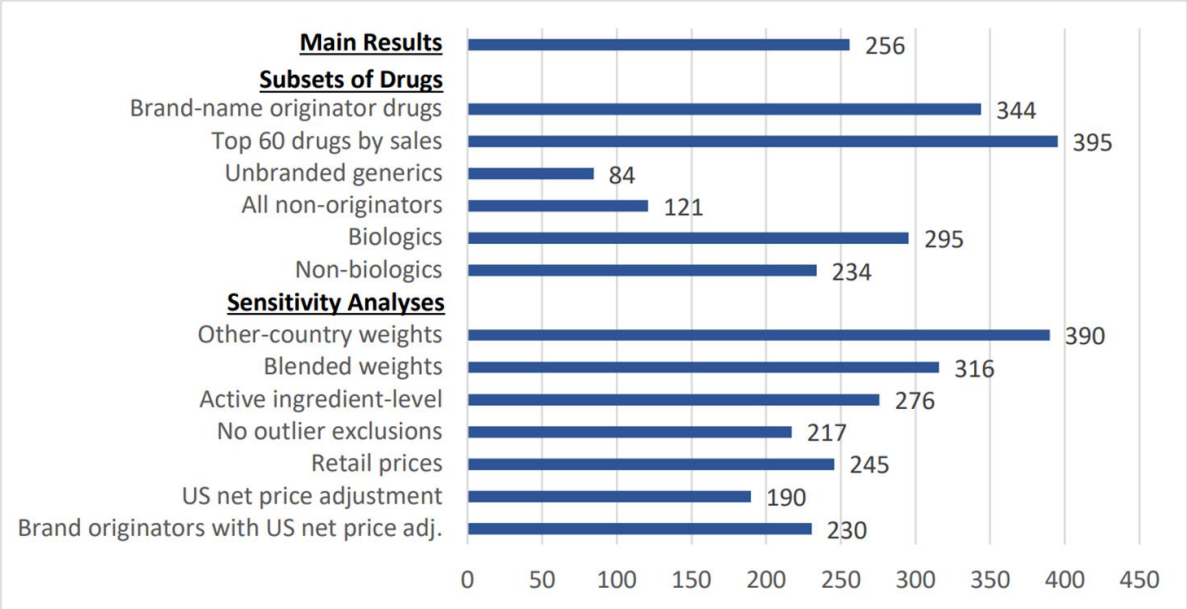
[24] The Commonwealth Fund, *Pharmacy Benefit Managers and Their Role in Drug Spending*, (April 22, 2019) available at https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf (last visited Aug. 14, 2023). Pharmacy benefit managers are intermediary companies that manage prescription 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).

[25] *Id*.

[26] *Id*.

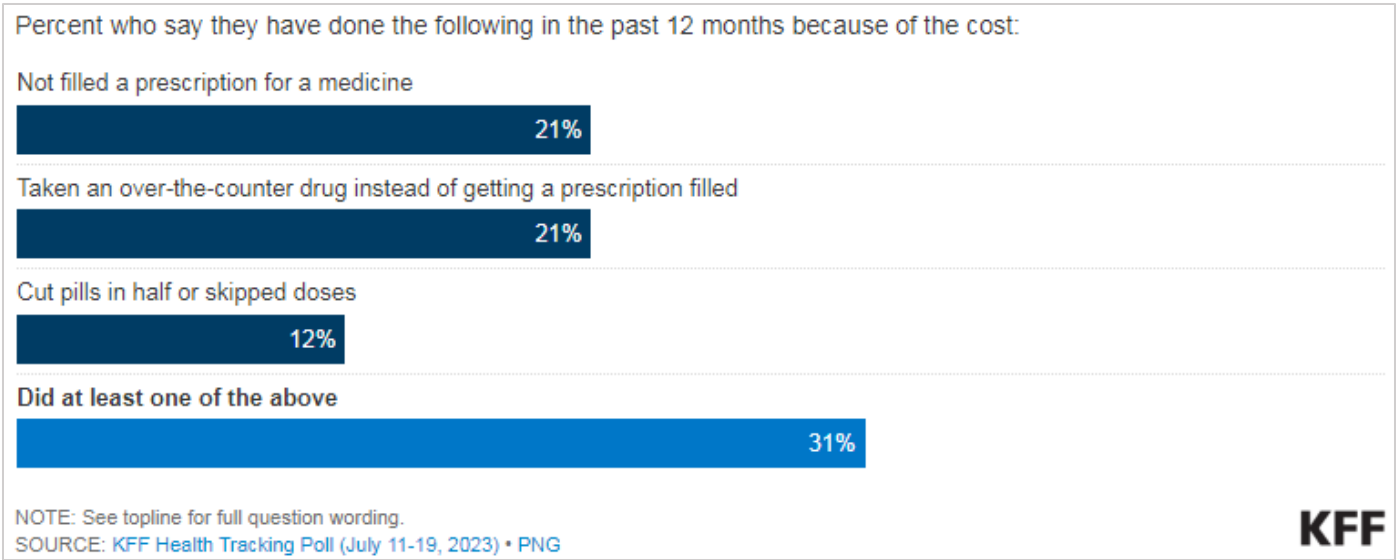
[27] Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, Alejandro U. Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corp. p. xiv (2021), https://www.rand.org/pubs/research_reports/RR2956.html (last visited Dec. 18, 2023). Authors analyzed IQVIA MIDAS

U.S. Drug Prices as a Percentage of Drug Prices in OECD Countries



Nonadherence

High prescription drug costs contribute to poor medication adherence which leads to adverse downstream effects on health care spending and health outcomes.[28] According to 2023 polling, six in ten adults say they currently take at least one prescription drug and a quarter say they currently take four or more prescription medications.[29] As shown by the graph below, about three in ten of the adults surveyed report not taking their medicines as prescribed at some point in the past year because of cost.[30]



sales and volume data for calendar year 2018. Comparison countries were the 32 OECD member countries at the time of the study. Authors compared the top 60 drugs by U.S. Sales at the active ingredient level.

