Health District
OF NORTHERN LARIMER COUNTY

3/5/2021

STAFF: ALYSON WILLIAMS ISSUE SUMMARY

SB21-175: PRESCRIPTION DRUG AFFORDABILITY BOARD

Details

Bill Sponsors: Senate – Jaquez Lewis (D) & Gonzales (D)
House – Caraveo (D) & Kennedy (D)

Background

The purpose of this issue summary is to provide an overview of the issue being addressed by the coming bill that is being finalized after publication deadline.

Bill Summary

The bill establishes a Prescription Drug Affordability Board (PDAB) to conduct affordability reviews and set upper payment limits on certain expensive prescription drugs.

Issue Summary

Prescription Drugs

Among 11 Organization for Economic Cooperation and Development (OECD) countries, the United States (U.S.) has the highest pharmaceutical spending per capita at $1443, well above the mean of $749 for all 11 countries.[1] Retail pharmaceutical spending averages $541 per capita in these OECD countries, while U.S. spending on retail pharmaceuticals is almost double, at $1026 per capita.[2]

From 2017 until 2026 prescription drug spending is anticipated to increase 6.3 percent per year.[3] Out-of-pocket costs for patients was $82 billion in 2019, but each patient's exposure to these costs varied dramatically.[4] For example, only 1.1 percent or 69 million prescriptions cost more than $125 for the patient; however, these medicines bring a high burden to patients and can only be offset by coupons or vouchers in commercial plans.[5] Approximately 58 percent of Americans report that they are currently taking at least one prescription drug while 25 percent take four or more prescription drugs.[6] A 2015 Consumer Reports poll found that 30 percent of people who take at least one prescription drug a month had unexpected spikes in the out-of-pocket cost of their drug(s) in the past year.[7]

In 2019, 9 percent of all new prescriptions were abandoned at retail pharmacies.[8] Abandonment represents patient care that is recommended by a provider but not received. Abandonment rates are less than 5

[1] Papanicolas I., Woskie L.R., & Jha AK. (2018). Health Care Spending in the United States and Other High-Income Countries. *JAMA,* 319(10):1024–1039. DOI:10.1001/jama.2018.1150
[2] Ibid.
[3] Cuckler, G.A. et al. (2018). National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs, 37*(3). DOI: 10.1377/hlthaff.2017.1655
[4] IQVIA Institute for Human Data Science (Aug. 2020). *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines.* Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us
[5] Ibid.
[6] Henry J Kaiser Family Foundation (2018). *Public opinion on prescription drugs and their prices.* Retrieved from https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/
[7] *Impact of Surging Drug Prices on Consumers: Hearings before the Democratic Steering and Policy Committee,* House, 114th Congress (2015) (Testimony of Lynn Quincy). Retrieved from http://www.healthcarevaluehub.org/files/3214/4969/6175/Consumers_Union_Drug_Prices_Testimony.pdf
[8] IQVIA Institute for Human Data Science (Aug. 2020). *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines.* Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us

percent when the prescription carries no out-of-pocket cost, but it rises to 45 percent when the cost is over $125 and 60 percent when the cost is over $500.[9]

