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PRESCRIPTION DRUG PRICING, IMPORTATION, REFERENCE PRICING, AND PHARMACY BENEFIT MANAGERS STUDY - BACKGROUND MEMORANDUM

Senate Bill No. 2212 (2021) directs a study of prescription drug pricing, importation, reference pricing, and the role pharmacy benefit managers play in drug pricing. The study must include input from the Public Employees Retirement System, Workforce Safety and Insurance, the Insurance Commissioner, the State Board of Pharmacy, prescription drug wholesalers in Canada, and the public.

BACKGROUND

As introduced, Senate Bill No. 2212 would have directed the State Department of Health to design a wholesale prescription drug importation program for the importation of prescription drugs from Canada in compliance with Section 804 of the Federal Food, Drug, and Cosmetic Act[1]. Section 804 directs the Secretary of the federal Department of Health and Human Services, after consultation with the United States Trade Representative and the Commissioner of Customs, to promulgate regulations permitting pharmacists and wholesalers to import Canadian prescription drugs into the United States. Several states, including Florida, Vermont, Colorado, Maine, New Mexico, and New Hampshire, have enacted laws establishing importation programs for prescription drugs from Canada.

On a per capita basis, the United States spends more on prescription drugs than any other country in the Organization for Economic Co-Operation and Development with prices in the United States averaging at least 2.56 times higher than the prices in 32 other counties.[2] Prices in the United States were higher than those in comparison countries for brand name originator drugs but lower than those in comparison countries for unbranded generic drugs. The price for prescription drugs can be measured at different levels, such as the price at which drugs are sold to wholesalers or the price offered to the public by retail pharmacies, which include wholesale and retail markups. Although the net price likely reflects rebates and other discounts paid by manufacturers after drugs are dispensed, those prices generally are not available.

According to the most recent data from the National Health Expenditures, the United States spent $369.7 billion on prescription drugs in 2019 and a projected $358.7 billion in 2020, or about 9 percent of the forecast of $4 trillion in 2020 national health care spending.[3] Prescription drug spending is forecast to remain at about 9 percent of national health care spending through 2028, which is down slightly from a previous average of about 10 percent of health care spending. According to the National Conference of State Legislatures, states are using various methods to address prescription drug spending by passing laws to allow for importation of drugs from abroad, limiting consumer cost-sharing to high-priced drugs, and requiring transparency in drug pricing by requiring manufacturers to justify drug price increases or provide data about research, advertising, and other costs.[4]

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[1] 21 U.S.C. 384.

[2] Mulcahy, Andrew W., Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro U. Becerra-Ornelas, International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies. Santa Monica, CA: RAND Corporation, 2021. https://www.rand.org/pubs/research_reports/RR2956.html.

[3] Centers for Medicare and Medicaid Services, "National Health Expenditure Projections 2019-2028," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected; and "National Health Expenditure Data: Historical," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

[4] See National Conference of State Legislatures, "Prescription Drug Policy Research Center," http://www.ncsl.org/research/health/ncsl-prescription-drug-policy-resources-center.aspx; and Deloitte, "State Drug Pricing Policies: Drug Companies and PBMs Should Prepare for Continued Activity," July 16, 2020, https://www2.deloitte.com/us/en/insights/industry/life-sciences/state-drug-pricing-legislation.html.

Drug Pricing

Pharmaceutical companies consider several factors when pricing their drugs, including a drug's uniqueness, competition from other companies, a drug's effectiveness, and the research and development costs incurred to bring a drug to market. Unlike other countries, the United States does not regulate the price of prescription drugs extensively which allows drug companies to set the price the market will bear. According to a May 6, 2021, report from the Congressional Research Service, although drug spending growth moderated in the early 2000s due in part to an economic recession and the expanded use of lower-cost generic drugs, drug spending spiked in 2014, due in part to the introduction of expensive new hepatitis C drugs, increasing spending 13.5 percent in 2014 and 8.8 percent in 2015, before slowing to an average of 3.4 percent annual growth from 2016 through 2019.[5] Although the pace of spending has declined since 2014, the Centers for Medicare and Medicaid Services forecasts retail drug spending could average 5.5 percent annual growth from 2020 through 2028, which would be faster than some other areas of health care spending in the United States during the same period. According to the United States Department of Labor Consumer Price Index, prescription drug prices have risen faster than prices for overall goods and services in the United States in most years from 2000 to 2020.[6]

In 2020, Health Affairs reported although generic drugs accounted for 90 percent of the 5.8 billion prescriptions in 2018, generic drugs comprised only 20 percent of drug spending while 10 percent of prescriptions for brand drugs constituted almost 80 percent of outpatient drug spending during the same period.[7] The report further indicated biologic or specialty drugs accounted for one-half of outpatient drug spending while only comprising of 2.2 percent of prescriptions.