[28] 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 Dec. 7, 2023).

[29] Ashley Kirzinger, Alez Montero, Grace Sparks, Isabelle Valdes, and Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices: Methodology*, KFF, (Aug. 21, 2023) https://www.kff.org/report-section/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs-methodology/ (last visited Dec. 5, 2023). Methodology: July 11-19, 2023, online and telephone survey among a nationally representative sample of 1,327 U.S. adults. Margin of sam pling error within the accepted ± 3 percentage points.

[30] *Id.*

The economic, clinical, and ethical consequences of medication non-adherence will continue to grow as the burden of chronic diseases intensifies.[31] Improving medication adherence provides an opportunity for major cost savings to healthcare systems.[32]

Pharmaceutical Regulation

The United States Food and Drug Administration

The United States Congress established the United States Food and Drug Administration (FDA) within the United States Department of Health and Human Services (HHS).[33] In part, FDA protects the public health by ensuring regulated drug products are safe and effective for human use.[34] Congress charges FDA to participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.[35]

Federal law classifies FDA regulated products as drugs,[36] biological products,[37,38] devices, or combination products.[39]

The FDA regulates the pharmaceutical distribution supply chain. The federal Food, Drug, and Cosmetic Act (FD&C Act) prohibits the introduction, delivery, and receipt of any drug in interstate commerce that is adulterated, misbranded, or unapproved by FDA.[40] The FD&C Act subjects the manufacturer, repackager, wholesale distributor, and dispenser to regulations according to their statutorily-defined roles in a transaction involving product.[41]

Patents

The United States Constitution gives Congress the power to enact laws relating to intellectual property.[42] Two forms of intellectual property (IP) rights incentivize the development of, and affect the pricing of, prescription drugs and biologics.[43] First, the United States Patent and Trademark Office may grant patents to drug manufacturers, which give the exclusive right to make and sell their novel pharmaceutical invention.[44] Second, for the term of the drug manufacturer's patent, the Food and Drug Administration (FDA) may grant regulatory exclusivities for innovative pharmaceuticals or

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[31] Rachelle Louise Cutler, Fernando Fernandez-Llimos, Michael Frommer, Charlie Benrimoj, and Victoria Garcia-Cardenas, *Economic impact of medication non-adherence by disease groups: a systematic review*, PubMed Central, National Library of Medicine (Jan. 21, 2018) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780689/ (last visited Dec. 7, 2023).
[32] *Id*.
[33] 21 U.S.C. § 393(a).
[34] 21 U.S.C. § 393(b)(2)(B).
[35] 21 U.S.C. § 393(3).
[36] The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines "drug" as articles recognized in the official United States Pharmacopeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans (or animals); articles (other than food) intended to affect the structure or any function of the human body (or animal body); and articles intended for use as a component in such articles. 21 U.S.C. § 321(g)(1).
[37] The Public Health Service Act (PHSA) defines "biological product" as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(i)(1).
[38] FDCA law applies to a biological product regulated by PHSA. 42 U.S.C. § 262(j).
[39] 21 U.S.C. § 360bbb-2(a).
[40] 21 U.S.C. § 331(a),(c); 21 U.S.C. § 355(a).
[41] 21 U.S.C. § 360eee(3), (10), (16), (29); 21 U.S.C. § 360eee-1(a)(1)-(2).
[42] "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.
[43] 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 Dec. 20, 2023).
[44] *Id*. Patents are issued by the United States Patent and Trademark Office. A patent's term is generally 20 years.

pharmaceuticals serving particular needs.[45] Regulatory exclusivities mean the FDA will not approve applications for a generic or biosimilar form of the drug.[46]

The FD&C Act requires drug manufacturers to secure approval for their new drug before it can lawfully go to market.[47] When a drug manufacturer files a new drug application with the FDA, the FDA wants proof of the drug manufacturer's patent.[48] A drug manufacturer must list, as part of its NDA, any patent that claims the drug that is the subject of the application, or a method of using that drug.[49]

Once the drug manufacturer's patent term and regulatory exclusivities expire, other manufacturers may enter the market with generics or biosimilar products.[50] If the market functions properly, this new participation will bring down the formerly elevated price of the patented product to competitive levels.[51]

In 2007, the U.S. Court of Appeals for the Federal Circuit[52] acknowledged "[t]hese two objectives – to reward innovators with higher profits and to keep prices reasonable for consumers – are in dialectic tension."[53] The Court observed "[t]here is no express provision in the patent statute that prohibits states from regulating the price of patented goods."[54] 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."[55]