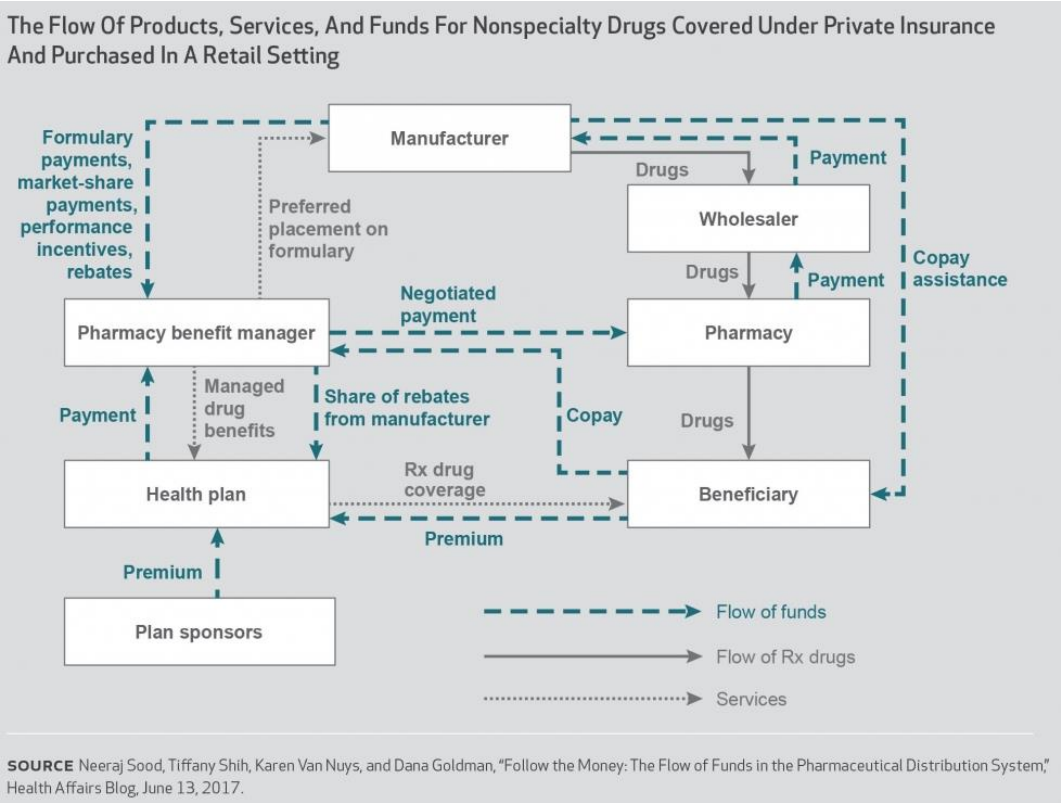
Prescription Drugs in Colorado

In 2019, more than 43.7 million prescription drugs were filled at pharmacies in Colorado, resulting in $6.74 billion of retail sales.[10] According to the Colorado Health Institute's (CHI) 2019 Colorado Health Access Survey, 10.8 percent of Coloradans cite the cost of prescription drugs as reason for not filling the medicines they are prescribed.[11]

In the 2019 Community Health Survey conducted by the Health District of Northern Larimer County, 55.1 percent of Larimer County residents reported taking or using more than one prescription drug at least once a week. Remaining consistent in comparison to the 2013 and 2016 Community Health Surveys, 9.7 percent of adult Larimer County residents reported being unable to have a prescription filled because they could not afford it during the preceding two years.[12] This rate is much higher among those who reported being uninsured (22.1 percent) and those who fell between 186 and 400 percent of the Federal Poverty Level (FPL)[13] (19.1 percent).

Supply Chain

The following graphic of the prescription drug supply chain illustrates the flow of payments and products through the system.



[9] Ibid.
[10] Henry J Kaiser Family Foundation (2020). *Health Costs & Budgets Indicators,* Retrieved from https://www.kff.org/state-category/health-costs-budgets/prescription-drugs/
[11] Colorado Health Institute [CHI] (2017). *Colorado Health Access Survey 2019: State of Colorado.* Retrieved from https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/State%20of%20Colorado_0.pdf
[12] With a 95% confidence interval ranging from 8% to 11.7%.
[13] The 2018 version of the Federal Poverty Level was utilized in the survey.

Brand-Name Drugs

The Federal Drug Administration (FDA) utilizes a structured framework for the approval all new brand-name drugs. To grant approval, the agency conducts an analysis of the target condition and other treatments in the market for the condition, assesses the benefits and risks of the drug, and evaluates risk-management strategies.[14] From preclinical testing to approval the average length of time for a new drug is 12 years, this time may be quicker due to the various designations and programs.[15] Brand-name drug sales accounted for 80.0 percent of total prescription drug revenue in 2019.[16] During the same year, 16 percent of patients that had commercial insurance used coupons to reduce their out-of-pocket costs.[17] A 2019 study found that 78 percent of 49 common top-selling brand-name drugs have seen an increase in both insurer and patient out-of-pocket costs by more than 50 percent, and 44 percent of the studied drugs have more than doubled in price.[18]

Generic Drugs

Generic drugs are identical to their brand-name counterparts and work in the same manner. These generics must be approved by the FDA and can only go to market after the patents and regulatory exclusivities have expired for the brand-name drug. The generic dispensing rate, which measures the proportion of drugs that are dispensed as generic rather than as brand-name, continued to grow in 2019, reaching 86.3 percent, an increase from 85.5 percent in 2018.[19] Generics are typically sold at prices that are 80 to 85 percent less than the cost of a brand-name drug.[20]

Specialty Drugs

The definition of a specialty drug is highly dependent on the entity utilizing the phrase, thus the definition can vary widely. The IQVIA Institute, defines it as a drug that treats a complex, chronic, or rare disease, and has at least four of the following characteristics: list price over $6,000 per year, maintained by a specialist medical provider, not self-administered, requires special handling in supply chain, requires patient payment assistance, distributed through non-traditional channels, and/or has significant side effects that require patient monitoring. [21] For 2019, Medicare defined a specialty tier drug as one that costs more than $670 per month.[22] The anticipated growth in prescription drug spending over the next decade is largely attributable to a larger percentage of that spending on specialty drugs.[23] Specialty drugs accounted for 46.5 percent of drug spending in 2017, a dramatic increase from 2012 (25%).[24,25] The use of specialty medicines grew by 5

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[14] U.S. Food and Drug Administration [FDA] (Jan. 2018). *Development & Approval Process (Drugs).* Retrieved from https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm

[15] Van Norman, G.A. (Apr. 2016). Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, *JACC Basic to Translational Science, 3*(1). DOI: https://doi.org/10.1016/j.jacbts.2016.03.002

[16] Martin, A.B., Hartman, M., Lassman, D., & Catlin, A. (Dec. 2020).National Health Care Spending in 2019: Steady Growth for the Fourth Consecutive Year, *Health Affairs 40*(1). Retrieved from https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.02022

[17] IQVIA Institute for Human Data Science (Aug. 2020). *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines.* Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us

[18] Wineinger, N.E., Zhang, Y., & Topol, E.J. (May 2019). Trends in Prices of Popular Brand-Name Prescription Drugs in the United States, *JAMA Netw Open.* 2019;2(5):e194791. doi:10.1001/jamanetworkopen.2019.4791

[19] Martin, A.B., Hartman, M., Lassman, D., & Catlin, A. (Dec. 2020).National Health Care Spending in 2019: Steady Growth for the Fourth Consecutive Year, *Health Affairs 40*(1). Retrieved from https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.02022

[20] FDA (Jan. 2018). *Generic Drugs: Questions & Answers.* Retrieved from https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm#q4

[21] IQVIA Institute (Oct. 2017). *Orphan Drugs in the United States: Providing Context for Use and Cost.* Retrieved from https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states.pdf

[22] Cubanski, J., Koma, W., & Neuman, T. (Feb. 1, 2019). Specialty Drugs in Medicare Part D in 2019. *Kaiser Family Foundation.* Retrieved from https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/

[23] Cuckler, G.A. et al. (2018). National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs, 37*(3). DOI: 10.1377/hlthaff.2017.1655

[24] Kleinke, J.D., & McGee, N. (2015). Breaking the Bank: Three Financing Models for Addressing the Drug Innovation Cost Crisis. *American Health & Drug Benefits, 8*(3). Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467013/

[25] IQVIA Institute (Apr. 19, 2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022.* Retrieved from https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

percent in 2018, more than double the rate of other drugs.[26] Using pharmacy claims data from Colorado's All-Payer Claims Database (APCD), the Center for Improving Value in Health Care (CIVHC) estimates that across all payers[27] and prior to rebates, specialty drugs represent only 1-2 percent of drug claims volume, but account for 37-49 percent of total drug spending.[28]

Wholesale Acquisition Cost (WAC)

Also known as list price, the wholesale acquisition cost (WAC) is similar to a suggested retail price created by the manufacturers for wholesalers or direct purchasers and is only occasionally relevant to the pricing of both generic and brand-name drugs.[29] Thus, the WAC is not based on any actual sales of a drug. It is defined in federal Medicaid statute as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price."[30] The WAC serves as a basis for negotiations between entities in the supply chain.

Prescription Drug Affordability Boards (PDAB) in Other States

Six states (Maine, Maryland, Massachusetts, New Hampshire, New York, and Ohio) have enacted legislation to establish drug affordability boards or commissions. The most common approach that these boards use to reduce prescription drug prices is through setting upper payment limits, however, other approaches have included negotiating supplemental rebates and formulary changes.[31] The payers under the purview of such a Board have included state-sponsored insurance, state-regulated insurance, and Medicaid.

Maryland's General Assembly authorized the creation of a Prescription Drug Affordability Board, as well as an advisory council, in 2019.[32] The Board was charged in statute to study the entire pharmaceutical distribution and payment system in Maryland and the policy options being used in other states and countries to lower the list price of pharmaceuticals (i.e. upper payment limits, reverse auction marketplaces, and bulk purchasing).

About this Issue Summary

This issue summary was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental and behavioral health, dental, preventive and health planning services to the communities it serves. This issue summary is accurate to staff knowledge as of date printed. For more information about this analysis or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.

[26] IQVIA Institute (May 2019). *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023.* Retrieved from https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023

[27] Includes commercial, Medicaid, Medicare Advantage, and Medicare Fee-for-Service Part D

[28] CIVHC (Jan. 2021). *Colorado prescription drug spending and the impact of drug rebates: a summary of payer-reported prescription drug spending and drug manufacturer rebates and other compensations, 2016-2018.* Retrieved https://www.civhc.org/wp-content/uploads/2021/01/CO-Drug-Rebate-Report_1.8.2020.pdf

[29] Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

[30] 42 USC § 1395w-3a(c)(6)(B)

[31] Manatt, Phelps & Phillips (Nov 2020). *State Drug Affordability Boards: Legislative Landscape and Future Implications.* Retrieved from https://www.jdsupra.com/legalnews/state-drug-affordability-boards-53701/

[32] Maryland Prescription Drug Affordability Board (2021). *Maryland Prescription Drug Affordability Board.* Retrieved from https://pdab.maryland.gov/index.html