Most health plans cover outpatient prescriptions through a distinct pharmacy benefit separate from coverage of medical services like physician and hospital care. Health plans typically contract with pharmacy benefit managers (PBMs) to negotiate drug prices with manufacturers and process prescription claims. Pharmacy benefit managers use formularies that contain the brand and generic prescription medications covered by a plan together with the patient cost-sharing requirements and utilization techniques to help control drug prices. Formularies generally have tiers with different out-of-pocket costs for patients based on various factors such as whether a drug is a generic, a preferred brand, or a nonpreferred brand.

Reference Pricing

Reference-based pricing is a health care cost containment model that limits what a group health plan will pay for certain prescription drugs. Under this approach, the insurer covers the prices of low-cost, benchmark prescription drugs in therapeutic clusters, which are deemed to be close substitutes for one another in treating specific illnesses. Patients who prefer a higher priced substitute in a cluster must pay the difference between the retail price of that drug and the reference price covered by the insurer. The practice of international or external reference pricing sets maximum prescription drug prices in one country based on what other countries pay and is used widely outside the United States.

According to an analysis of 16 studies describing nine reference pricing policies from six countries, including Canada, Germany, Norway, and Spain, the American Journal of Managed Care, "found reference pricing policies led to decreases in drug prices and increases in utilization of targeted medications, while also reducing payer and patient expenditures" and also determined the policies did not lead to increased use of medical services such as office visits and hospitalization.[8] The use of reference pricing in various countries has been linked to reduced patient out-of-pocket and total payer expenditures and achieved cost-savings without a negative impact on resource consumption. Three studies that evaluated changes in patient expenditures found out-of-pocket savings ranging from 12 to 18 percent per month with four studies reporting a reduction of 14 to 52 percent on targeted drug classes on payer expenditures.

Over the last few years, states have introduced and passed dozens of bills that would reduce prescription drug prices and spending using several strategies, including the use of international reference pricing to set an upper

[5]Frequently Asked Questions About Prescription Drug Pricing and Policy, Congressional Research Service, May 6, 2021. https://crsreports.congress.gov/product/pdf/R/R44832.

[6]See United States Bureau of Labor Statistics, "Measuring Price Change in the CPI: Medical care," https://www.bls.gov/cpi/factsheets/medical-care.htm.

[7]Balancing Lower U.S. Prescription Drug Prices and Innovation, Health Affairs Blog, November 24, 2020. https://www.healthaffairs.org/do/10.1377/hblog20201123.804451/full/.

[8]A Systematic Review of Reference Pricing: Implications for US Prescription Drug Spending, Am J Managed Care, November 2012, Volume 18, Issue 11. https://www.ajmc.com/view/a-systematic-review-of-reference-pricing-implications-for-us-prescription-drug-spending.

payment limit for purchasers.[9] According to the National Academy for State Health Policy, there are three key design choices that states face as part of the effort to create upper payment limits, including identifying the target populations, the site of the regulated transaction, and the acquisition of information, while also considering which countries to include as reference points, the target price to be paid, which drugs to include in the program, what remedies to impose on manufacturers that resist the structure, and how to ensure cost-savings accrue to patients and plans. Although many bills have passed, states are likely to face at least four legal hurdles when attempting to set an upper payment limit based on an international reference price, including preemption challenges arising under the patent statute, dormant commerce clause challenges, Medicaid barriers, and federal Employee Retirement Income Security Act of 1974 arguments.[10]

Pharmacy Benefit Managers

North Dakota Century Code Section 19-03.6-01 defines "pharmacy benefit manager" as a "person that performs pharmacy benefits management and includes any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency." Pharmacy benefit managers (PBMs) serve as middlemen and administer prescription drug plans and negotiate prices with pharmaceutical companies for inclusion in health insurance coverage lists, also known as formularies. Pharmacy benefit managers negotiate drug prices and rebates with a drug manufacturer and in exchange for rebates, PBMs will put certain drugs on formularies. The PBM also manages the payer's formulary list, and in exchange, the payer pays the PBM for administrative services for the actual drug and for the dispensing of the drug. In some cases, a PBM contracts with a pharmacy to dispense drugs directly and pays the pharmacy a drug dispensing fee.