Florida Department of Business and Professional Regulation

The Florida Department of Business and Professional Regulation (DBPR)'s Division of Drugs, Devices, and Cosmetics regulates prescription drug manufacturers under the Florida Drug and Cosmetic Act.[56] The Florida Drug and Cosmetic Act safeguards the public health and promotes the public welfare by protecting the public from injury by product use and merchandising deceit involving drugs, devices, and cosmetics.[57] The Florida Drug and Cosmetic Act conforms with FDA drug laws and regulations.[58]

In Florida, 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.[59] Before operating in Florida, drug manufacturers must first obtain a permit issued by DBPR[60] and comply with statutory and regulatory requirements.[61] A prohibited act under the Florida Drug and Cosmetic Act includes the failure to obtain a permit or registration or operating without a valid permit.[62] DBPR rules classify the failure to obtain proper permitting as a level two Administrative Complaint with a fine ranging from $1,000 to $3,000 per

[45] Erin Ward, Kevin Hickey, and Kevin Richards, *Drug Prices: The Role of Patents and Regulatory Exclusivities*, Congressional Research Service (Feb. 10, 2021) https://crsreports.congress.gov/product/pdf/R/R46679 (last visited Dec. 20., 2023)
[46] *Id*. Regulatory exclusivities vary in length from six months to 12 years, depending on the basis for exclusivity.
[47] 21 U.S.C. § 355(a).
[48] 21 U.S.C. § 355(b)(1).
[49] *Id*.
[50] *Biotechnology Industry Organization v. District of Columbia,* 496 F.3d 1369, 1373 (Fed. Cir. 2007).
[51] *Id*.
[52] 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).
[53] *Biotechnology Industry Organization*, 496 Fed. at 1373.
[54] *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).
[55] *Id*., citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).
[56] S. 499.05(1), F.S.
[57] S. 499.002(1)(a), F.S.
[58] S. 499.002(1)(b), F.S.
[59] S. 499.003(29), F.S. 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.
[60] S. 499.01(1), F.S.
[61] Rule 61n-1.015, F.A.C.
[62] S. 499.005(22), F.S.

violation, and up to permanent suspension or revocation of permits.[63] A knowing failure to obtain a permit or registration or operating without a valid permit is a second degree felony.[64]

Prescription Drug Manufacturer Permit

Drugs manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.[65] A prescription drug manufacturer who manufacturers or distributes prescription drugs in Florida must obtain a prescription drug manufacturer permit from DBPR. 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.[66] The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.[67]

Nonresident Prescription Drug Manufacturer Permit

A prescription drug manufacturer located outside of Florida who distributes prescription drugs in Florida must obtain a nonresident prescription drug manufacturer permit from DBPR.[68] The permitted manufacturer must comply with all of the same requirements as prescription drug manufacturers operating in Florida.[69] They must simultaneously comply with the licensing and permitting requirement of their home jurisdiction. If the nonresident manufacturer intends to distribute prescription drugs for which it is not the original manufacturer, an out-of-state prescription drug wholesale distributor permit is required. If a nonresident prescription drug manufacturer intends to import prescription drugs from a foreign county into Florida, they must provide DBPR a list identifying each prescription drug it intends to import. If a nonresident prescription drug manufacturer imports their product into Florida, they must also document FDA approval for importation.[70]

The table below reflects the number of active drug manufacturer permits issued by DBPR.[71]

Permit Type	Active Permits (as of Nov. 30, 2023)
Resident Prescription Drug Manufacturer	99
Nonresident Prescription Drug Manufacturer	755

Drug Manufacturer's Reportable Drug Price Increases

In 2023, Florida established a new reporting requirement for all prescription drug manufacturer and nonresident prescription drug manufacturer permitholders.[72] Specifically, permitholders must notify DBPR of a drug price increase on the date the increase becomes effective. [73] The reporting requirement 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

[63] Rule 61n-1.024(5), F.A.C. DBPR has broad authority to deny, suspend, or revoke a permit or registration for a violation of state or federal law under s. 499.067, F.S.
[64] SS. 499.0051(3), 499.01(4)(g), F.S.
[65] S. 499.003(28), F.S.
[66] S. 499.01(2)(a), F.S.
[67] S. 499.003(16), F.S.
[68] S. 499.01(2)(c), F.S.
[69] *Id*.
[70] S. 499.01(2)(c), F.S.
[71] Email from Department of Business and Professional Regulation on file with the Florida House Health and Human Services Committee (Dec. 28, 2023).
[72] Ch. 23-29, Laws of Fla.
[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.

WAC in the previous three calendar years. 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.[75]

Since the law's effective date of July 1, 2023, DBPR has received price increase reports from several drug manufacturers.[76] 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.[77] The first annual reports are due April 1, 2024.

Florida Agency for Health Care Administration

The Florida 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.[78]

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. AHCA administers the Florida Medicaid program, which is governed by both the federal and state governments and financed by both federal and state funds.

Florida uses a comprehensive managed care delivery model for primary and acute care services for the vast majority of Medicaid enrollees, the Statewide Medicaid Managed Care (SMMC) program.[79] The SMMC program provides acute health care services through managed care plans contracted with AHCA in the 11 regions across the state. Specialty plans are also available to serve distinct populations, such as the Children's Medical Services Network for children with special health care needs, or those in the child welfare system. Medicaid recipients with HIV/AIDS, serious mental illness, dual enrollment with Medicare, chronic obstructive pulmonary disease, congestive heart failure, or cardiovascular disease may also select from specialized plans.

Under federal Medicaid law, prescription drug coverage is an optional benefit states may choose to cover; Florida Medicaid covers prescription drugs.[80]

In addition to federally negotiated rebates, Florida Medicaid also negotiates for state-only manufacturer rebates, as 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.[81]

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.

[75] S. 499.026(1), F.S.
[76] Email from Department of Business and Professional Regulation on file with the Florida House Health and Human Services Committee (Dec. 28, 2023).
[77] S. 499.026(3), F.S.
[78] Office of Program Policy Analysis and Government Accountability, *Agency for Health Care Administration*, https://oppaga.fl.gov/ProgramSummary/ProgramDetail?programNumber=5048 (last visited Jan. 17, 2024).
[79] S. 409.964, F.S.
[80] S. 409.973(1)(x), F.S.
[81] 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%.

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.[82]

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.[83]

Florida Canadian Prescription Drug Importation Program

The FD&C Act requires the HHS Secretary to regulate pharmacists and wholesalers who import prescription drugs from Canada into the United States.[84] With this regulatory power, HHS allows a state to sponsor a Section 804 Importation Program (SIP) [85] if the state regulates wholesale drug distribution and the practice of pharmacy and submits a proposal to FDA that describes a program to facilitate and supervise prescription drug imports from Canada.[86] FDA reviews SIP proposals and decides whether to approve or deny.[87]

Unless the FDA grants a state an exemption, SIP authorization to import prescription drugs from Canada automatically terminates after two years.[88] FDA may extend an authorization period for up to two years at a time.[89]

In 2019, Florida established the Canadian Prescription Drug Importation Program within AHCA to create a process by which certain state-funded entities may import safe and effective prescription drugs from eligible Canadian suppliers at lower cost to the state.[90] In November 2020, AHCA officially submitted its Section 804 Importation Proposal to FDA for Florida's Canadian Prescription Drug Importation Program.[91] Florida sued FDA in August 2022 because FDA had yet to render a decision on the proposal.[92]

In January 2024, FDA authorized Florida's Drug Importation Program for a two-year period – beginning on the date FDA receives notification that the first imported shipment of drugs. Before Florida imports prescription drugs from Canada, AHCA must fulfill three obligations:

1. Submit additional drug-specific information for the FDA's review and approval,
2. Ensure that the drugs Florida seeks to import have been test for, among other things, authenticity and compliance with the FDA-approved drugs' specifications and standards, and
3. Relabel the drugs to be consistent with FDA-approved labeling.

In addition, AHCA must submit a quarterly report to the FDA that includes information about the imported drugs, costs savings, and any potential safety and quality issues.[93]

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[82] Ss. 409.912; 409.912(5)(a); 409.91195; 409.91196, F.S.
[83] *Id*.
[84] 21 U.S.C. § 804(b)
[85] Under the federal Food Drug & Cosmetic Act, the section 804 importation program (SIP) allows proposals from states or Native American tribes to import certain prescription drugs from Canada. FDA may authorize a SIP that will significantly reduce costs without imposing additional risk to public health and safety. U.S. Food & Drug Administration, *FDA News Release: FDA Authorizes Florida's Drug Importation Program*, U.S. Department of Health and Human Services (Jan. 5, 2024) https://www.fda.gov/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program (last visited Jan. 17, 2024).
[86] 21 C.F.R. § 251.2
[87] 21 C.F.R. § 251.4
[88] 21 C.F.R. § 251.6
[89] 21 C.F.R. § 251.8
[90] Ch. 19-99, Laws of Fla.
[91] The Executive Office of the Governor, *News Release: Governor Ron DeSantis Announces Florida's Submittal of Drug Importation Proposal to Federal Government*, State of Florida (Nov. 23, 2020) https://www.flgov.com/2020/11/23/governor-ron-desantis-announces-floridas-submittal-of-drug-importation-proposal-to-federal-government/ (last visited Jan. 17, 2024).
[92] Anthony Izaguirre, *Florida sues FDA over 'delay' of low-cost drug importations*, AP News (Aug. 31, 2022) https://apnews.com/article/health-lawsuits-florida-ron-desantis-57be1dbd66aae00b1912db8319352b01 (last visited Jan. 17, 2024).
[93] U.S. Food & Drug Administration, *FDA News Release: FDA Authorizes Florida's Drug Importation Program*, U.S. Department of Health and Human Services (Jan. 5, 2024) https://www.fda.gov/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program (last visited Jan. 17, 2024).

The Government of Canada issued a statement in response to the FDA's decision. According to Health Canada, Canada's Food and Drugs Act prohibits certain drugs intended for the Canadian market from being sold for consumption outside of Canada if that sale could cause, or worsen, a drug shortage in Canada. This includes all drugs that are eligible for bulk importation into the United States.[94]

AHCA is still in the process of implementing this program.