According to a 2016 report from the Pharmaceutical Care Management Association, PBMs implement prescription drug benefits for over 266 million Americans who have health insurance from a variety of sponsors.[11] Aside from providing various services including developing and maintaining formularies, processing claims, and negotiating discounts and rebates between payers and manufacturers, PBMs manage plans for millions of Americans who have health insurance from a variety of sponsors, including commercial health plans, self-insured employer plans, Medicare Part D plans, state government employee plans, and Medicaid managed care organization plans. According to the Kaiser Family Foundation, of the 3.7 billion retail prescriptions in 2019, approximately three-quarters of prescriptions are processed by PBMs.

Although most state laws focus on the role of other actors in the supply chain, some states are imposing additional regulations on PBMs, such as requiring PBMs to register with the state as third-party benefit administrators, prohibiting gag clauses in pharmacy contracts with PBMs which bar pharmacists from telling consumers about less expensive options for filling a prescription, and making public PBM bids for services to provide more transparency.[12] There also are recent federal laws banning gag clauses in Medicare and commercial insurance.[13] In 2016, Vermont approved a law requiring manufacturer disclosure for drugs that underwent large percentage price increases and directing state regulators to compile a list of the drugs used by Vermont residents which experience the largest annual price increases. The Vermont law further requires manufacturers to justify the price increase to the state attorney general.

Importation

Under current law, the importation of unapproved drugs, including foreign-made versions of Food and Drug Administration (FDA)-approved drugs with limited exceptions, generally is prohibited. Before a drug may be sold in the United States, it must be approved by the FDA and because the FDA's premarket approval requirements

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[9]The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs. August 10, 2020. https://www.nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs/#toggle-id-1.

[10]*Id.*

[11]PBMs: Generating Savings for Plan Sponsors and Consumers, Pharmaceutical Care Management Association, February 2016. https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.

[12]LaVita Tuff, "Trending Now: State Legislation that Bans Pharmacy Benefit Managers' 'Gag Clauses,'" National Academy for State Health Policy, January 30, 2018, at https://nashp.org/trending-now-state-legislation-that-bans-pharmacy-benefit-managers-gag-clauses/. See also from the National Academy for State Health Policy: "States Save on Rx Spending by Using Reverse Auctions for Pharmacy Benefit Manager Service Procurement," August 24, 2020, https://www.nashp.org/states-save-on-rx-spending-by-using-reverse-auctions-for-pharmacy-benefit-manager-service-procurement/; "2020 State Legislative Action to Lower Pharmaceutical Costs," updated December 8, 2020, https://www.nashp.org/rx-legislative-tracker/; and State Drug Pricing Laws: 2017-2020, updated December 3, 2020, https://www.nashp.org/rx-laws/.

[13]P.L. 115-262 and P.L. 115-263.

are so detailed and explicit, no drug that a consumer might import technically would fulfill all the approval elements. The federal Prescription Drug Marketing Act of 1987 clarified even for a drug the FDA had approved for sale in the United States which had been sold or transferred to a foreign country, only the manufacturer of the FDA-approved prescription drug is authorized to bring the drug back into the United States.[14]

Although Congress enacted the federal Medicine Equity and Drug Safety (MEDS) Act[15], and subsequently the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003[16], to allow pharmacists and wholesalers to import unapproved versions of FDA-approved prescription drugs from Canada, the Secretary of the Department of Health and Human Services had not certified to Congress that the promulgation will not pose additional risk to the public's health and safety or result in a significant reduction in the cost of covered products to the American consumer.[17] On September 23, 2020, the Department of Health and Human Services Secretary Alex Azar made the necessary certification to Congress and promulgated the final rule to implement the MEDS Act and allow for the importation of certain prescription drugs from Canada.

SUGGESTED STUDY APPROACH

The committee may wish to proceed with the study by seeking input from various stakeholders, including the Public Employees Retirement System, Workforce Safety and Insurance, the Insurance Commissioner, the State Board of Pharmacy, the Pharmacists Association, prescription drug wholesalers in Canada, and the public relating to drug pricing, importation, reference pricing, and pharmacy benefit managers.

[14]FFDCA §801(d)(1)(A).
[15]P.L. 106-387
[16]P.L. 108-173
[17]FFDCA §804(l) [21 U.S.C. §384(l)].