Trade Secret Information

Florida Uniform Trade Secrets Act

The Florida Uniform Trade Secrets Act (FUTSA) 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. Protected information includes a proprietor's formula, pattern, compilation, program, device, method, technique, or process.[95]

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.[96] A proprietor combats actual or threatened trade secret misappropriation with an action in court for injunctive relief and damages.[97]

Florida Public Records Requirements

Article I, s. 24(a) of the Florida Constitution sets forth the state's public policy regarding access to government records. This section guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government. The Legislature, however, may provide by general law for the exemption of records from the requirements of art. I, s. 24(a) of the Florida Constitution.[98] The general law must state with specificity the public necessity justifying the exemption[99] and must be no broader than necessary to accomplish its purpose.[100]

Public policy regarding access to government records is addressed further in s. 119.07(1), F.S., which guarantees every person a right to inspect and copy any state, county, or municipal record, unless the record is exempt. Furthermore, the Open Government Sunset Review Act[101] provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. An identifiable public purpose is served if the exemption meets one of the following purposes:[102]

- Allow the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protect sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protect trade or business secrets.

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[94] Health Canada, *Statement from Health Canada on FDA decision on Florida bulk drug importation plan*, Government of Canada (Jan. 8, 2024) https://www.canada.ca/en/health-canada/news/2024/01/statement-from-health-canada-on-fda-decision-on-florida-bulk-drug-importation-plan.html (last visited Jan. 17, 2024).
[95] S. 688.002(4), F.S.
[96] S. 688.002(2), F.S.
[97] Ss. 688.003, 688.004, F.S.
[98] Article I, s. 24(c), Fla. Const.
[99] This portion of a public record exemption is commonly referred to as a "public necessity statement."
[100] Article I, s. 24.(c), FLA. CONST.
[101] Section 119.15, F.S.
[102] Section 119.15(6)(b), F.S.

Section 119.0715 specifically addresses trade secret information held by a state agency. Using the same definition of "trade secret" as found in chapter 688, this section makes trade secrets held by a state agency confidential and exempt from constitutional and statutory public records access requirements. Specifically, the information is exempt from public disclosure requirements, but since the information is also confidential, the agency is prohibited from sharing the information even if it chose to waive the exemption. State agencies are allowed to share trade secret information with other agencies, if within the scope of the other agency's official duties.

A state agency's contractor is also obligated to comply with constitutional and statutory public records requirements, including the requirement to maintain the confidentiality of records made confidential by law, such as trade secret material.[103]

Current law treats Medicaid program federal and state supplemental rebate amounts and percentages, and manufacturer prices, as confidential and exempt from the public disclosure requirements of the Florida Constitution and Ch. 119, F.S. This trade secret protection extends to the portions of AHCA's P&T Committee meetings during which supplemental rebate information is discussed.[104]

Health Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of health insurers and health maintenance organizations (HMOs) under the Florida Insurance Code (Code), Chapters 624, 627 and 641, F.S. The AHCA regulates the quality of care by HMOs under part III of ch. 641, F.S.

All persons who transact insurance in this state must comply with the Code.[105] The OIR has the authority to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[106] and may investigate any matter relating to insurance.[107]

Health Maintenance Organizations

A health maintenance organization (HMO) is any organization authorized under the Florida Insurance Code which:

- Provides, through arrangements with other persons, emergency care, inpatient hospital services, physician care, ambulatory diagnostic treatment, and preventative health care services.
- Provides, either directly or through arrangements with other persons, health care services to persons enrolled with such organization, on a prepaid per capita or prepaid aggregate fixed-sum basis.
- Provides, either directly or through arrangements with other persons, comprehensive health care services which subscribers are entitled to receive pursuant to a contract.
- Provides physician services, by physicians licensed under chs. 458, 459, 460, and 461, F.S., directly through physicians who are either employees or partners of such organization or under arrangements with a physician or any group of physicians.
- If offering services through a managed care system, has a system in which a primary physician licensed under chs. 458, 459, 460, or 461, F.S., is designated for each subscriber upon request of a subscriber requesting service by a physician licensed under any of those chapters and is responsible for coordinating the health care of the subscriber of the respectively requested service and for referring the subscriber to other providers of the same discipline when necessary.[108]

[103] Section 119.0701, F.S.
[104] S. 409.91196, F.S.
[105] S. 624.11, F.S.
[106] S. 624.307(4), F.S.
[107] S. 624.307(3), F.S.
[108] S. 641.19(12), F.S.

An HMO must apply for and obtain a certificate of authority to operate in Florida.[109] Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[110] As part of the certificate process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[111] Once an HMO is issued a certificate, the HMO may enter into contracts in Florida to provide an agreed-upon set of comprehensive health care services, including drugs, to subscribers in exchange for a prepaid per capita sum or a prepaid aggregate fixed sum.[112]

Health Insurers

OIR reports that the individual health insurance market in Florida covers about two million people, and another 1.8 million receive coverage through the group health insurance market. Total premiums for the major medical market exceeded $23.5 billion in 2020 with approximately $12.5 billion in the individual market and $11.0 billion in the group market.[113]

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 2020, FHIAB reports that health insurance coverage by market segment consisted of:

- Individual Coverage – 1,962,686, an increase of 196,879 covered lives or 11.15%.
- Small Group (1-50 members) – 436,241, a decrease of 40,949 covered lives or 8.58%.
- Large Group (51+ members) – 1,408,647, a decrease of 83,036 covered lives or 5.57%.
- Total Market – 3,807,574, an increase of 72,894 covered lives or 1.95%.[114]

The declining trends in group enrollment have generally slowed down since the advent of the Affordable Care Act but were higher in 2020 possibly due to COVID-19 and its effects on employment. Other contributing factors may be that carriers have been active in developing products that help employers reduce costs by self-insuring. In addition, some small employers have chosen to stop offering coverage for their employees and their dependents as their employees can often pay less by purchasing a policy through the federal marketplace if those employees qualify for a subsidy.[115]

State Group Insurance Program

The State 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).[116] DMS contracts with Optum Rx, a pharmacy benefit manager, to administer the Prescription Drug Plan.[117]

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[109] S. 641.21(1), F.S.
[110] S. 641.21(1)(1), F.S.
[111] S. 641.495, F.S.
[112] Ss. 641.19(4), 641.31(1), F.S.
[113] *Supra*, FN 107.
[114] Florida Health Insurance Advisory Board, *2021 Florida Health Insurance Market Report*, Florida Office of Insurance Regulation (adopted Nov. 4, 2021) https://floir.com/docs-sf/default-source/life-and-health/health-insurance-advisory-board-reports/fhiab-2021-market-report---adopted-by-board-(11-4-21).pdf?sfvrsn=7da6c23c_4 (last visited Jan. 20, 2024).
[115] *Id*.
[116] S. 110.12315, F.S.
[117] Department of Management Services, *myFlorida, Prescription Drug Plan*, https://www.mybenefits.myflorida.com/health/prescription_drug_plan (last visited Jan. 20, 2024).

International Reference Pricing

International reference pricing (IRP), also known as external reference pricing, refers to the practice of using the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark, or reference price, that informs price setting or price negotiation of the product in the home jurisdiction.[118] In other words, reference pricing sets an upper payment limit for purchasers.[119] Reference pricing is a cost-containment policy strategy to ensure the maximum price paid for a drug is not excessive relative to its price in other countries.[120]

While the technical aspects of reference pricing vary by country, the practice is widespread. Most countries in the European Union as well as Australia, Brazil, Canada, Egypt, Jordan, and South Africa use some form of reference pricing.[121]

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.[122]

International Reference Pricing Models

The precise impact of a reference pricing model depends on the variables chosen during the decision point phase.[123] Rather than serving as the primary negotiation tool, reference pricing tends to supplement other drug-pricing policies.[124] Generally, researchers anticipate substantial short-term savings in prices for established drugs because of the significant divide in prices between the United States and other high-income countries.[125] 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.[126]

When short-term savings later declined in Italy and Sweden in the early 2000s, both countries scrapped their international reference pricing models.[127] In addition, researchers caution that 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.[128]

To thread the needle, some researchers believe a long-term, sustainable reference pricing policy that avoids price gaming and manipulation considers an alignment between drug prices and the value they bring.[129]

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[118] Dominic Voehler, Benjamin Koethe, Patricia Synnott, and Daniel Ollendorf, *The impact of external reference pricing on pharmaceutical costs and market dynamics*, p.1, 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 Dec. 12, 2023).
[119] 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 Dec. 12, 2023).
[120] *Supra*, FN 117 at 1.
[121] 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 Dec. 12, 2023).
[122] *Supra*, FN 27 at 3.
[123] Variables include the selection of target populations, the regulated transaction / point of sale, the drugs, the countries, the formula to calculate price, the frequency of price revisions, the granularity of prices and quantity, the data source(s), remedies for noncompliance, and ensuring benefits accrue to patients.
[124] *Supra*, FN 120.
[125] *Supra*, FN 117 at 7.
[126] *Supra*, FN 120.
[127] *Id*.
[128] *Supra*, FN 117 at 7.
[129] *Id*.

Medicare: Most Favored Nation Model

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.[130] Medicare Part B covers physician care, outpatient services, and some home health and preventative services.[131] Medicare pays most health care practitioners for Part B outpatient prescription drugs and biologicals administered as part of, or incident to, a physician service, and drugs furnished for use with covered durable medical equipment.[132] Reimbursement for Part B covered drugs and biologicals is based on a statutory formula, which is the drug's average sales price plus a 6 percent add-on payment.[133]

The Most Favored Nation (MFN) model is a Medicare rate methodology recently published by CMS for prescription drugs, biologicals, and biosimilars in the Medicare Part B program. Under the MFN model, Medicare would pay no more than the lowest price paid in a similarly situated OECD member country.[134] The OECD countries comprise a set of countries that share with the U.S. both democratic principles and a commitment to market-based economies.[135]

The MFN model advanced initially as an interim rule in 2020 by CMS.[136] CMS's goal 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.[137] The interim rule did not address Medicare Part D drug spending.

The MFN model targets a specific 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.[138]

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.). [139] To identify those countries, CMS developed an eligibility threshold of a least 60% of the U.S. Gross Domestic Product (GDP) per capita, updated quarterly.[140] For the first quarter of 2021, the CMS interim rule reported that the first basket group yielded 22 qualifying OECD member countries.[141]

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-

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[130] 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 Dec. 20, 2023).
[131] *Id*.
[132] Centers for Medicare and Medicaid Services, *Part B Drugs and Biologicals*, U.S. Department of Health and Human Services (last updated Sept. 6, 2023) https://www.cms.gov/cms-guide-medical-technology-companies-and-other-interested-parties/payment/part-b-drugs (last visited Jan. 17, 2024).
[133] *Id.*
[134] Most Favored Nation (MFN) Model, 85 Fed. Reg. 76180 (Nov. 27, 2020).
[135] *Id*. at 76199.
[136] *Supra*, FN 133.
[137] *Id*. at 76180-76181
[138] *Id*. at 76181, 76187.
[139] 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.
[140] 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.
[141] 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.

eligible beneficiary spending, and $28.5 billion for beneficiaries.[142] 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.[143]

CMS never implemented the 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.[144]

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 while eschewing regulation that governs the price a manufacturer can charge for a product.[145]

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 salience, 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.[146]

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.[147]

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 floor. To avoid triggering the manufacturer's best price obligation

[142] 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).
[143] *Id*.
[144] 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).
[145] *Id*., *Supra*, FN 117.
[146] *Supra*, FN 117.
[147] *Id.*

in other states, the NASHP Model promotes a state supplement rebate agreement since state supplemental agreements are not subject to the best price floor. [148]

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 purchasers and payers to participate on behalf of the state's residents. For a risk-averse approach, the NASHP Model recommends an ERISA[149] plan opt-in provision to avoid federal preemption issues.[150]

The acquisition of relevant international pricing information is necessary for a payer or regulator to set the benchmark price.[151] 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[152] that records international sales and volume or use publicly available data from other countries.[153] 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.[154] 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 to account for these discounts.[155]

Furthermore, the NASHP Model cautions that some international pricing information is unavailable due to trade secret protections.[156]

Market-Based International Index Model

The Market-Based International 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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[148] *Id*.; *See* 42 U.S.C. 1396r-8(b)(3)(A)(i)(II), (c)(1)(C)(i); Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KFF (Nov. 12, 2019) https://www.kff.org/report-section/understanding-the-medicare-prescription-drug-rebate-issue-brief/#endnote_link_438418-9 (last visited Jan. 17, 2024).

[149] 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 Dec. 21, 2023).

[150] 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.

[151] *Supra*, FN 118.

[152] 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).

[153] 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. 17, 2024).

[154] *Supra*, FN 27.

[155] *Id*.

[156] *Supra*, FN 118. *See, also,* Steven M. Lieberman, Paul B. Ginsburg, and Kavita K. Patel, *Balancing Lower U.S. Prescription Drug Prices and Innovation – Part 1*, Health Affairs (Nov. 24, 2020) https://www.healthaffairs.org/content/forefront/balancing-lower-u-s-prescription-drug-prices-and-innovation-part-1 (last visited Jan. 20, 2024).

- 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 consumer 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.

Effect of the Bill

International Reference Pricing Index

The bill creates a statutory framework for AHCA to build an international reference pricing index for prescription drugs 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 international reference pricing index. The bill details a three-pronged approach to building and maintaining the index: country-selection, drug pricing data acquisition, and the upper payment limit calculation.

Reference Price Source Countries

As to the first prong, the bill requires AHCA, through its contracted vendor, to designate a selection group of eligible countries that will comprise Florida's international reference pricing index. The bill deems eligible countries as follows:

- Countries with a real GDP per capita of at least 40% of US GDP per capita, and
- Countries without single-payer health systems (i.e., 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 US GDP per capita, which is $63,700 according to the most recent estimate found in the U.S. Central Intelligence Agency's World Factbook. This means 40% of US GDP per capita is $25,480.

The table below identifies countries which currently meet the 40% GDP threshold and do not appear to rely exclusively on a single-payer health system.[157]

Country	Real GDP per capita	Real GDP per capita as a percentage of US GDP per capita ($63,700)
Austria	$54,100	84.9%
Belgium	$51,700	81.1%
Czech Republic	$40,700	63.8%
Denmark	$59,700	93.7%
Germany	$53,200	83.5%
Ireland	$102,500	160.9%

[157] U.S. Central Intelligence Agency's World Factbook, 2021.

Israel	$42,100	66.0%
Japan	$40,800	64.0%
Netherlands	$56,600	88.8%
Poland	$34,900	54.7%
Portugal	$33,700	52.9%
Romania	$30,800	48.4%
Singapore	$106,000	166.4%
Slovakia	$31,900	50.0%
Switzerland	$71,000	111.4%
The Bahamas	$30,200	47.4%

AHCA, through its contracted vendor, must reevaluate the selection group of countries annually. If a sourced country falls below the 40% threshold, those countries will be excluded for the next year. If a non-sourced country meets or exceeds the 40% threshold but operates a single payer health care system, that country will be excluded. If a non-sourced country meets or exceeds the 40% threshold and does not operate a single payer health care system, that country will be included for the next year.

The bill requires AHCA, through its contracted vendor, to tier the selection group of countries in two or more tiers, using an established index measuring the level of health care system market orientation in each country. A tiered listing of the selection group of countries is important to afford greater weight to prices derived from countries with pure market-driven health care systems.

Drug Pricing Data Acquisition

To obtain international and U.S. pricing data for the purpose of establishing reference prices, the bill creates a price reporting requirement for drug manufacturers. Starting October 1, 2025, drug manufacturers with a DBPR-issued prescription drug manufacturer, or nonresident manufacturer, permit must provide AHCA annual reports of international prescription drug pricing data.

Specifically, the bill requires the annual report to record the amounts for prescription drug paid by insurers, government benefit programs, and persons without health insurance in the countries included in the AHCA-established list of price source countries. The drug manufacturer may present these amounts in one of two modes:

- actual outpatient payment or reimbursement amounts, both net of rebates and other forms of discounts, or
- average payment amounts, weighted by utilization volume, if fully documented to AHCA.

Manufacturers may provide supplemental pricing data at any time throughout the year based on a change in the price of a prescription drug in one of the source countries.

The bill requires DBPR to enforce a permitted drug manufacturer's compliance with these new reporting requirements. DBPR must fine a noncompliant drug manufacturer $10,000 per day for the first 30 days. After the first 30 days, the bill requires DBPR to suspend a drug manufacturer's permit if the drug manufacturer remains out-of-compliance with the new reporting requirement.

Upper Payment Limit Calculation

The bill requires upper payment limits for each prescription drug to ensure patients and third-party payers in Florida will not a pay a higher price for the same prescription drug sold for less in international markets. To accomplish this purpose, the bill requires AHCA, through a contracted vendor, to compare

the source countries' prescription drug pricing data reported by drug manufacturers using publicly available, reliable, and consistent exchange rate source. The exchange rate source could be a commercial vendor or a government entity.

The bill establishes the following three-step process to calculate upper payment limits for each prescription drug.

1. The bill directs the comparative analysis of pricing data to yield the lowest price for each prescription drug across the selection group of countries selected for Florida's international reference pricing index.
2. AHCA, through its contracted vendor, adjusts the lowest price figure for each prescription drug by accounting for a country's variation in volume and GDP.
3. Finally, AHCA, through its contracted vendor, weighs the adjusted lowest price on a tiered-scale that measures the level of health care system market orientation in each country.

The upper payment limit calculation gives Florida the ability to derive the lowest price for each prescription drug sold across the international markets sourced by Florida's international reference pricing index.

AHCA's contracted vendor must reevaluate reference prices annually. In addition, the contracted 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 drug manufacturer. The contracted vendor must send AHCA updated reference prices by January 1st of every year. Then, within 10 days of receipt, AHCA must publish references prices online.

Third party payers and pharmacies serving cash-paying patients will reference these internationally benchmarked lowest prices to determine the maximum amount that they will pay to cover each prescription drug. Ultimately, the upper payment calculation leverages purchasing power on the demand side of the supply chain as well as the prices that other countries are willing to pay for the same prescription drugs.

Insurer and Pharmacy Rate Regulation

The bill applies the upper payment limit to third party payers, including Medicaid, the State Group Insurance Program, and commercial health insurers and HMOs. The bill prohibits these payers from paying an amount more than the upper payment limit in any drug reimbursement transaction. These entities must refer to a prescription drug's reference price on Florida's international reference pricing index at the point-of-sale.

The bill requires covered health insurers to pass on the savings generated by international drug reference pricing to their policyholders. Specifically, the bill requires covered health insurers to use the savings to cut their policyholders cost sharing and premiums. As an accountability measure, the bill requires covered health insurers to document anticipated savings and premium reductions in their rate filings – beginning with the first-rate filing following the availability of reference prices.

The bill requires covered health insurers to assess the actuarial effect of Florida's international drug reference pricing program for each prescription drug the insurer covers for each plan year. By April 1st of every year, the bill requires covered health insurers to submit a report on the assessed effect to OIR Regulation or AHCA.

The bill also makes the reference price upper payment limit applicable to retail pharmacy transactions not involving third party payers: a pharmacy cannot charge a cash-paying patient an amount that exceeds the international reference price for that prescription drug.

The bill's upper payment limit does not apply to the pharmacy's dispensing fee, or fees to administer the prescribed drug; these practitioner fees would be accounted for separately, according to the contract with the payer.

Implementation Reporting

The bill requires OIR and AHCA to submit a joint report every year to the Governor, the President of the Senate, and the Speaker of the House of Representatives that details the following:

- The impact of the covered health insurers experience with Florida's international drug reference pricing program.
- The savings realized compared to prescription drug pricing in the United States without applying Florida's international drug reference pricing program.
- Any problems encountered.
- Any barriers to access prescription drugs.
- The domestic and foreign prescription drug market response.
- The impact on prescription drug program or beneficiary plan access to prescription drugs.
- Quality of care.
- Program costs.

This annual reporting requirement begins with the first annual report due January 1, 2026.

The bill provides an effective date of July 1, 2024.

B. SECTION DIRECTORY:

Section 1: Creating s. 499.044, F.S., relating to international drug reference pricing.
Section 2: Amending s. 465.0244, F.S., relating to information disclosure and reference pricing.
Section 3: Amending s. 627.6044, F.S., relating to use of a specific methodology for payment of claims.
Section 4: Amending s. 641.30, F.S., relating to construction and relationship to other laws.
Section 5: Creating an unnumbered section of law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   AHCA anticipates spending $1,500,000 to implement the international drug reference pricing program. In addition, AHCA anticipates the need for $250,000 in recurring funds for program maintenance and enhancement and one FTE with a compensation package of $80,327.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

Local governments providing prescription drug coverage for employees will experience financial savings.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

HMOs and health insurers, and their employer and individual policy holders, will experience savings due to reductions in drug costs and commensurate reductions in premiums and other forms of cost-sharing.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides AHCA, DBPR, and OIR with sufficient rulemaking authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES