2nd Edition

Reducing Prescription Drug Costs in Colorado

Cost Drivers and Strategies to Address Them

January 2021

COLORADO
Department of Health Care Policy & Financing

Contents

Forward to *Reducing Prescription Drug Costs in Colorado,* 2nd Edition

Since the Colorado Department of Health Care Policy & Financing (the Department) published the first edition of *Reducing Prescription Drug Costs in Colorado* in 2019, the prices of prescription drugs have continued to rise, largely unabated and unchallenged. The Department over the past year has continued to research and study the cost of prescription drugs and has updated this report with recent data, analyses and recommendations. The additions to this report have not changed the bottom line: **prescription drugs costs are the leading contributor to rising health care costs.**

2020 Updates to This Report

This second edition of the report updates data and details how far Colorado has come in implementing the initiatives outlined in the first report. It also provides recommendations on how we can continue to battle rising prescription drug costs. More specifically, key updates in this report include:

- *Updated data and analysis:* Throughout the report, the Department has updated statistics and state data where more recent data or reports were available.
- *Drug Importation in Colorado, International Pricing Report:* Last year, this report focused on Colorado's Canadian importation program. When fully implemented, this program could result in an average of 61% savings on imported drugs from Canada, based on an initial analysis of 167 brand-name drugs completed in March 2020. This year, the Department has completed a new analysis of cost savings associated with importing drugs from additional foreign countries, including the importation of biologic drugs. The new report compares drug pricing in Canada, France and Australia to Colorado's pricing. If importing from Canada, Colorado consumers, employers, and other payers could expect to save an average of 63% on the 50 drugs analyzed. Importing from France and Australia could deliver even higher savings — an average of 84% and 78%, respectively. Changing federal statute to allow importation from countries other than Canada would also reduce the pressure on Canada as the sole conduit of reduced foreign prices for Americans and allow the US to import a greater variety of prescription drugs to meet the dynamic and evolving demands of U.S. consumers. The expansion of the program to include the importation of biologics would be an additional significant cost savings opportunity. A summary is included on pages 42-45, and the full report is in Appendix V.
- *Prescriber Tool:* In the 2019 report, the Department detailed how it would create a tool for all prescribers in the state that would improve prescription drug cost control, reduce opioid addiction risk and improve patient health. Since then, the Department has begun implementing Phase I of the tool. The first module of this phase provides patient-specific opioid risk metrics and medication monitoring to prescribers via electronic medical record systems and will be operational in January 2021. The second module will provide real-time, patient-specific pharmacy benefit and drug cost information to prescribers. This will include information such as patient co-pays, drug prices to employers and payers, covered therapeutic equivalent drugs and utilization management policies like prior authorizations. This latter feature, along with the incorporation of the tool into electronic medical records,

improves ease of administration for prescribers. This information will help health care providers prescribe the most cost-effective and efficacious drugs covered by a patient's health plan and is expected to be operational by June 2021. See the full update on pages 46-48.

- *Specialty Drug Pipeline Report:* This is a new Department report, which provides an overview of the impact of specialty and orphan drugs on drug expenditures and provides insight into which drugs are currently in the development pipeline. The report also looks at specific disease states and related innovative therapies that will likely represent the therapies of the future. The report focuses specifically on gene therapy, chimeric antigen receptor T-cell (CAR T-cell) therapy, exon skipping therapy and clustered regularly interspaced short palindromic repeats, or CRISPR, whose researchers were awarded the 2020 Nobel Prize in Chemistry. To illuminate the effect that these innovative therapies have on health plan expenditures, an analysis of fiscal year (FY) 2019-20 claims data from Colorado Medicaid revealed that 1.42% of the prescriptions written to care for Medicaid recipients were so expensive, they represented 48% of total pharmacy expenditures, up from 44% in CY 2018. A summary is included on pages 23-25 and the full report is available in Appendix VI.
- *CIVHC Rebate Report:* Last year's report illuminated the dramatic impact that rebates have on the drug market for both payers and drug manufacturers. To gain more insight into this relationship, the Center for Improving Value in Health Care (CIVHC) conducted an analysis from the 2016-2018 claims using the Colorado All Payer Claims Database (CO APCD), which houses payments on Medicare, Medicaid, all commercial insured consumers in Colorado and some self-funded plans as well. Across all payers in Colorado the amount they received in rebates rose from $850 million dollars in 2016 to $1.12 billion in 2018, an increase of 32%. These rebates complicate an already-complex process of tracking the total cost of prescription drugs across payers. While rebates may reduce the size and growth of overall drug spending by payers in the short-term, they incentivize the increased use of high cost drugs.
- *State Policy Updates:* In the first report, Colorado highlighted the work of a few key states leading in policy in 2019. During the 2020 state legislative sessions across the U.S., 431 bills related to prescription drugs were introduced, and 38 were signed into law by states across the country. The Department has added some examples of legislation that has passed related to transparency, rebates, oversight boards, regulating pharmacy benefit managers (PBMs), and importing drugs from Canada and other countries. See the updated 2020 policy review starting on page 35.

Executive Summary

Introduction and Purpose

The Polis administration is committed to saving people money on health care, and that includes implementing solutions to significantly improve the affordability of prescription drugs. This report is intended to inform meaningful dialogue about how to control the cost of prescription drugs to benefit all Coloradans, their employers, and public plans supported through taxpayer dollars, such as Health First Colorado (Colorado's Medicaid program) and the state employee benefit plan. To accomplish this goal, this report provides an overview of various drivers of rising prescription drug costs, and potential state and federal strategies for controlling those costs. The Department welcomes feedback on the report, requests for additional research on areas of keen interest, and feedback on how future iterations of the report can enhance Colorado's ability to lower prescription drug costs.

Prescription drug costs are the fastest-growing consumer health care expense in the U.S., a trend that is unlikely to change in the coming years without disruption in the industry.[1,2] Branded and specialty drug costs are growing significantly faster than inflation rates. Pharmaceutical industry profits are disproportionately high compared to other parts of the health care sector. Specialty drugs, in particular, represent a disproportionate financial burden on all payers. As Figure 1 illustrates, specialty drugs represent only about 1-2% of the prescriptions filled, but account for anywhere between 33-49% of prescription spending in the commercial, Medicaid, and Medicare markets. Even generic drugs are contributing to the overall increase in drug costs.[3] The cost burden of prescriptions is not just taking a toll on the financial well-being of Colorado families, employers and the government; it also has the tragic effect of people foregoing their medications because they can't afford them. Left uninterrupted, prescription drug cost trends will continue upward on the current unsustainable trajectory.

Figure 1. Specialty Drug Percentage of Prescriptions and Percentage of Total Prescription Expenditures[4]

Specialty Drug Percent Total Pharmacy Volume and Spend, 2018		
Payer Type	**% Total Prescription Volume**	**% Total Prescription Spend**
Commercial	2%	49%
Medicaid	1%	44%
Medicare Advantage	1%	33%
Medicare FFS	1%	37%

*Note: Percent total volume and percent total spending was calculated based on monthly pharmacy claims submitted by payers to the CO APCD. Assignment of specialty drugs used Megallan RX Management™ guidelines.

1 Altarum Institute. (2017). *Insights from Monthly National Price Indices Through June 2017* (No. 17-08; Health Sector Economic Indicators). Altarum Institute. https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_Aug_2017.pdf

2 American Academy of Actuaries. (2018). *Prescription Drug Spending in the U.S. Health Care System: An Actuarial Perspective* (Issue Brief). American Academy of Actuaries. https://www.actuary.org/content/prescription-drug-spending-us-health-care-system

3 Aitken, M., & Kleinrock, M. (2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*. IQVIA Institute for Human Data Science. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

4 Center for Improving Value in Health Care (CIVHC). (2020) 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.

The pharmaceutical industry plays an essential role in our health care system. Pharmaceutical companies develop and distribute some of the greatest innovations in health care. The release of COVID-19 vaccines alone will save lives while enabling economies around the globe to open up and recover. The result of prescription drug innovation and best practices is improved health, millions of lives saved and a strong economy.

Clearly, the positive impacts of pharmaceutical advances are not in dispute; the innovations from the industry, as well as researchers employed by universities, charities, and federal and state agencies are paramount. The purpose of this report, however, is to identify opportunities to better control prescription drug costs while maintaining the enormous benefits of drug therapy and innovation. Ultimately, this affordability quest will improve the accessibility of prescription drug therapies to all Coloradans while releasing the stranglehold that prescription drug costs have on employers, Colorado families and our state's budget. It is that quest that will propel the balance of this report.

Cost Drivers

High prescription drug prices continue in part because of complex pricing models, a lack of pricing transparency, anti-competitive practices, effective yet pernicious marketing, and biased legislation boosted by well-financed lobbying efforts. For the purposes of this report, we have segmented cost drivers and solutions into three categories:

- Lack of transparency and lack of pricing practices that benefit Colorado
- Anti-competitive practices
- Marketing and lobbying investment

This report includes a deeper dive into each of these three drivers and outlines state-controlled as well as federally-controlled opportunities to address them.

The icons included throughout the report represent three primary thematic areas:

Lack of Transparency and Pricing Practices

- Lack of transparency into prescription drug prices; pricing methodologies that are unrelated to the cost of drug research, development, manufacturing and distribution; reimbursement methodologies that don't hold drug manufacturers accountable for their clinical promises
- Inadequate price controls, especially for specialty drugs
  - An internal analysis of 2019 claims data from Colorado Medicaid revealed that 48% of total pharmacy expenditures were for specialty drugs, which only represented 1.42% of prescriptions.
- Prohibition for public programs like Medicare to negotiate drug prices directly
- Rebates and other manufacturer compensation paid to middlemen, like PBMs or insurance carriers, often retained in the form of profits
  - In 2018, commercial payers received $179 million in rebates, or 15% of the $1.18 billion spent on prescription drugs, reflecting only insured (not self-funded) business. (See Appendix IV for details.)
- Hospital drug therapy price markups as well as variation in pricing between dispensing settings

Anti-Competitive Practices

- Patent laws and market exclusivity that delay access to lower priced generic drugs
- Anti-competitive practices among pharmaceutical companies, such as price-fixing or coupons and rebates for brand name or specialty drugs
- Rising manufacturer, carrier and PBM profits, exacerbated by industry mergers

Marketing and Lobbying Investment

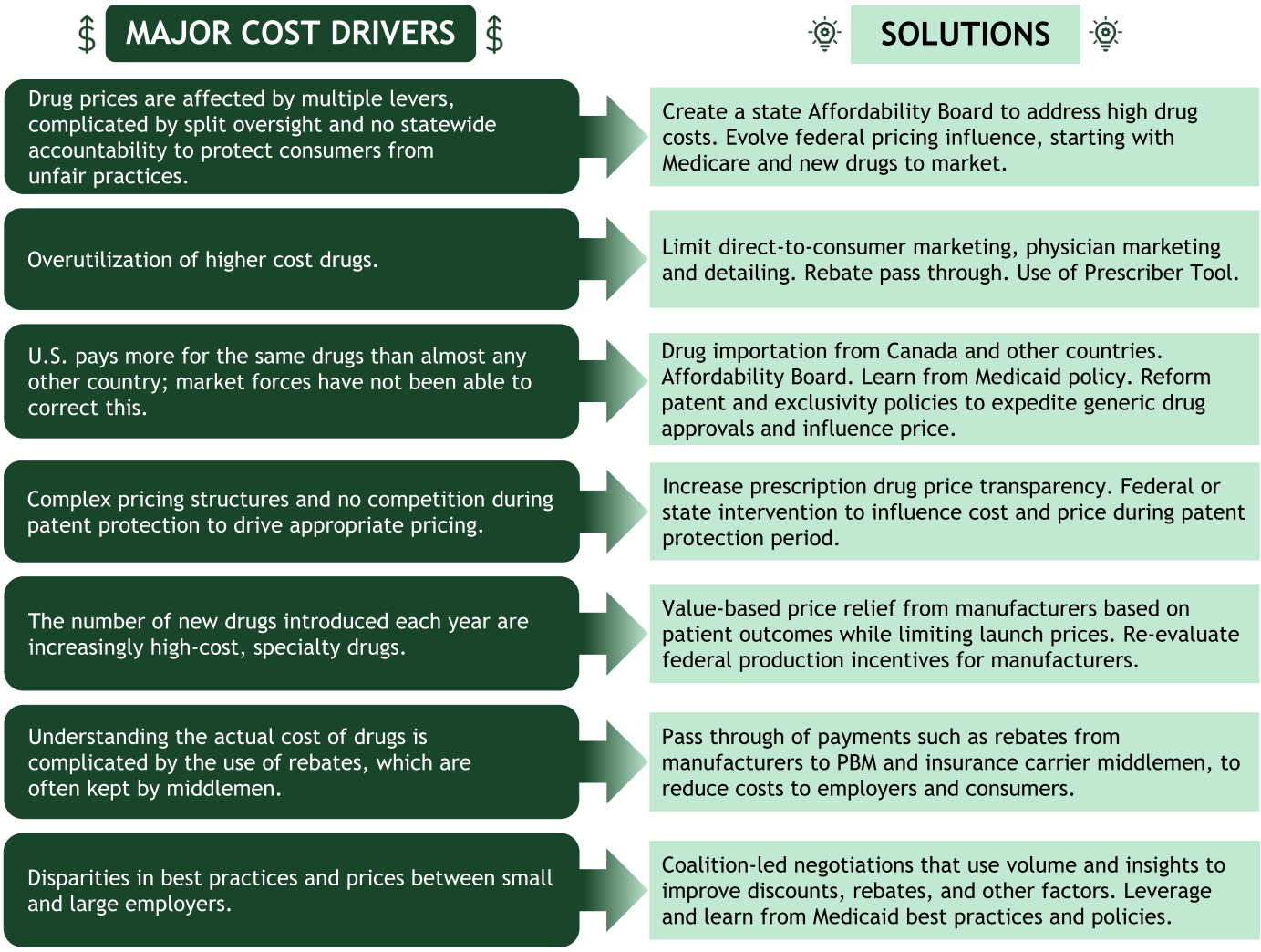
- Rebates and discounts that influence prescriber and insurance carrier decision making
- Manufacturer investment and focus on specialty drugs
- Costs related to marketing, including direct-to-consumer and direct-to-physician marketing, which increase prices and result in the increased utilization of higher cost drugs
- Pharmaceutical industry lobbying, which results in legislation and policy that benefits the industry to the detriment of consumers', employers', and public payers' prices and affordability

Prioritized Solutions

Tackling the soaring cost of prescription drugs would optimally include a coordinated response by the federal government, state government, and the private sector to improve transparency, combat anti-competitive trade practices, and enhance the leverage of large purchasers to negotiate better drug prices for consumers. In the short run, state policymakers should focus on the quick wins that can be addressed through state policy:

- Creating an **Affordability Board** to study and impact prescription drug costs
- **Transparency** in prices, profits and rebates
- **Passing along rebates** and related savings to employers and consumers
- Providing **prescribers access to patient specific affordability information** and evidence-based guidance
- Increasing **value-based contracts** and payments
- Preparing state laws to parallel federal laws that would enable **drug importation from other countries,** in addition to Canada

Over the long run, states, businesses and consumers must work to enact federal-level policy changes to more systemically contain costs and enhance access to life-saving treatments. The chart on the next page provides an overview of state and federal affordability solutions. Taken together, these changes would have a meaningful impact on the cost Coloradans, employers, and public programs like Colorado Medicaid pay for drugs, while leading to better health outcomes as more Coloradans gain access to affordable medications.



Solutions for Saving Colorado Money on Prescription Drugs

This report reviews attainable policies that other states have successfully enacted for our consideration. This includes policies that improve price transparency, limit cost increases, require notice or reporting if there are price increases, improve prescriber education, create oversight boards and create public-private partnerships to meet state needs.

During each Colorado Legislative Session, the General Assembly and other stakeholders have an opportunity to play a significant role in improving the affordability of prescription drugs for the betterment of Coloradan families, our employers, public plans supported by taxpayer dollars and the state's budget. This is especially important during this economic downturn that could take years to recover from. If there was ever a time to focus our attention and energy on prescription drug affordability, it is now.

Solutions for Saving Coloradans Money on Prescription Drug Costs that Require Federal Action

Many of the regulations and laws that fuel the drivers of our unprecedented pharmaceutical prices and cost trends are controlled at the federal level. This report discusses a variety of related federal opportunities to better control prescription drug costs, including:

- **Expanding drug importation** to include other countries beyond Canada and the importation of biologics as an eligible drug class
- **Reforming patent and exclusivity laws** and regulations that prevent competition while expediting approvals for generic drugs to enter the market
- Looking to **international drug pricing models** and connecting U.S. prices to other countries
- Adding **price and cost consideration** to the FDA approval process
- **Limiting direct-to-consumer advertising**

On November 10, 2020, President-elect Joe Biden said, "My transition team will soon be starting its work to flesh out the details so that we can hit the ground running tackling cost, increasing access, lowering the price of prescription drugs. Families are reeling right now...all over the country, enduring illnesses, faced with risky choices, losing their employer plans in droves—over 10 million have already lost their employer plans. They need a lifeline, and they need it now."[5] Federal and state lawmakers can implement solutions now to improve the lives of Coloradans already straining under the weight of the pandemic and the associated economic downturn.

Solutions Based on Drug Types

The costs of prescription drugs are not evenly spread across drug type. There are three types of drugs discussed in this report: branded or brand-name drugs, specialty drugs and generic drugs.

Figures 2 and 3 provide an overview of the volume of prescriptions dispensed and the total cost by percentage for each drug type.

Figure 2. State Prescriptions and Expenditures by Drug Type, Colorado Medicaid FY2020[6]

Drug Type	% prescribed	% of expenditures
Generic	84%	13%
Brand-name	14%	39%
Specialty	1%	48%

Source: Colorado Department of Health Care Policy & Financing, internal analysis

Drug Types

Brand-name drugs: A brand-name drug is a drug marketed under a proprietary, trademark-protected name.

Specialty drugs: Specialty drugs are generally considered to be those drugs and biologics that are complex to manufacture, can be complex to administer, may require special patient monitoring and are high cost.

Generic drugs: Generic drug products contain the identical amounts of the same active ingredient(s) as the brand-name product.

For more definitions, please see Appendix I.

5 Biden, J. (2020, November 20). *Transcript of Remarks in Wilmington, DE.* Talk 2020. https://www.wsj.com/talk2020

6 Internal analysis of claims data from Colorado Medicaid, 2020

Figure 3. Colorado State Prescriptions and Expenditures by Drug Type, All Payers 2018[7]

Drug Type	% prescribed	% of expenditures
Generic	84%	19% ($751m)
Brand Name (non-specialty)	15%	39% ($1.5b)
Specialty Drug	1%	42% ($1.6b)

Source: CIVHC analysis, 2020

Across public and private payers, the factors influencing the amount spent on each of these drugs types are varied and the solutions have the potential to affect one, two or all three drug types. The chart below outlines which solutions in this report primarily address each drug type.

SOLUTIONS	Generic Drugs	Brand Name Drugs	Specialty Drugs
Prescription Drug Affordability Board		•	•
Regulate prices by connecting U.S. Prices to international prices (price indexing) or by other evolving methodologies	•	•	•
Expedite generic drug approvals by reforming patent and exclusivity laws and regulations that prevent competition		•	•
Expanding drug importation beyond Canada to include other countries and biologics		•	•
Reform drug approval, patent or exclusivity regulations to include pricing considerations		•	•
FDA-based clinical performance requirements	•	•	•
Limit or eliminate direct-to-consumer advertisement		•	•
Information for prescribers (Prescriber Tool)	•	•	
Value based contracts		•	•
Increase drug pricing transparency	•	•	•
Rebate and discount passthrough		•	•
Tackling marketing and physician detailing	•	•	•
Public and private partnerships to improve access	•	•	
Hospital drug acquisition cost and pricing, and site of service opportunities to reduce employer and consumer prices		•	•
Education and partnership with employers on best practices, including negotiating better discounts and rebates with PBMs	•	•	•
Prescription Drug Monitoring Program (PDMP) access	•	•	

7 Center for Improving Value in Health Care (CIVHC) internal analysis, 2020

Learning from Medicaid Policy

Medicaid is more sheltered from the burden of rising drug prices compared to commercial payers. While prescription drugs are the leading driver of rising health care costs in the commercial arena, Colorado Medicaid prescription drug expenses have been relatively flat on a per member basis over the past six years. In addition to the many cost control initiatives the Department has implemented, this is a credit to federal protections in place for state Medicaid programs, such as:

- The Medicaid Drug Rebate Program requires that manufacturers offer their "best price" to Medicaid programs
- Medicaid rebates are increased when drug prices increase faster than inflation
- All rebates are passed through to the program at both the federal and state level (not kept by the PBM middlemen)
- Supplemental rebates can be negotiated in excess of the mandated rebate in exchange for preferred formulary status.

When reviewing options for lowering prescription drug costs in the commercial market, policy makers should follow and learn from Medicaid policy.

The Department Invites Your Collaborative Partnership

This report was produced by the Department of Health Care Policy & Financing. The Department also gathered input from a variety of stakeholders, including experts, carriers, providers, employer representatives and consumer advocates.

Thank you for reviewing this report and engaging in the quest to develop new policies and best practices that can better control the cost of prescription drugs for the benefit of Coloradans, our employers, public programs like Colorado Medicaid and other state purchasers.

Industry Trends and Background Information

Prescription Drug Cost, Utilization, and Trends

Since 2019, the Department has continued to research and review opportunities to address the prices of prescription drugs as they have continued to rise, unabated and unchallenged. As a nation, U.S. prescription drug prices rise faster than all other medical goods or services. Since 2014, prescription drug prices have increased 33%, compared to an average of 17% for other medical services.[8] Nearly two-thirds of Americans are going without their prescriptions due to cost, compounded by a struggling economy;[9] to that point, in Colorado, with the downturn in the economy, 22% are more worried about losing their homes and feeding their families than filling their medications.[10,11]

Millions of people live happier, healthier lives through advances in pharmaceutical research and the careful, conscientious application of medical therapies. Prescription drugs are, after all, the first line of offense and defense in the battles against illness and serious injury and in managing chronic conditions. In fact, in a study conducted in the years 2013 through 2016, 45.8% of American adults reported taking at least one prescription drug in the past 30 days.[12] Still, many of the pharmaceutical drugs that Coloradans require to thrive are inordinately expensive. In 2018, prescription medications accounted for 19% of health insurance costs paid by employers, with total spending increasing 25% from 2014-2018.[13] A 2020 analysis of 2018 claims from the Colorado All Payer Claims Database (CO APCD) shows Colorado spent nearly $4 billion, or 13% of total health care spending ($23 billion), on prescription drugs. This is an increase of over $300 million since 2016".[14]

While government and family budgets struggle to afford prescription drug costs, manufacturer net revenues from pharmaceutical sales grew by an estimated 5.2% from 2018-2019.[15] In the month of January 2020 alone, over 100 drug manufacturers increased the price of 619 brand-name drugs by an average of 5.2%.[16] From January 1 to June 30, 2020, as the COVID-19 pandemic swept the nation, driving the U.S. into recession, drug manufacturers increased the prices of 857 brand-name and generic drugs by an average of 6.8%.[17]

Left uninterrupted, prescription drug cost trends are projected to continue upward. The latest federal estimates say that total U.S. prescription drug spending will grow 60% from 2019 to

8 Marsh, T. (2020, September 17). Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service. Good Rx. https://www.goodrx.com/blog/prescription-drugs-rise-faster-than-medical-goods-or-services/

9 Ibid

10 Colorado Health Foundation. (2020). *Pulse: the Colorado Health Foundation Poll.* Colorado Health Foundation. https://copulsepoll.org/results

11 *Senate Bill 207 Hearing,* (2020) (testimony of Joann Ginal).

12 National Center for Health Statistics. (2018). Health, United States, 2018 Data Finder, Table 38. https://www.cdc.gov/nchs/data/hus/2018/038.pdf

13 Health Care Cost Institute. (2020). 2018 Health Care Cost and Utilization Report (Health Care Cost and Utilization Report). Health Care Cost Institute. https://healthcostinstitute.org/images/pdfs/HCCI_2018_Health_Care_Cost_and_Utilization_Report.pdf

14 Center for Improving Value in Health Care (CIVHC). (2020) 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.

15 Aitken, M., Kleinrock, M., Campanelli, G., Tawil, C., & Vokey, M. (2020). Medicine Spending and Affordability in the U.S. Understanding Patients' Costs for Medicines. IQVIA Institute for Human Data Science.

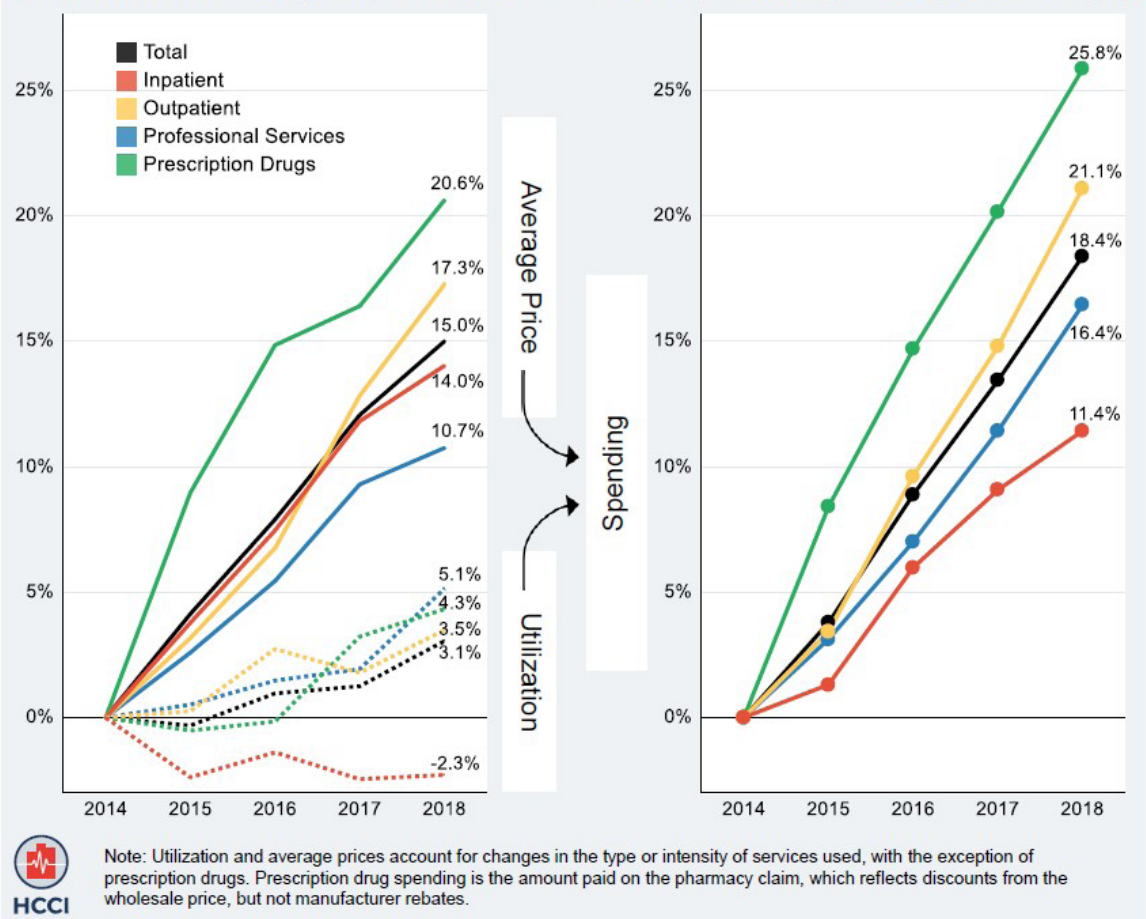
16 Marsh, T. (2020, February 6). Over 600 Drugs Saw Price Hikes in January – What Does It Mean for Consumers? Good Rx. https://www.goodrx.com/blog/january-2020-drug-increases-recap/#:~:text=In%20total%2C%20over%20100%20manufacturers,by%20an%20average%20of%205.2%25

17 Jay, E. F. (2020, October 18). 7 ways to save on medications in the pandemic. Next Avenue. https://www.forbes.com/sites/nextavenue/2020/10/18/7-ways-to-save-on-medications-in-the-pandemic/

2027, from $360.3 billion to $576.7 billion.[18] This unsustainable growth is evidenced by the fact that 14 of the 20 best-selling prescription drugs have increased in price by double-digit percentages since January 2016, with 11 drugs increasing by more than 15%.[19]

Figure 4 shows the growth in health care costs from 2014 -2018 across four spending categories: Inpatient, Outpatient, Professional Services, and Prescription Drugs. Total cost per person is a function of the utilization of prescription drugs and health care services and the price of pharmaceutical drugs and health care services. The chart illustrates that while utilization rates have gone up by about 3-5% (except inpatient, which has gone down by 2.3%), the prices have gone up by double digits in all categories. In both the price and total spending, prescription drugs are the leading category for increases in health care spending.

Figure 4. Cumulative Change in Spending per Person, Utilization, and Average Price by Service Category, 2014-2018[20]



Source: Health Care Cost Institute (HCC) 2018 Health Care Cost and Utilization Report.

18 Office of the Actuary. (2019). *CMS Office of the Actuary Releases 2018-2027 Projections of National Health Expenditures* [Press Release]. Centers for Medicare and Medicaid Services. https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2018-2027-projections-national-health-expenditures

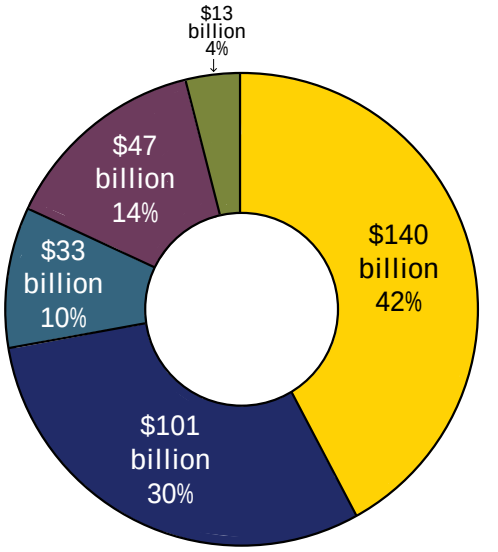
19 Democratic Staff. (2018). *Skyrocketing Drug Prices: Year One of the Trump Administration* [Staff Report]. Committee on Oversight and Government Reform, US House of Representatives. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Skyrocketing%20Drug%20Prices-Year%20One%20of%20the%20Trump%20Administration.pdf

20 Health Care Cost Institute. (2020). *2018 Health Care Cost and Utilization Report* (Health Care Cost and Utilization Report). Health Care Cost Institute. https://healthcostinstitute.org/images/pdfs/HCCI_2018_Health_Care_Cost_and_Utilization_Report.pdf

These escalating costs from new, expensive therapies and cost increases for existing medications are also placing pressure on government health care programs. Medicare and Medicaid together accounted for 40% of retail prescription drug spending in the U.S. in 2017.[21] Medicare Part B and Part D spending are projected to increase faster than any other category of health spending over the next five years.[22] On a national basis, Medicaid has also seen prescription drug spending rise precipitously with the introduction of new specialty drugs.

Overall, prescription drug costs in the U.S. are financed by private/commercial health coverage (representing 42% of national spending, or $140 billion), Medicare Part D (30%, or $101 billion) and Medicaid (10%, or $33 billion). Out-of-pocket costs paid by consumers are also significant, representing 14%, or $47 billion.[23]

Figure 5. U.S. Retail Prescription Drug Spending by Payer, 2017[24]



Total U.S. Retail Prescription Drug Spending in 2017: $333 billion
Total Prescription drug spending accounts for rebates.
SOURCE: Kaiser Family Foundation analysis of 2017 data from the National Health Expenditure Accounts.

According to a report by the IQVIA Institute for Human Data Science, the use of prescription drugs is increasing in the U.S. due to a number of contributing factors, including an aging population, an increase in the use of medications that treat mental health and diabetes, and changes in clinical practice guidelines.[25] Colorado's population ages 65 and older reached 805,950 in 2018, an increase of 293,100 or 57.2% from 2008. The share of the population over age 65 in Colorado is now just over 14.7%.[26] That makes Colorado the second-fastest aging population over 65 behind Alaska and Nevada.[27]

21 Kaiser Family Foundation. (2019, January 29). 10 Essential Facts About Medicare and Prescription Drug Spending. KFF. https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/

22 Boards of Trustees. (2019). *The 2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.* Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf

23 Cubanski, J., Rae, M., Young, K., & Damico, A. (2019, May 20). How does prescription drug spending and use compare across large employer plans, Medicare Part D, and Medicaid? Peterson-KFF Health System Tracker. https://www.healthsystemtracker.org/chart-collection/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/

24 Ibid

25 Aitken, M., & Kleinrock, M. (2018). Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022. IQVIA Institute for Human Data Science. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

26 Colorado State Demography Office. (2019). *Age and Gender Population Data. Colorado Demography.* https://demography.dola.colorado.gov/population/age-gender-population-data/

27 DeGroen, Cindy. (2020) Colorado Department of Local Affairs. 2020 Annual Demography Summit. Colorado Population Trends and the Impact of COVID-19. Publications and Presentations. Oct. Presentation. https://demography.dola.colorado.gov/demography/publications-and-presentations/

The U.S. Pays the Highest Prices for Pharmaceutical Drugs in the World

"U.S. prices are higher than any other country," concluded a 2018 U.S. Department of Health and Human Services (HHS) study, which found that for 19 of the top 27 Medicare drugs, the highest price among comparison countries was in the U.S. The 17-country price survey concluded that U.S. drug prices are "1.8 times that of the average international price from the drug manufacturer in the first quarter of 2018."[28] A 2017 study from The Commonwealth Fund reported similar results. Prescription drug spending per capita in the U.S. ranges from 30% to 190% greater than in the nine other high-income countries of Sweden, Norway, the Netherlands, Australia, United Kingdom, France, Canada, Germany and Switzerland. In the 1980s, several countries spent about the same amount per capita as the U.S., but in the 1990s and early 2000s, spending on prescription medications grew much more rapidly in the U.S. than in the other nations (see Figure 16, page 43).[29]

Many Coloradans Aren't Taking Their Drugs Appropriately Because They Can't Afford Them, Often Leading to Worse Health Outcomes That Are More Costly

A Kaiser Family Foundation (KFF) Health Tracking Poll from February 2019 found that one in four Americans who are taking medications are struggling to afford them.[30] The high cost of prescription drugs also has a direct impact on patient compliance with their medications; in fact, in 2017, 11.4% of Americans did not take their medicine as prescribed in order to save money.[31] Similarly, 10.8% of Coloradans did not fill a prescription due to cost in 2019, with variations by geographic area; for example, in Pueblo County, it was 18.3%.[32] Patients not taking their medication may experience worse overall health and increased health care utilization on services such as emergency room visits and hospitalizations, further driving up the cost of health care.

From the AARP

Given the high utilization of prescriptions by seniors, the American Association of Retired Persons (AARP) has taken an active role in evaluating the impact of increasing drug costs. For example, in 2017, the average annual retail cost for 754 brand- name, generic and specialty prescription drugs used to treat chronic conditions was almost $20,000 per year. This average annual cost was nearly 20% higher than the average Social Security retirement benefit ($16,848).

SOURCE: S Schondelmeyer, S. W., & Purvis, L. (2019). Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018 (Rx Price Watch). AARP Public Policy Institute. https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf

28 Office of the Assistant Secretary for Planning and Evaluation. (2018). *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. U.S. Department of Health & Human Services.* https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf

29 Sarnak, D. O., Squires, D., & Bishop, S. (2017). *Prescription Drug Spending Why Is the U.S. an Outlier?* The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier

30 Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 1). KFF Health Tracking Poll – February 2019: Prescription Drugs. KFF. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

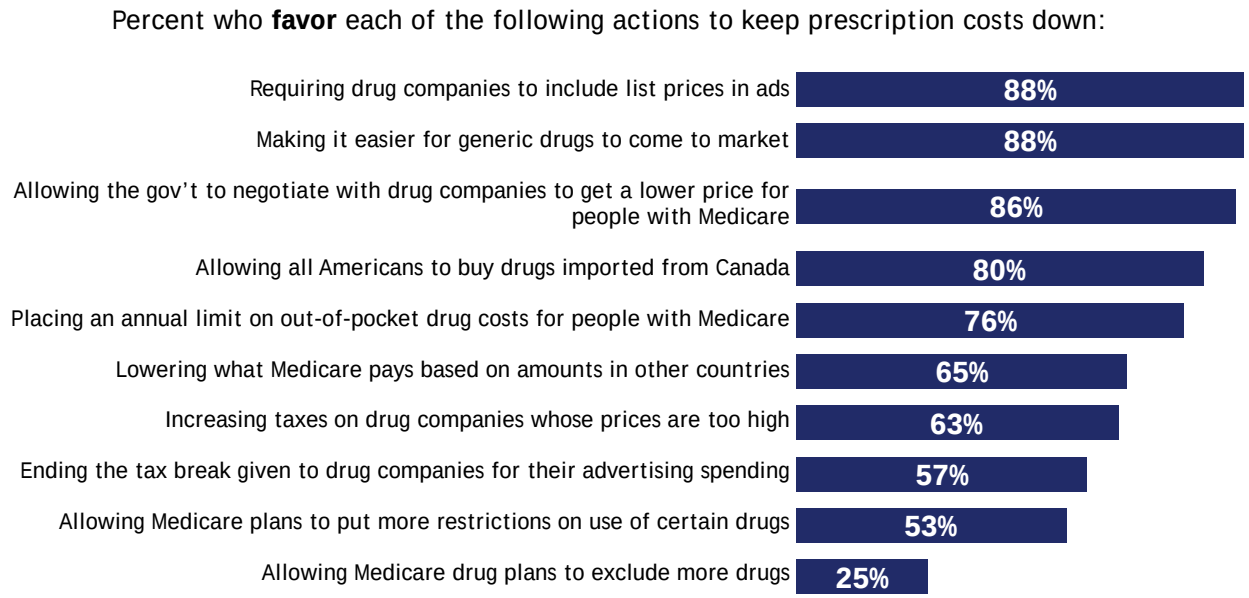
31 Cohen, R. A., Boersma, P., & Vahratian, A. (2019). Strategies Used by Adults Aged 18–64 to Reduce Their Prescription Drug Costs, 2017 (NCHS Data Brief No. 333). US Department of Health & Human Services. https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf

32 Colorado Health Institute, The Colorado Trust, & The Colorado Health Foundation. (2020). *2019 Colorado Health Access Survey: Progress in Peril.* https://www.coloradohealthinstitute.org/research/CHAS

The amount that patients are paying for their medication out-of-pocket is increasing. Seniors with Medicare coverage paid $16.1 billion out-of-pocket in 2019, a 27% increase over the previous five years.[33] As prescription drug and out-of-pocket costs continue to soar, individuals have to make choices between taking their drugs, skipping doses, or purchasing other necessities, such as food, rent, or school supplies.[34] When the out-of-pocket costs for a patient are over $125, 45% of those drugs are never picked up from the pharmacy. When the costs are $500 or more, 60% of those prescriptions are not picked up. These numbers represent care that a physician has recommended, but a patient never receives, putting the patient at risk of illness, suffering, or death.[35]

In a 2019 report, the Kaiser Family Foundation found that nearly 8 in 10 Americans believe prescription drugs costs are unreasonable.[36] The overwhelming majority of Americans favor government action to bring down the price of prescription drugs, including actions such as price transparency requirements, importing drugs from Canada, price negotiations and making it easier for generic drugs to come to market, as noted in Figure 6.

Figure 6. Majority Favor Most Actions to Keep Prescription Cost Down[37]



SOURCE: KFF Health Tracking Poll (conducted February 14-24, 2019).

33 Aitken, M., Kleinrock, M., Campanelli, G., Tawil, C., & Vokey, M. (2020). *Medicine Spending and Affordability in the U.S. Understanding Patients' Costs for Medicines.* IQVIA Institute for Human Data Science.
34 McGrail, S. (2020, July 3). Pharmaceutical Companies Hike Drug Prices During COVID-19 Pandemic. PharmaNews Intelligence. https://pharmanewsintel.com/news/pharmaceutical-companies-hike-drug-prices-during-covid-19-pandemic
35 Aitken, M., Kleinrock, M., Campanelli, G., Tawil, C., & Vokey, M. (2020). *Medicine Spending and Affordability in the U.S. Understanding Patients' Costs for Medicines.* IQVIA Institute for Human Data Science.
36 Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 1). KFF Health Tracking Poll – February 2019: Prescription Drugs. KFF. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/
37 Ibid

Major Drivers of Prescription Drug Prices

Patent Protections

Patent protections—originally implemented to encourage innovation—allow pharmaceutical companies to set their own market prices, sometimes for decades. These laws have the effect of delaying competition from generic manufacturers, driving up costs for consumers, and protecting inflated prices. U.S. federal patent law, codified in Title 35 of the United States Code, gives manufacturers intellectual property rights, and Title 21 under the federal Food and Drug statutes outlines exclusivity protection, which allows pharmaceutical companies to have market exclusivity for a drug for a period of time after the patent is filed.[38,39] The purpose of these laws is to create an incentive for the manufacturer to make the risky, costly investments in research and development that are necessary to bring new therapies to market.

During this time of patent protection, manufacturers are permitted to establish their market price without competition from generic manufacturers that would drive the price down. This is a significant contributor to rising prescription drug costs, which we have a shared opportunity to tackle through adjustments in federal law.[40]

Further exacerbating this impact on prescription drug costs, drug manufacturers file new patents on existing drugs for new, often minor, formulation changes.[41] For example, if a drug is currently in tablet form, a newly released capsule form of the drug would extend the protection period for the drug. This practice is just one type of "evergreening" (any of various legal, business and technological strategies used to extend patents), which allowed approximately 78% of new patents filed to be for existing drugs.[42] Filing for new patents is especially common for blockbuster drugs: among the 100 best-selling drugs, more than 70% had their patent protections extended at least once, and almost half had their patent protection extended more than once.[43] This limits competition for an extended period of time arguably an inappropriate period of time—because potential competitors cannot file an FDA application for approval if a drug has patents, even if the drug is past the period of exclusivity. This practice ensures that prices will remain high, without competition—which further incentivizes pharmaceutical manufacturers to file new patents. All these practices increase the prices of prescription drugs for health plans, employers, public programs like Medicaid and Medicare, and, ultimately, consumers.

38 Patents, US Code Title 35 (2019)
39 Federal Food, Drug, and Cosmetic Act, US Code Title 21 § 301-399i
40 Gupta, H., Kumar, S., Roy, S. K., & Gaud, R. S. (2010). Patent protection strategies. *Journal of Pharmacy and Bioallied Sciences*, 2(1), 2–7.
41 Kumar, A., & Nanda, A. (2017). Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries. *Pharmaceutical Regulatory Affairs: Open Access*, 06(01). https://doi.org/10.4172/2167-7689.1000185
42 Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences,* 5(3), 590–647. https://doi.org/10.1093/jlb/lsy022
43 Ibid

Anti-Competitive Practices and Price Fixing

In addition to market exclusivity protections, manufacturers utilize other mechanisms to maintain price controls once exclusivity and patent periods are over. For example, brand drug manufacturers are permitted to pay generic drug manufacturers to delay or abandon the launch of a generic version of certain drugs. These drug makers sidestep competition by offering patent settlements that pay generic companies not to bring lower-cost alternatives to market. These "pay-for-delay" patent settlements effectively block all other generic drug competition for a growing number of brand-name drugs.

According to a Federal Trade Commission study, these anti-competitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[44] Since 2001, the Federal Trade Commission has filed several lawsuits to stop these deals, and it has testified in support of legislation to end such "pay-for-delay" settlements. Still, there have been no policy changes.[45]

Another strategy for large brand-name manufacturers is to create generic subsidiary companies or partner with a generic manufacturer to prevent competitors from entering the market. These practices ensure a virtual monopoly on the generic drug, keeping prices high. Manufacturers can also use rebates to maintain their market share. "Manufacturers have used the rebate program to introduce an authorized generic with a lower required rebate, allowing them to maintain their monopoly position," said Kristi Martin, senior vice president at consulting firm Waxman Strategies.[46]

A coalition of Attorneys General from 51 states and territories filed a lawsuit on June 10, 2020, against 26 generic drug manufacturers, accusing them of "widespread conspiracy to fix prices and divide

Humira

AbbVie has numerous patent protections for their drug, Humira, to prevent likely competitors from entering the market with biosimilar drugs. Intellectual property laws are complex, and several components of a drug can be patented, such as how the drug is manufactured, how it is administered, dosages, inactive ingredients and packaging. The initial patent for Humira expired in December 2016, but AbbVie secured more than 100 additional patents to cover small changes like manufacturing methods and the drug's formulation. As a result, while the price of Humira is going down in other countries, it is continuing to increase in the U.S., where AbbVie's existing patent protections will remain in effect until at least July 2023.[1,2]

In FY 2019-20, Colorado Medicaid spent over $58 million on claims for Humira, which averaged $35,175 per client over the year.

1 Hakim, D. (2018, January 6). Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher. The New York Times. https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html

2 Koons, C. (2017, September 7). This Shield of Patents Protects the World's Best-Selling Drug. Bloomberg Businessweek. https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug#:~:text=Over%20Humira's%20lifetime%2C%20AbbVie%20has,%2416%20billion%20in%20annual%20sales.

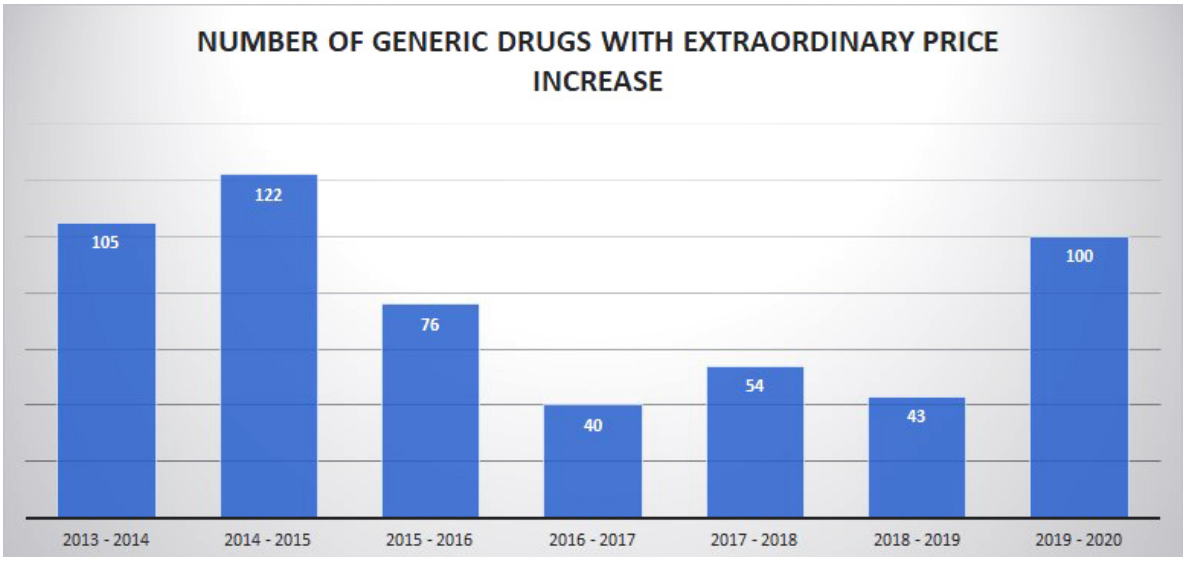
44 FTC Staff. (2010). *Pay-for-Delay: How drug Company Pay-Offs Cost Consumers Billions*. Federal Trade Commission. https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

45 Federal Trade Commission. (2018, October 31). Pay for Delay. FTC Media Resources. https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

46 Dickson, V. (2018, June 19). MACPAC proposes changes to Medicaid drug rebate program. Modern Healthcare. https://www.modernhealthcare.com/article/20180619/NEWS/180619894/macpac-proposes-changes-to-medicaid-drug-rebate-program

market share."[47] This is one of several lawsuits that have been filed against manufacturers in an ongoing investigation into price fixing, market allocation, bid rigging and other anti-competitive conduct. According to the Department of Justice in another filed lawsuit, consumers were overcharged by at least $350 million by one drug manufacturer alone as the result of its participation in three conspiracies.[48] Figure 7 shows how many generic drugs went through an "extraordinary" price increase, defined as an increase of 100% or more from the previous year. In total, there were 443 generic drugs that experienced 540 price increases.

Figure 7. Number of Generic Drugs with an Extraordinary Price Increase FY2013-14 through FY2019-20[49]



Specialty Drugs

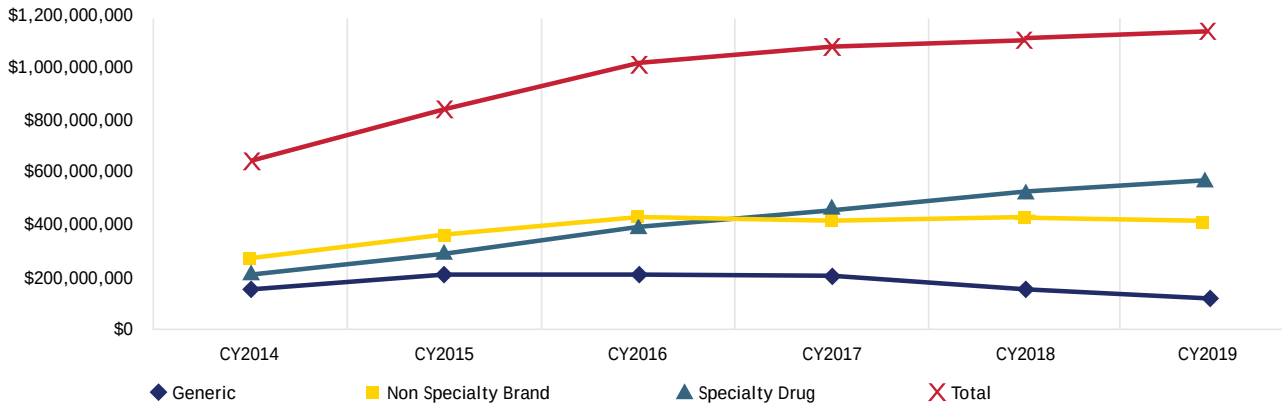
Specialty drugs—considered highly complex, highly specialized, or very expensive—represent a significant portion of pharmaceutical spending. Among all Medicaid payers nationally in 2019, specialty drugs represented 48.5% of net spending while only comprising 1.3% of utilization.[50] In comparison, an analysis of FY2019-2020 claims data from Colorado Medicaid revealed that 48% of total pharmacy expenditures were for specialty drugs, while only representing 1.42% of actual prescriptions (See Figure 2). At the same time, nearly half of the $1.18 billion spent by private insurers (insured business only, not including self-funded) on prescription drugs was for specialty drugs (49%). This is significantly higher than brand-name drugs (31%) and generics (19%).[51] Similar to the results for Colorado Medicaid, for private payers, specialty drugs represented nearly half of all prescription drug costs while only representing 1-2% of all

47 State of Connecticut v. Sandoz Inc, (United States District Court for the District of Connecticut 2020). https://ag.ny.gov/sites/default/files/final_redacted_public_derm_complaint.pdf
48 Office of Public Affairs. (2020). *Seventh Generic Drug Manufacturer Is Charged In Ongoing Criminal Antitrust Investigation* [Press Release]. Department of Justice. https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation
49 Footnote: Internal analysis of HCPF data
50 Stevens, S., Delk, M., Brown, D., Andrews, C., & Phelps, T. (2020). Medicaid Trend Report (5th edition; Magellan Rx Management Medicaid Trend Report). Magellan Rx Management. https://www1.magellanrx.com/read-watch-listen/read/our-publications/medicaid-pharmacy-trend-report/
51 Center for Improving Value in Health Care (CIVHC). (2020) 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.

prescriptions filled, (see Figure 1). Regardless of payers, specialty drugs now represent almost half of our nation's prescription drug spending. Tackling prescription drug costs in a meaningful way requires focused effort on addressing the prices of specialty drugs.

A notable example is Zolgensma, a drug approved by the FDA in May of 2019 to treat spinal muscular atrophy, a rare genetic disorder in children. It is the most expensive drug on the market, with the pharmaceutical company charging $2.125 million per patient to private insurance payers.[52] However, Zolgensma—like most other commercially produced pharmaceuticals—was developed with the help of millions of dollars in subsidies and donations from taxpayers, charities, and non-profit research institutions (see Appendix VII). In essence, this means that people are paying for the drugs multiple times—paying through taxes to help develop them, then purchasing them when they need them for treatment.

Figure 8. Colorado Medicaid Total Pharmacy and Physician-Administered Drug Expenditures by Calendar Year and Drug Type



Source: Colorado Medicaid, internal analysis (2020)

Specialty drugs are a dominant driver of drug expenditures. Per capita spending on specialty drugs accounts for $384 of the $895 average spent on medicines per person every year, or 43%, before rebates.[53] Over six years (2014-2019), Colorado Medicaid's prescription drug benefit costs, before credits from manufacturer rebates, rose 77%, with 72% of that growth driven by specialty drugs. That is an increase of approximately 12.8% each year, before rebates. However, the trends were not evenly spread. From 2014-2019, a period of six years:

- Generic drug spending slightly decreased (9% over the period, or 1.5% per year)
- Brand-name drug spending increased slightly (56% over the period, or about 9.3% per year)
- Specialty prescription drugs rose 164%, or an average of 27.3% per year

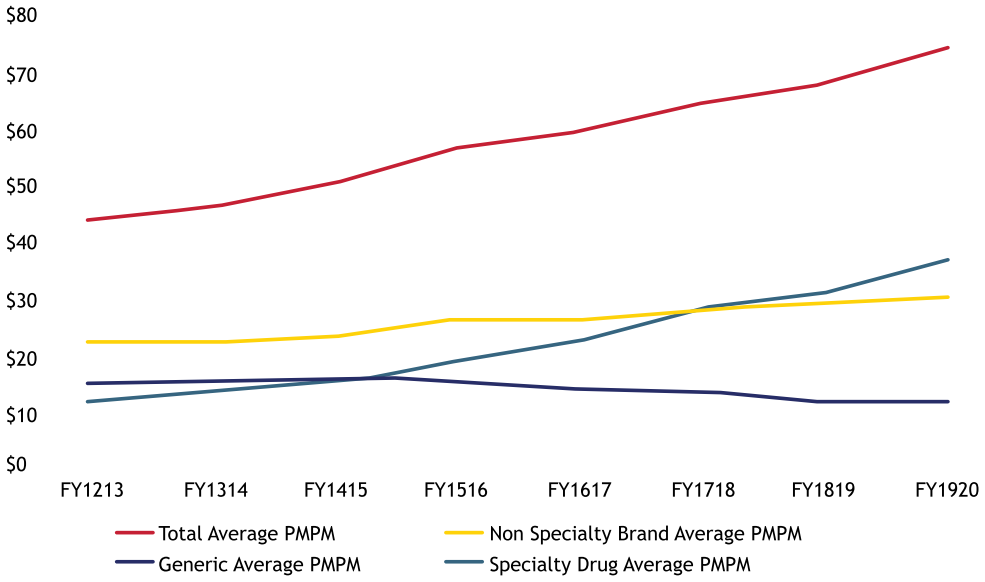
In a Colorado Medicaid analysis released in 2020, the Department found specialty drug costs increased over 11% between FY2018-2019 and FY2019-2020, before rebates.[54]

52 Humer, J. M., Caroline. (2019, May 24). Novartis $2 million gene therapy for rare disorder is world's most expensive drug. Reuters. https://www.reuters.com/article/us-novartis-genetherapy-idUSKCN1SU1ZP

53 Aitken, M., & Kleinrock, M. (2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022.* IQVIA Institute for Human Data Science. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

54 Colorado Department of Health Care Policy & Financing. (January 2020) ACC Implementation Legislative Report FY19-20. https://www.colorado.gov/pacific/hcpf/publications

Figure 9. Rising Prescription Costs, Per Member Per Month (PMPM) in Colorado Medicaid, Before Rebates



Source: Colorado Medicaid internal analysis. (2020)

Specialty drugs that utilize breakthrough research, harness new genetic and biologic medicine, and treat rare diseases are extraordinarily valuable.

Specialty drugs represent hope and quality of life for many individuals who previously had none. Determining the price of such drugs is complex, considering the cost of research and development, quality of life, and low volume of patients using the the drug. However, current pricing models are unsustainable for patients, for employers and for payers — both public and private.[55]

Orphan and Specialty Drugs in the Pipeline

The Orphan Drug Act was created in 1983 to "provide incentives for the development of potentially promising orphan drugs that may not otherwise be developed and approved."[56] These incentives include tax incentives for clinical testing, exemption from the required prescription drug user fee with the drug application, and seven years of market exclusivity.[57] The Act has successfully improved research in the area of rare disease, but it may also have paved the way for higher cost therapy and new income streams. In 2019, the FDA approved 48 new drugs. Twenty-one of those were for rare or orphan diseases, which are diseases affecting 200,000 or fewer Americans.[58]

46 **new drugs launched in 2017**

75% **were specialty drugs**

$12 billion **spent on new drugs in 2017**

80% **was spent on specialty drugs**

Specialty drugs are dominating the pipeline of drugs in development.

SOURCE: Center for Drug Evaluation and Research. (2018). Advancing Health Through Innovation 2017 New Drug Therapy Approvals [New Drug Therapy Approvals]. US Food & Drug Administration.

55 Aitken, M., & Kleinrock, M. (2018). *Medicine Use and Spending in the U.S.: A review of 2017 and Outlook to 2022.* IQVIA Institute for Human Data Science. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022

56 Food and Drug Administration (2019). Orphan drug regulations: Regulatory history. FDA. https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/orphan-drug-regulations-regulatory-history

57 Ibid

58 Center for Drug Evaluation and Research. (2020). *New drug therapy approvals 2019.* Food and Drug Administration. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019

According to a 2019 study by America's Health Insurance Plans, a trade association of health insurance companies, the average annual cost (based on list price) of an orphan drug in 2017 was $186,758.[59] Due to the lack of competition or access to alternative therapies, payers and patients are forced to utilize the highly expensive orphan or specialty drug.

The high prices, the increasing availability, and the increasing utilization of specialty drugs has resulted in manufacturers increasing their investment and focus on them. The blue box on page 22 illustrates the dominance in specialty drug investment over other research and development. Left unchecked, this strategic investment decision trajectory by manufacturers will have a profound economic impact on the cost of pharmaceutical therapy and the associated prescription drug benefits cost to consumers, employers and public programs, like Medicaid, in the years to come.

Three factors are creating a perfect storm that is fueling rising prescription drug cost trends: the extended patent protection period, a manufacturer focus on specialty drugs, and the lack of transparency and oversight into the pricing of specialty drugs.

The Prescription Drug Pipeline: What is coming next?

The Department has prepared a *Prescription Drug Pipeline Report* in 2020 (Appendix VI) with an overview of drugs that are in the late stages of approval and may have a significant impact on patient health and/or on expenditures. The drug pipeline refers to the set of pharmaceutical drugs that are in the process of being developed, researched, and approved for market adoption. After a manufacturer develops a drug and obtains approval to test it in humans, a three-phase process is used to assess whether the drug is safe and effective for use in humans. Monitoring the drugs that are in Phase 2 or 3 trials and estimating their approval dates allows stakeholders to prepare for the impact of a new drug hitting the market. Currently, many of the drugs in the drug pipeline target the COVID-19 virus, hemophilia (A and B), Duchenne muscular dystrophy, spinal muscular atrophy, cystic fibrosis, sickle cell disease, nonalcoholic steatohepatitis (NASH), atopic dermatitis, or specific cancers (for example, acute lymphocytic leukemia or multiple myeloma). Some of the drug types being developed include gene therapies, chimeric antigen receptor T-cell (CAR T-cell) therapies, clustered regularly interspaced short palindromic repeats gene editing technologies (CRISPR), or exon skipping therapies.

59 America's Health Insurance Plans. (2019). *The Rise of Orphan Drugs* [Issue Brief]. AHIP. https://www.ahip.org/wp-content/uploads/IB_OrphanDrugs-1004.pdf

Gene Therapy Example: valoctocogene roxaparvovec

This therapy is intended to treat severe hemophilia A and will enable patients to produce their own coagulation Factor VIII to achieve adequate clotting levels.[1] If approved, this will be a breakthrough therapy for hemophilia patients. The FDA issued a complete response letter (meaning the FDA did not approve the application with the submitted information) in August 2020, requesting the drug manufacturer to provide more follow-up data to assess how well the therapy maintains its effect over time.[2] This additional information should provide more safety and efficacy data to help the FDA make a final determination on whether or not the drug is approved. Since this additional follow-up clinical data will be completed prior to approval, health care providers and payers will have more robust evidence to guide clinical decision making, such as when the drug should be used, which patients are anticipated to receive the best effects, and how long the treatment is expected to last (durability). In addition, after a drug of this nature is approved and available in the U.S. market, a much larger number of patients with different but commonly accompanying health conditions can receive it. In some cases, new clinical information may be learned after the approval process, which, in severe cases of safety concerns, can lead to removal of the drug from the market. Valoctocogene roxaparvovec has a projected one-time price of $2 to $3 million per patient.[3]

1 Roctavian (formerly Valrox/BMN 270). (2020, August 25). *Hemophilia News Today.* https://hemophilianewstoday.com/bmn-270/
2 Carvalho, J. (2020, August 19). FDA delays decision on roctavian, hemophilia a gene therapy candidate, for a year or more. Hemophilia News Today. https://hemophilianewstoday.com/2020/08/19/fda-delays-decision-roctavian-hemophilia-a-gene-therapy
3 Ahle, S. (2020, March 1). Biomarin sets high price tag for hemophilia gene therapy candidate. ASH Clinical News. https://www.ashclinicalnews.org/online-exclusives/biomarin-sets-2-3-million-price-tag-hemophilia-gene-therapy-candidate/

Upcoming Drug Therapies

Gene Therapy: To address diseases related to a particular gene mutation, a working copy of a missing or dysfunctional gene is created and placed into a vector, such as a virus (for example, an adeno-associated virus, which does not cause known disease or harm). The vector then transports the gene to the target cells within the patient's body, where the gene is incorporated into the cell nucleus and creates the desired change.[60] This methodology is highly specialized, is currently used in rare diseases, and often is very expensive. The FDA has received 900 applications for gene therapy clinical studies.[61]

Chimeric Antigen Receptor T-cell (CAR T-cell) Therapy: CAR T-cell therapy is a unique treatment because the therapy is manufactured using the patient's own immune system cells. The drug manufacturing process begins by extracting blood from the patient (leukapheresis) and sending T-cells from the patient's blood to a specialized lab where they are modified so they can better recognize and attack cancer cells. The modified cells are then packaged and sent to the original patient, where they are administered through an IV infusion.[62] These therapies are intended to be once-per-lifetime treatments. The CAR T-cell therapies already on the market are priced at $373,000 - $475,000 per treatment.[63,64]

60 How does gene replacement therapy work? (n.d.). Retrieved from https://exploregenetherapy.com/how-gene-replacement-therapy-works
61 Office of the Commissioner. (2020). *FDA Continues Strong Support of Innovation in Development of Gene Therapy Products* [Press Release]. Food & Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-continues-strong-support-innovation-development-gene-therapy-products
62 CAR T-cell therapy. (n.d.). National Cancer Institute. Retrieved December 3, 2020, from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy
63 Andrews, M. (2018, July 17). Staggering prices slow insurers' coverage of car-t cancer therapy. Kaiser Health News. https://khn.org/news/staggering-prices-slow-insurers-coverage-of-car-t-cancer-therapy/
64 *Gilead's second act in cell therapy gets its first approval.* (n.d.). BioPharma Dive. Retrieved December 3, 2020, from https://www.biopharmadive.com/news/gileads-second-act-in-cell-therapy-gets-its-first-approval/582295/

Clustered regularly interspaced short palindromic repeats (CRISPR) gene editing technologies: This complex mechanism uses a naturally-occurring system by which bacteria prevent viral infections by identifying and targeting genetic sequences for destruction. The 2020 Nobel Prize in Chemistry was given to Jennifer Doudna and Emmanuelle Charpentier for their discovery of this gene editing technique.[65] The most advanced clinical studies for drug treatments using this technology are for blood diseases, such as sickle cell anemia and thalassemia. However, CRISPR treatments have potential to treat a wide range of diseases including cystic fibrosis, hereditary blindness, and cancer. These therapies utilizing CRISPR technology are expected to be priced in the range of $1 to $2 million per treatment.[66,67]

Exon skipping therapies: There are three exon skipping therapies currently approved. They are intended to treat Duchenne muscular dystrophy (DMD), an inherited and often terminal disease occurring primarily in young boys. Exon skipping drugs fix or repair the missing part of the gene so that it may function more normally and produce a protein called dystrophin. The exon skipping therapies are examples of when approvals are based on surrogate markers or biomarkers as the measured outcome.[68] While these drugs have been proven to affect changes in biomarkers, these changes do not always translate into clinical outcome improvements and may need further study. Approved therapies on the market are currently priced in the range of $300,000-$748,000 per patient, per year.[69,70] Dosing for these therapies is based on a patient's weight and therefore can vary significantly in price.

Hospital Pricing Markup and Site of Care Pricing Differentials

The methods hospitals use to determine their drug therapy prices also impact how much a health plan, employer and, ultimately, a consumer pays for that drug. A hospital may contract with a specialty pharmacy or wholesaler to acquire the drug at a particular price and then charge the health plan a higher price, which results in an increase in profits to the hospital.

A growing body of research examining the site of care where injectable and infused drugs are administered indicates that commercial payers reimburse hospitals and hospital clinics at a higher rate than physician offices.[71] Analysis done by the Partnership for Health Analytic Research shows that physician offices and hospital clinics treat similar numbers of patients, but hospitals receive a larger share of gross profits.[72] Accordingly, health plans often work with

65 Ledford, H., & Callaway, E. (2020). Pioneers of revolutionary CRISPR gene editing win chemistry Nobel. *Nature*, 586(7829), 346–347. https://doi.org/10.1038/d41586-020-02765-9

66 Terry, M. (2019, November 19). *CRISPR therapeutics and Vertex: Promising gene therapy data for sickle cell disease and beta thalassemia. BioSpace.* https://www.biospace.com/article/crispr-therapeutics-and-vertex-report-promising-results-in-crispr-trials

67 Cystic Fibrosis Foundation. (n.d.). *Gene Editing for Cystic Fibrosis.* Retrieved December 3, 2020, from https://www.cff.org//Research/Research-Into-the-Disease/Restore-CFTR-Function/Gene-Editing-for-Cystic-Fibrosis/

68 Katz R. (2004). Biomarkers and surrogate markers: an FDA perspective. *NeuroRx: the journal of the American Society for Experimental NeuroTherapeutics,* 1(2), 189–195 https://www.sciencedirect.com/science/article/abs/pii/S1545534306700347

69 Figueiredo, M. (n.d.). *Vyondys 53 available to duchenne patients in the U.S. R*etrieved December 3, 2020, from https://musculardystrophynews.com/2019/12/20/vyondys-53-available-duchenne-patients-in-the-us/

70 F*DA gives speedy approval to another Duchenne drug.* (n.d.). BioPharma Dive. Retrieved December 3, 2020, from https://www.biopharmadive.com/news/viltolarsen-duchenne-fda-approval-ns-pharma/583410/

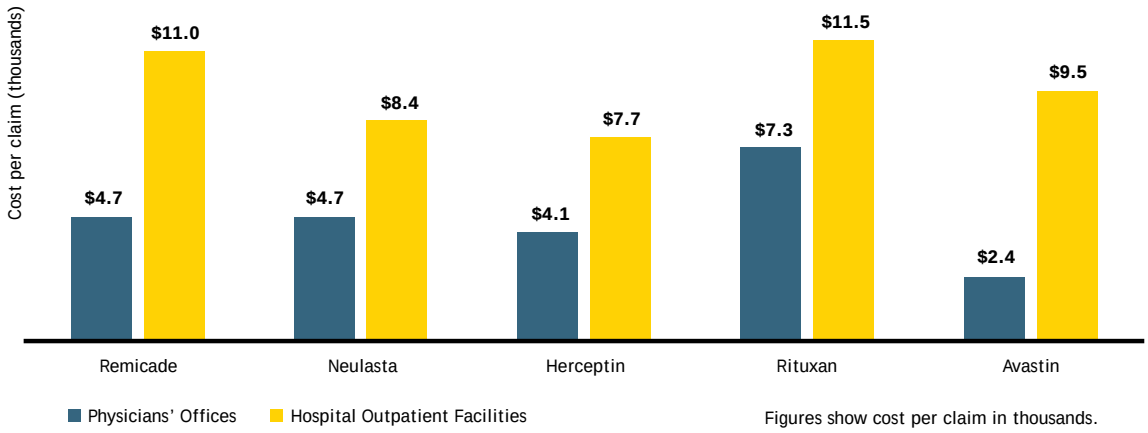
71 Winn, A. N., Keating, N. L., Trogdon, J. G., Basch, E. M., & Dusetzina, S. B. (2018). Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA Oncology, 4(4), 580. https://doi.org/10.1001/jamaoncol.2017.5544

72 Ortendahl, J. D., & Bognar, K. (2019). *Estimation of Hospital Share of Gross Profits for Physician-Administered Medicines Reimbursed by Commercial Insurers.* Partnership for Health Analytic Research LLC. http://www.pharllc.com/wp-content/uploads/2019/09/Hospital-Margin-Analysis-Report-Slide-Doc.pdf

patients to coordinate or redirect drug therapy administration to the most cost-effective site of care, such as home infusion or a physician's office.

An example of the cost difference by site of care is the average cost per unit of Remicade, which is used to treat rheumatoid arthritis, among other illnesses. In a physician's office, a single dose is $90. In a hospital outpatient clinic, however, that same dose is $227, over 150% more costly. This difference is closely aligned with the 148% price difference average associated with the examples in the chart below.[73] Figure 10 illustrates that this discrepancy in the cost of the same drug at different sites is not isolated to Remicade alone." [If the previous sentence was discussing averages, it would go well here.] "In order to control costs, it is vital that there be plans and coordination in place to encourage patients to receive their medications in more cost-effective settings when they have a choice.

Figure 10. Claims Costs for Outpatient Specialty Drugs Are as Much as 3.9 Times Higher in Hospital Settings.[74]



SOURCE: Drug Channels Institute analysis of 2017 Medical Pharmacy Trend Report, Magellan Rx Management, 2018

Medicare's Inability to Negotiate Prices

One of the largest purchasers of prescription drugs is the Medicare program. Despite its size and influence, CMS is prohibited by law from negotiating directly with pharmaceutical manufacturers for lower drug prices. All negotiation with pharmaceutical manufacturers is through Medicare Part D plans and the PBMs that administer them. Congress banned the federal government from negotiating directly with pharmaceutical manufacturers for better prices on prescription drugs for Medicare Part D in 2003. Although 92% of Americans believe that policy should be overturned,[75] numerous proposals to do so have been defeated. A bipartisan group of former governors and senators, citing research from the Congressional Budget Office (CBO), concluded that allowing the federal government to negotiate drug prices would save an average of $11 billion per year.[76] A 2019 CBO letter estimates that the drug price negotiation provisions

73 Fein, A. J. (2018, August 8). Still Possible: Hospitals Overcharge Health Plans for Specialty Drugs. *Drug Channels*. https://www.drugchannels.net/2018/08/still-possible-hospitals-overcharge.html

74 Ibid

75 Cubanski, J., & Neuman, T. (2018). *Searching for Savings in Medicare Drug Price Negotiations* [Issue brief]. KFF. http://files.kff.org/attachment/issue-brief-searching-for-savings-in-medicare-drug-price-negotiations

76 *Fact Sheet: How much money could Medicare save by negotiating prescription drug prices?* (2016). Committee for a Responsible Federal Budget. https://www.crfb.org/press-releases/fact-sheet-how-much-money-could-medicare-save-negotiating-prescription-drug-prices

in a bill introduced in 2019, H.R. 3, among other provisions, would achieve $345 billion in Medicare savings between 2023 and 2029.[77]

Nonetheless, Medicare recognizes the importance in addressing increasing drug costs. On Nov. 20, 2020, the U.S. Department of Health & Human Services announced a drug payment model that will lower Medicare Part B payments for certain drugs to the lowest price paid in similar countries.[78] Medicare Part B covers drugs which typically need to be administered in a doctor's office or hospital outpatient setting. HHS estimates that the cost savings to the government and patients will be more than $85 billion over seven years. This savings potential just underscores the fact that the U.S. pays the highest drug prices in the developed world, and that we have a shared opportunity to implement such pricing controls across all payer types to the benefit of consumers as well as public programs like Medicaid, commercial payers and self-funded employer benefit plans.

Prescription Drug Rebates

In the commercial market, a rebate is the return of part of the purchase price by the seller to the buyer.[79] For commercial health plan carriers, the rebates are paid by the manufacturers to a PBM or a carrier middleman to encourage the use of a particular drug by lowering the net cost of the drug paid by the health plan. In Colorado, a study of the 2018 commercial rebates and other compensation paid by manufacturers to insurance carriers and their PBMs indicates that such payments to middlemen represented 22% of specialty drug spending and 18% of brand-name drug spending. That year, commercial payers received approximately $179 million in rebates reflecting the amount received for insured business and a very limited number of self-funded plans. The report also indicated that between 2016 and 2018, rebates increased by about 50%, rising from 11% to become 16% of prescription drug spending.[80] The consequences of high rebates and other PBM/carrier compensation may include:

- The lack of transparency into the pricing of a drug enables manufacturers to increase a drug's price to accommodate the payment of rebates to middlemen like PBMs and insurance carriers.
- Rebates in the commercial arena reward insurance carriers and PBMs for giving drugs preferred formulary status, often drugs with a higher list price. This misaligned incentive may result in the increased utilization of higher cost drugs, thereby increasing the cost of the prescription drug benefit to employers and consumers.
- PBMs and carriers may or may not share some or all manufacturer rebates and other such compensation paid to them with employers and other clients. This increases PBM and health plan profits and increases the net cost of the prescription drug benefit to employers and consumers. PBMs and carrier retention of rebates and other manufacturer compensation is concurrent with significant increases in carrier profits and the acquisition of PBMs by insurance carriers.[81]

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77 Swagel, Phillip (Nov 2019) Letter from the Congressional Budget Office to Committee on Energy and Commerce, U.S. House of Representatives https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf

78 U.S. Department of Health & Human Services. (2020) Trump Administration Announces Prescription Drug Payment Model to Put American Patients First. Nov. 20. https://www.hhs.gov/about/news/2020/11/20/trump-administration-announces-prescription-drug-payment-model-to-put-american-patients-first.htm

79 Alston, M., Dieguez, G., & Tomicki, S. (2018). *A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices.* Milliman. https://www.milliman.com/en/insight/a-primer-on-prescription-drug-rebates-insights-into-why-rebates-are-a-target-for-reducing

80 See Appendix VI: Center for Improving Value in Health Care (CIVHC). (2020) 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.

81 *Drug Pricing in America: A Prescription for Change, Part III,* (2019) (testimony of John M. Prince). https://www.finance.senate.gov/imo/media/doc/John%20Prince%20OptumRx%20Testimony%20Senate%20Finance%20Committee_04.09.19.pdf

Figure 11 indicates a 146% increase in prescription drug rebates as a percent of overall costs over a 5-year period for a large national group benefit plan with members in Colorado. This large self-funded group has contracted with one of the nation's largest PBMs to receive 100% of rebates. These rebates represent a 163% increase in payments back to the group benefit plan available to offset their prescription drug costs—an increase from $3.9 million to $10.24 million over the 5-year period. This example illustrates the positive financial impact on the plan when all rebates are passed through to the plan.

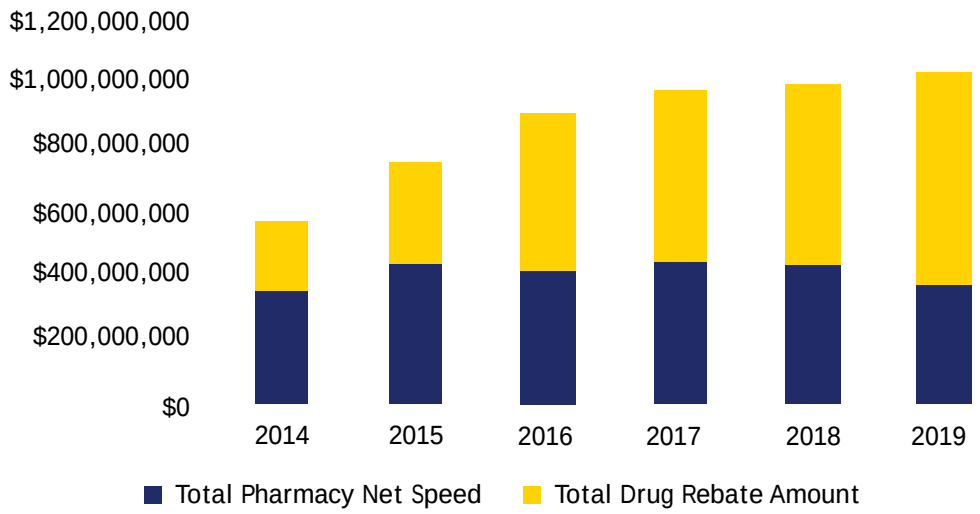
Figure 11. Rebate Through the Years for a Large National Fund

Year	Total Drug Rebate Amount	Rebate Percentage of Total Paid Amount
2014	$3,887,231	9.93%
2015	$5,381,390	12.91%
2016	$5,727,7890	13.09%
2017	$8,467,045	20.73%
2018	$10,243,478	24.39%

SOURCE: Mercer

If employers are not receiving 100% of the manufacturer rebate, or if they are relying on a specific rebate guarantee per prescription that is not increasing each year, they are paying too much for their prescription drug benefit and inviting increasing profits for their contracted middlemen PBMs and insurance carriers.

Figure 12. Total Colorado Medicaid Pharmacy Expenditure, Including Rebate Offset, 2014-2019[82]



Source: Colorado Medicaid (2020)

While Medicaid rebates are different, the increase in the actual rebates to Colorado Medicaid as a percent of total prescription drug expenditures as noted in Figure 12 reinforces the directional increase in the value of rebates. In Medicaid, 100% of rebates flow to the state and federal government, enabling Colorado Medicaid to reduce its prescription drug benefit cost-driving savings that benefit the state budget and taxpayers.

82 Internal analysis of Colorado Medicaid (2020)

Without transparency into rebates and other related compensation among drug manufacturers and carriers/PBMs, many employers, union trusts, municipalities and the like—especially small employers and individuals—are only experiencing the increase in rising prescription drug costs and not the concurrent increase in rebates and other compensation to offset them. Given that Colorado is a small employer state, the lack of transparency into rebates and lack of rebate and other manufacturer compensation pass-through is likely having an even more adverse impact on rising prescription drug costs to both the small employer and individual markets, where bargaining power is extremely limited.

In a speech to the Bipartisan Policy Center in February 2019, U.S. Secretary of Health & Human Services Alex Azar said more than $150 billion of drug rebates are passed around the system each year, largely without public knowledge and sometimes without public benefit.[83]

The U.S. Department of Health & Human Services recognized that manufacturer rebates are driving increasing drug list prices and patient out-of-pocket expenses. In response, a federal regulation was passed which will be effective in 2022 that expressly excludes manufacturer drug rebates paid to pharmacy benefit managers and Part D plans from safe harbor protection under the federal Anti-Kickback Statute (AKS).[84] The regulation also creates a new safe harbor, protecting manufacturer discounts provided directly to patients at the pharmacy counter. In effect, the rule will prohibit manufacturers from paying rebates to PBMs and Part D plans while incentivizing manufacturers to offer discounts directly to Medicare patients at the point of sale. HHS expects the regulation will help lower drug list prices and out-of-pocket costs.

Pharmacy Benefit Managers (PBMs): Pricing, Profits and Consolidation

In addition to the practice of retaining rebates and other compensation from drug manufacturers (i.e., discounts, market share allowances, etc.), carriers or PBMs may be benefiting from higher list prices as well as the widening gap between what the carrier/PBM pays for the drug and the retail price they charge the employer or consumer for the drug. The higher price is incorporated into the price of individual and employer insurance policies.

There is also some concern about consolidation in the industry. As of 2018, three PBM companies control 72% of the prescription drug market: Express Scripts owned by Cigna, CVS Caremark owned by Aetna, and OptumRx owned by UnitedHealth Group.[85]

- OptumRx (UnitedHealth Group) acquired Catamaran in 2015[86] (which was Cigna's contracted PBM at the time).
- Cigna acquired Express Scripts in 2018[87] after Express Scripts had already acquired Medco in 2012.

83 Azar II, A. M. (2019, February 1). *Remarks to the Bipartisan Policy Center* [Text]. The Bipartisan Policy Center, Washington DC. https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-to-the-bipartisan-policy-center.html

84 U.S. Department of Health & Human Services. (2020) Fact Sheet: Trump Administration Finalizes Proposal to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients. Nov. 20. https://www.hhs.gov/about/news/2020/11/20/fact-sheet-trump-administration-finalizes-proposal-to-lower-drug-costs.html

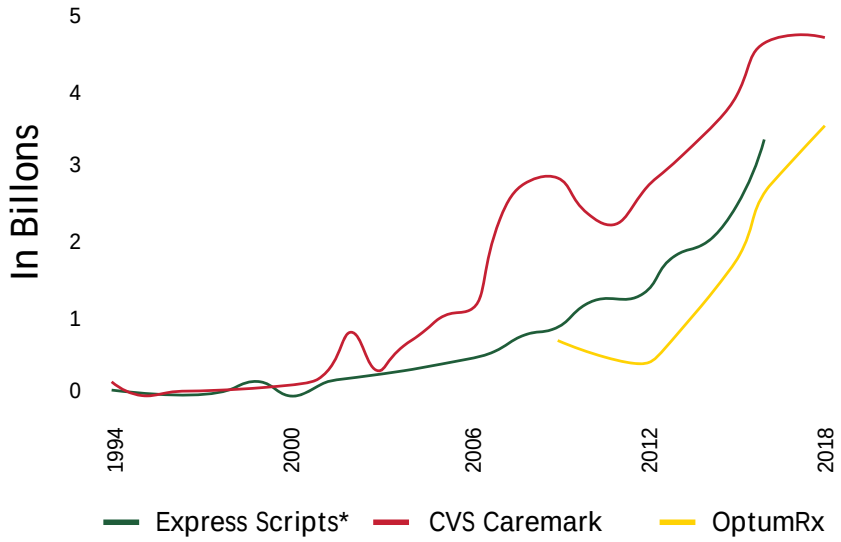
85 Herper, M. (2018, March 8). Cigna's $54 Billion Purchase Of Express Scripts Could Upend The Prescription Drug Market. *Forbes*. https://www.forbes.com/sites/matthewherper/2018/03/08/cignas-54-billion-purchase-of-express-scripts-could-upend-the-prescription-drug-market/

86 Optum. (2015). OptumRx, *Catamaran Complete Combination* [Press Release]. Optum. https://www.optum.com/about-us/news/optumrx-catamaran-complete-combination.html

87 Cigna. (2018). *Cigna Completes Combination with Express Scripts, Establishing a Blueprint to Transform the Health Care System* [Press Release]. Cigna. https://www.cigna.com/about-us/newsroom/news-and-views/press-releases/2018/cigna-completes-combination-with-express-scripts-establishing-a-blueprint-to-transform-the-health-care-system?rel=0

- CVS acquired Aetna in 2018, after it acquired Caremark Rx, a PBM, in 2007.[88]
- Anthem terminated its relationship with Express Scripts and created its own PBM holding company in 2019.[89]

Figure 13. Annual PBM Profits



*Figures unavailable for 2017 and 2018

SOURCE: National Community Pharmacists Association (NCPA)

The alignment of PBMs and insurance carriers is correlated with significant increases in PBM profits as noted in Figure 13.

Rising Prescription Drug Manufacturer Profits

The average profit margins among large pharmaceutical manufacturers are higher than most other industries, such as carmakers, oil and gas, or media. Between 2000-2018, the 35 largest pharmaceutical companies had on average about 6% more net income than other large nonpharmaceutical companies, totaling $11.5 trillion in gross profit.[90] Total revenues for the top 10 pharmaceutical companies range from $24 to $81 billion in 2018, impacting overall prescription drug costs ultimately paid by consumers, employers and other payers.[91] These staggering numbers are an illustration of the difference between the price of drugs and the cost, underscoring the opportunity to lower prescription drug prices to the benefit of consumers, employers, union trusts and other payers.

88 CVSHealth. (2018). *CVS Health Completes Acquisition of Aetna, Marking the Start of Transforming the Consumer Health Experience | CVS Health* [Press Release]. CVS Health. https://cvshealth.com/news-and-insights/press-releases/cvs-health-completes-acquisition-of-aetna-marking-the-start-of

89 Anthem. (2019). *Anthem Reports Fourth Quarter and Full Year 2018 Results Reflecting Strong Core Performance | Anthem, Inc.* [Press Release]. Anthem. https://ir.antheminc.com/news-releases/news-release-details/anthem-reports-fourth-quarter-and-full-year-2018-results

90 Ledley, F. D., McCoy, S. S., Vaughan, G., & Cleary, E. G. (2020). Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies. *JAMA*, 323(9), 834. https://doi.org/10.1001/jama.2020.0442

91 GlobalData. (2019). *GlobalData presents growth snapshot of top 20 pharma companies by revenue in 2018.* GlobalData. https://www.globaldata.com/growth-snapshot-of-the-top-20-pharmaceutical-companies-by-revenue-in-2018/

The common claim that high prices are the result of research and development is also in dispute, given how manufacturers receive money for research from government agencies, charities, and advocacy groups.[92,93,94] As an example, the National Institutes of Health (NIH) funds over $40 billion in medical research every year. NIH funds research that examines fundamental biological and chemical mechanisms of body and disease, which is a vital first step in drug therapy development.[95] In September 2020, the U.S. House Oversight Committee declared that the main driver of pharmaceutical cost was not research and development, but the pursuit of profit.[96] As an example, in an interview on Mad Money on CNBC, CEO Jean-Jacques Bienaime stated that BioMarin's price-setting for their new adult phenylketonuria (PKU) drug, a $4 billion market opportunity, was based on the current market cost of treatment, which BioMarin also manufactures and prices, not the cost of research and development.[97] Improvements in transparency policy would enable policymakers to better understand prescription drug prices, related revenues impacting the overall cost of health care, and manufacturer profits as drivers of rising health care costs.

Prescription Drug Promotional Marketing

In the past 20 years, spending on medical marketing in the U.S. increased from $17.7 billion to $29.9 billion per year. At the same time, drug companies paid more than $11 billion in fines for off-label or deceptive marketing.[98]

Drug companies spend about $40 billion a year more on sales and marketing expenses than on research and development of new drugs, as noted in Figure 14 below. Concluding that pharmaceutical marketing in the U.S. is driving up costs without adding measurable benefits to consumers, the American Medical Association in 2015 called for a ban on prescription drug advertising.[99]

92 Mazzucato, M. (2015, October 27). Op-Ed: How taxpayers prop up Big Pharma, and how to cap that. *Los Angeles Times.* https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html

93 Cleary, E. G., Beierlein, J. M., Khanuja, N. S., McNamee, L. M., & Ledley, F. D. (2018). Contribution of NIH funding to new drug approvals 2010–2016. *Proceedings of the National Academy of Sciences*, 115(10), 2329–2334. https://doi.org/10.1073/pnas.1715368115

94 Begley, S. (2007, January 26). Why Nonprofits Fund For-Profit Companies Doing Drug Research. *Wall Street Journal*. https://www.wsj.com/articles/SB116976906018088360

95 National Institute of Health. (2020) *Budget*. https://www.nih.gov/about-nih/what-we-do/budget

96 McAuliff, M. (2020, September 30). Drug company executives defend exorbitant price hikes in hearing. *Kaiser Health News*. https://www.nbcnews.com/health/health-news/high-drug-prices-driven-profits-house-panel-report-finds-n1241589

97 Cramer, J. (2019, November 15). Biomarin pharmaceutical CEO: substantial profits ahead. In *Mad Money.* CNBC. https://www.youtube.com/watch?v=YTCaxRP8dwo&feature=youtu.be

98 Schwartz, L. M., & Woloshin, S. (2019). Medical Marketing in the United States, 1997-2016. *JAMA*, 321(1), 80. https://doi.org/10.1001/jama.2018.19320

99 "AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices," American Medical Association Press Release, November 17, 2015, https://www.ama-assn.org/press-center/press-releases/ama-calls-ban-dtc-ads-prescription-drugs-and-medical-devices.

Figure 14. Total Revenue and Spending by Category, Top 10 Pharmaceutical Firms, 2014.

Company	Total Revenue ($bn)	R&D Spend ($bn)	Sales & Marketing Spend ($bn)	Profit ($bn)	Profit Margin (%)
Johnson & Johnson (U.S.)	71.3	8.2	17.5	13.8	19
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (U.S.)	51.6	6.6	11.4	22.0	43
Hoffmann-La Roche (Swiss)	50.3	9.3	9.0	12.0	24
Sanofi (France)	44.4	6.3	9.1	8.5	11
Merck (U.S.)	44.0	7.5	9.5	4.4	10
GSK (UK)	41.4	5.3	9.9	8.5	21
AstraZeneca (UK)	25.7	4.3	7.3	2.6	10
Eli Lilly (U.S.)	23.1	5.5	5.7	4.7	20
AbbVie (U.S.)	18.8	2.9	4.3	4.1	22

SOURCE: BBC 100

Unrestricted prescription drug advertising is permitted only in the U.S. and New Zealand. This is a notable utilization and cost driver ripe for policy change at the federal level.

Direct-to-consumer marketing is the costly promotion of prescription products directly to potential patients,[101] a practice which began in the U.S. in the early 1980s. The FDA regulates the advertisements in accordance with federal laws and regulations, which include requirements that the advertisements be balanced. However, over the years and through policy revisions, FDA oversight has weakened. For example, in 2002, HHS required that all regulatory warning letters be reviewed and approved by the FDA's Office of Chief Counsel before being issued to pharmaceutical companies. This requirement reduced the number of letters being issued.[102] Another difficulty the FDA has historically faced over the years has been the low number of dedicated staff members overseeing this policy.[103] Finally, direct-to-consumer advertisements by drug manufacturers are protected through a series of court decisions that have held that product advertisement is a form of commercial speech under the First Amendment.[104]

100 Anderson, R. (2014, November 6). Pharmaceutical industry gets high on fat profits. *BBC News.* https://www.bbc.com/news/business-28212223

101 Ventola, C. L. (2011). Direct-to-Consumer Pharmaceutical Advertising. *Pharmacy and Therapeutics,* 36(10), 669–684. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/

102 Dunn, A. (2018, October 3). FDA could set record low for drug marketing warning letters — again. BioPharma Dive. https://www.biopharmadive.com/news/fda-marketing-drug-warning-letters-record-low-trend/538688/

103 Ventola, C. L. (2011). Direct-to-Consumer Pharmaceutical Advertising. *Pharmacy and Therapeutics,* 36(10), 669–684. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/

104 Brannon, V. C. (2019). *Drug Price Disclosures and the First Amendment [*CRS Legal Sidebar]. Congressional Research Service. https://fas.org/sgp/crs/misc/LSB10298.pdf

Alkermes's Approach to Marketing Vivitrol in Justice Systems

Alkermes makes Vivitrol, a monthly injection to block opioid receptors in the brain. There are multiple similar FDA-approved options to treat and manage opioid addiction; Vivitrol is just one option. To increase their market share, Alkermes has chosen to market their product directly to the criminal justice system, including drug courts, judges, corrections officials, local law enforcement officers, and incarcerated individuals. Following this marketing, some drug courts are demonstrating a preference for using and recommending Vivitrol, even without strong evidence that it is more effective than less expensive options.

In Colorado, Alkermes has marketed to the Department of Corrections by offering "free" first doses of the drug just prior to release as detailed in 9News' six-month investigation published in May 2019: "An opioid addiction treatment that costs up to $1,300 a shot is costing Colorado taxpayers millions." The investigation followed individuals who were heavily targeted in marketing campaigns after treatment, looking at costs and effectiveness of the treatment.[105] Individuals leaving the corrections system may qualify for Colorado Medicaid coverage, in which case the State of Colorado pays for subsequent doses. Concurrent with these practices, Colorado Medicaid has seen a significant increase in costs for Vivitrol from $373,624 in 2014 to more than $8.8 million in 2019.[106] This medication is significantly more costly and harder to initiate than the equally effective medication for opioid addiction, buprenorphine.[107]

105 Vanderveen, C., Newman, Z., Hewson, A., & Grady, M. (2019, May 8). An opioid addiction treatment that costs up to $1,300 a shot is costing Colorado taxpayers millions. *KUSA.Com*. https://www.9news.com/article/news/investigations/medical-cost/an-opioid-addiction-treatment-that-costs-up-to-1300-a-shot-is-costing-colorado-taxpayers-millions/73-43a5166c-a222-41d2-bb89-2b0a8a1e1fb9

106 Analysis of calendar year claims data conducted by the Department of Health Care Policy & Financing, May 2019.

107 Lee, J. D., Nunes, E. V., Novo, P., Bachrach, K., Bailey, G. L., Bhatt, S., Farkas, S., Fishman, M., Gauthier, P., Hodgkins, C. C., King, J., Lindblad, R., Liu, D., Matthews, A. G., May, J., Peavy, K. M., Ross, S., Salazar, D., Schkolnik, P., … Rotrosen, J. (2018). Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial. *Lancet* (London, England), 391(10118), 309–318. https://doi.org/10.1016/S0140-6736(17)32812-X

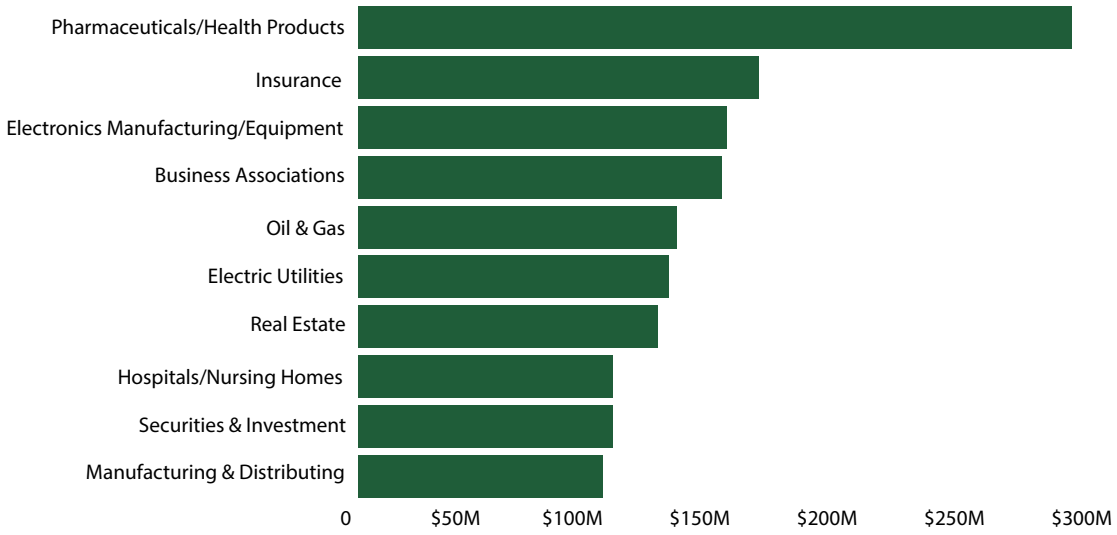
Marketing to Physicians

Pharmaceutical companies spend even more money marketing to physicians than directly to consumers. In 2016, of the $29.9 billion that pharmaceutical companies spent on marketing, $9.6 billion was for direct-to-consumer marketing while over $20 billion was spent on marketing to medical professionals.[108] In a study from the University of California-Los Angeles, a team analyzed the prescribing behavior of over 25,000 physicians at academic medical centers (AMCs) across the country, for 262 drugs throughout eight pharmaceutical categories between 2006 and 2012. The report found that AMCs that enacted policies limiting physician detailing were associated with a 1.67 percentage point decrease in the market share of detailed drugs."[109] Two publicly accessible websites now make pharmaceutical payments to prescribers more transparent: ProPublica and a CMS website created under the Sunshine Act.[110]

Lobbying Contributions to Drive Industry Policy

One significant challenge to making policy changes that would address rising prescription drug prices is the amount of money the pharmaceutical industry invests in lobbying efforts. The pharmaceutical industry spends more on lobbying efforts than any other type of industry, at more than $280 million per year just in federal lobbying efforts, as illustrated below.[111]

Figure 15. Top 10 Industries by Federal Lobbying Spending, 2018



SOURCE: The Center for Responsive Politics

108 Schwartz, L. M., & Woloshin, S. (2019). Medical Marketing in the United States, 1997-2016. *JAMA*, 321(1), 80. https://doi.org/10.1001/jama.2018.19320

109 Larkin, I., Ang, D., Steinhart, J., Chao, M., Patterson, M., Sah, S., Wu, T., Schoenbaum, M., Hutchins, D., Brennan, T., & Loewenstein, G. (2017). Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing. *JAMA*, 317(17), 1785. https://doi.org/10.1001/jama.2017.4039

110 ProPublica tool can be found at https://projects.propublica.org/docdollars/ and the CMS website can be found at https://www.cms.gov/openpayments/

111 Evers-Hillstrom, K. (2019, January 25). Lobbying spending reaches $3.4 billion in 2018, highest in 8 years. *OpenSecrets News*. https://www.opensecrets.org/news/2019/01/lobbying-spending-reaches-3-4-billion-in-18/

Learning from Other States

2018-2020 State Policy Update

In the past few years, several state governments acted to regulate the prescription drug market. During the 2020 state legislative sessions, 431 bills related to prescription drugs were introduced and 38 were signed into law; 159 of those bills introduced focused on regulating pharmacy benefit managers (PBMs), 71 bills focused on cost sharing and coupons, and 61 bills related to drug cost transparency.[112] The low passage rate of the 2020 introduced bills is likely a result of COVID-19 disrupting many legislative session calendars in mid-March. Many state legislatures were forced to adjourn early.[113]

In 2019, 272 bills related to prescription drugs were introduced and 51 were signed into law by states across the country. Roughly, 52 of the bills introduced related to price transparency and five passed.

In 2018, 178 bills related to prescription drugs were introduced and 46 were signed into law. Many of the bills passed related to regulating pharmacy benefit managers. Other legislation focused on mandating disclosures to government accountability agencies.[114]

For the full list of state prescription drug legislation, please visit the National Academy for State Health Policy (NASHP) website www.nashp.org/rx-legislative-tracker/[115]

In 2020, the Colorado Department of Health Care Policy & Financing supported a number of bills introduced to the Colorado General Assembly regarding transparency in drug pricing, rebate pass-through and expansion of drug importation. While none of these bills passed due to the truncated session caused by the COVID-19 pandemic, the sponsors had strong support and were expecting a favorable outcome.

Importation and Manufacturing

During the 2020 legislative session, **New Hampshire**[116] (HB 1280) and **New Mexico**[117] (SB 1), joined the growing list of states that have enacted legislation to establish an importation program for prescription drugs from Canada. Previous states that have passed similar legislation include Colorado, Maine, Vermont and Florida.[118]

112 *State legislative action to lower pharmaceutical costs.* (2020, October 27). National Academy for State Health Policy. https://www.nashp.org/rx-legislative-tracker/

113 *2020 Legislative Session Calendar.* (2020, October 28). National Conference of State Legislatures. https://www.ncsl.org/portals/1/Documents/ncsl/2020_session_calendar.pdf

114 Analysis of State Prescription Drug Legislative Tracker 2018, National Academy for State Health Policy, https://www.nashp.org/wp-content/uploads/2019/01/RxTracker-Final-2018.pdf

115 The National Academy for State Health Policy. (2020, November 24). *State Legislative Action to Lower Pharmaceutical Costs.* The National Academy for State Health Policy. https://www.nashp.org/rx-legislative-tracker/

116 Relative to co-payments for insulin, establishing a wholesale prescription drug importation program, establishing a New Hampshire prescription drug affordability board, establishing the prescription drug competitive marketplace, relative to the pricing of generic prescription drugs, relative to prior authorization for prescription drug coverage, and requiring insurance coverage for epinephrine auto-injectors, HB1280, 2020 Regular Session (2020). https://legiscan.com/NH/bill/HB1280/2020

117 Wholesale Prescription Drug Importation Act, SB1, New Mexico Legislature, Regular Session 2020 (2020). https://www.nmlegis.gov/Legislation/Legislation?Chamber=S&LegType=B&LegNo=1&year=20

118 Freed, M. (2020, October 8). 10 FAQs on prescription drug importation. *Kaiser Family Foundation.* https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/

Public-Private Partnership Opportunities

In 2019 in **Utah**, over 100 health care entities came together to create their own drug manufacturing company locally. The goal is to combat arbitrary pricing and prevent local shortages of essential drugs.[119]

Transparency and Cost Control

In 2020, several bills were introduced across the nation that required drug manufacturers to report on price increases and high cost drugs entering the market and required state insurance regulators to post publicly information that is collected from manufacturers and insurers.

Minnesota passed legislation (SF 1098, 2020) requiring drug manufacturers to submit a report for each drug priced more than $100 for a course of treatment and for any price increase of more than 10% over a 12-month period. The bill also requires manufacturers to submit pricing information for new brand-name drugs priced higher than Medicare prices for a 30-day supply of a specialty drug. The Commissioner of Health must post certain reported information on the Department of Health's website.[120]

New Hampshire passed similar legislation (H B703, 2020) requiring manufacturers to provide notice if a new prescription drug is introduced to the market at a wholesale acquisition cost (WAC) that exceeds the threshold for a specialty drug under the Medicare Part D program.[121]

Utah passed legislation (HB 272, 2020) requiring manufacturers to report detailed pricing information for drugs with a wholesale acquisition cost (WAC) of $100 or more for a 30-day supply and for any price increase greater than 16% over the preceding two calendar years or 10% in one year. The bill also requires insurers to report a list of the 25 drugs for which the insurer spent the most on in the preceding plan year and the percentage increase in premiums attributable to the increased pharmaceutical costs of all drugs. The bill requires the Insurance Department to publish prescription drug information on their website.[122]

West Virginia proposed legislation (HB 4583, 2020) requiring manufacturers to report on brand-name, specialty, and generic drugs with a WAC of at least $100 for a 30-day supply and a WAC increase of 40% or greater over the preceding three years or 15% or greater in the previous calendar year. Similar to Utah's bill, each health benefit plan would have been required to submit the names of the 25 most frequently prescribed drugs across all plans and the percent increase in premiums that were attributable to prescription drugs across all plans. The auditor would then create a searchable pharmaceutical price transparency website.[123]

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119 McKellar, K. (2018, September 6). New Utah drug company to fight nation's "crazy" drug prices, shortages. Deseret News. *Health Affairs*, 39(7), 1185-1193.https://www.deseret.com/2018/9/6/20652851/new-utah-drug-company-to-fight-nation-s-crazy-drug-prices-shortages Health Affairs, 39(7), 1185-1193.

120 Prescription Drug Transparency, S.F. 1098, Minnesota Senate, 2020 (2020). https://www.senate.mn/departments/scr/billsumm/summary_display_from_db.php?ls=91&id=7319

121 High-Cost Prescription Drugs, HB 703, New Hampshire House, 2020 (2020). https://www.nh.gov/insurance/legal/high-cost-prescription-drugs.htm

122 Pharmacy Benefit Amendments, HB 272, Utah State Legislature, 2020 General Session (2020). https://le.utah.gov/~2020/bills/static/HB0272.html

123 Requiring Accountable Pharmaceutical Transparency, Oversight, and Reporting Act, HB 4583, West Virginia Legislature, 2020 Regular Session (2020). http://www.wvlegislature.gov/Bill_Text_HTML/2020_SESSIONS/RS/bills/HB4583%20INTR.pdf

In 2019, **Washington** (HB 1224, 2019) and Colorado (HB19-1131, 2019) passed legislation relating to pricing information and disclosures. HB19-1131 requires manufacturers to disclose the WAC of a drug and the name of three generic drugs from the same therapeutic class when providing information to a prescriber.[124] HB1224 requires health insurers, PBMs, and manufacturers to submit data to the Health Care Authority for the purpose of creating a report on the impact of high cost drugs on health care costs.[125]

Oregon (HB 2658, 2019) passed legislation requiring manufacturers to give advance notice of price increases for brand-name drugs with an increase of 10% or more over the last year.[126]

Texas (HB 2536, 2019) passed legislation requiring disclosure within 30 days of a 15% or more price increase from the preceding year. The bill also requires annual reports from manufacturers for approved drugs with a WAC of $100 or more for a 30-day supply.

Maine (LD 1162, 2019) passed legislation requiring manufacturers to report to the state on 75 higher cost drugs, with a fine of $10,000 per day after the deadline for manufacturers failing to report required information.[127]

In 2018, **New Hampshire** (HB 1418, 2018), passed legislation requiring the Department of Human Services to develop a list of critical prescription drugs where there is a public interest in understanding the pricing. The Department must require the manufacturers to report information on costs of production, research and development, marketing and advertising, and prices charged for drugs on the list.[128]

Oregon (HB 4005, 2018), similarly, passed legislation requiring drug manufacturers to annually report prices of drugs and costs associated with developing and marketing drugs to the Department of Consumer and Business Services.

Vermont (S 92, 2018) passed legislation requiring pharmacists to dispense the lowest priced generic and requires manufacturers to make various disclosures to the state Attorney General about costs and drug launch prices.

Pharmacy Benefit Managers

In December 2020, the U.S. Supreme Court issued a ruling in *Rutledge v. Pharmaceutical Care Management Association (PCMS)* regarding PBM reimbursement transparency. At issue in the case was a law passed in Arkansas (SB 688, 2015) requiring PBMs to reimburse Arkansas pharmacies an amount not less than what pharmacies pay to acquire drugs. The Supreme Court ruled the federal Employee Retirement Income Security Act of 1974 (ERISA) did not preempt the Arkansas state law, allowing the state law to stay in place. The result of this decision may pave the way for more states to pass legislation regulating PBMs.[129]

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124 Prescription Drug Cost Education, HB19-1131, Colorado General Assembly, https://leg.colorado.gov/bills/hb19-1131 Concerning prescription drug cost transparency, no. HB1224 (2019). https://app.leg.wa.gov/billsummary?BillNumber=1224&Year=2019

125 Concerning prescription drug cost transparency, no. HB1224 (2019). https://app.leg.wa.gov/billsummary?BillNumber=1224&Year=2019; Prescription drug price transparency, https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/prescription-drug-price-transparency#background

126 Relating to prescription drug costs, no. HB2658 (2020). https://olis.leg.state.or.us/liz/2019R1/Measures/Overview/HB2658

127 An Act to Further Expand Drug Price Transparency, no. LD 1162 (SP 350) (2019). http://mainelegislature.org/LawMakerWeb/summary.asp?ID=280072309

128 Relative establishing a commission to study greater transparency in pharmaceutical costs and drug rebate programs, no. HB1418 (2018). http://gencourt.state.nh.us/bill_status/bill_status.aspx?lsr=2010&sy=2018&sortoption=&txtsessionyear=2018&txtbillnumber=HB1418

129 In Major Victory for States, Supreme Court Clears the Way for the State Health Reform, December 15, 2020, https://www.nashp.org/in-major-victory-for-states-supreme-court-clears-the-way-for-state-health-reform/

Legislation regarding PBMs focused primarily on rebate transparency and/or licensing. A PBM is a company that manages prescription drug benefits on behalf of health insurers. Health plans often contract with PBMs to negotiate discounts from retail pharmacies, maintain the drug formulary (the list of drugs covered by the health plan and their associated co-pays) and pay claims for drugs dispensed to consumers by retail pharmacies.

Georgia passed a bill (HB 946, 2020) requiring PBMs to file any reimbursement methodologies with the Insurance Commissioner to use in determining maximum allowable cost (MAC) appeals.[130]

Georgia SB 313 (enacted 2020) requires a PBM to offer a health plan the ability to receive 100% of all rebates and other payments the PBM receives from pharmaceutical manufacturers. PBMs must apply any third-party payment or other out-of-pocket expenses made on behalf of an insured toward an insured's cost share or co-pay responsibility.[131]

In **Maine** SP 466, Public Law Chapter 469 (enacted 2019) requires that all compensation related to prescription drug benefits from pharmaceutical manufacturers to carriers/ PBMs to be either passed directly to the consumer at the point-of-sale to reduce costs or to the insurer for the explicit purpose of lowering premiums.[132]

Indiana passed legislation (SB 241, 2020) requiring PBMs to be licensed under the Department of Insurance. The bill authorizes the Insurance Commissioner to adopt rules to specify licensure, financial standards and reporting requirements.[133]

Rebates

Four states have passed laws related to prescription drug rebates. Some require carriers and PBMs to report on rebates and discounts; others require rebate savings to be passed through to save consumers money.

Iowa (SF 563, 2020) passed legislation requiring PBMs to submit an annual report to the State Commissioner of Insurance with information on prescription drugs prices and rebates received by the PBM for the prior calendar year. The Commissioner must make information collected public.[134]

New Hampshire (SB 63, 2020) passed legislation requiring all rebates remitted by or on behalf of a pharmaceutical manufacturer, directly or indirectly, to an insurer or to a PBM under contract with an insurer to be emitted directly to a covered person at the point of sale retained by the insurer to offset premium costs.[135]

130 Insurance; extensive revisions regarding pharmacy benefits managers; provide, HB 946, 2019-2020 Regular Session (2020). http://www.legis.ga.gov/Legislation/en-US/display/20192020/HB/946

131 Pharmacy Benefits Managers; regulation and licensure; extensive revisions; provide, no. SB313 (2020). http://www.legis.ga.gov/legislation/en-US/Display/20192020/SB/313

132 An Act To Protect Consumers from Unfair Practices Related to Pharmacy Benefits Management, no. S.P. 466 (2019). https://legislature.maine.gov/bills/display_ps.asp?snum=129&paper=SP0466&PID=1456

133 Pharmacy benefit managers, SB 241, Indiana General Assembly, 2020 Regular Session (2020). https://iga.in.gov/legislative/2020/bills/senate/241

134 2019 Summary of Legislation, Iowa General Assembly, Regular Session, https://www.legis.iowa.gov/docs/publications/SOL/1050511.pdf#SF563

135 Relative to sharing of insurer rebates with enrollees, no. SB63 (2020). http://gencourt.state.nh.us/bill_status/bill_status.aspx?lsr=1103&sy=2020&sortoption=&txtsessionyear=2020&txtbillnumber=SB63

Virginia (SB 251, 2020) passed legislation requiring carriers to submit quarterly reports detailing the aggregate amount of rebates received by the PBM, rebates distributed to the appropriate health benefit plan, and rebates passed on to the enrollee of each health benefit plan to reduce their deductible.[136] The Bill also states that no carrier, on its own or through its contracted PBM or representative of a pharmacy benefits manager, shall conduct spread pricing in the Commonwealth.

In 2020, **Georgia** enacted SB 313, **which requires** a PBM to offer a health plan the ability to receive 100% of all rebates and other payments the PBM receives from pharmaceutical manufacturers. PBMs must apply any third-party payment or other out-of-pocket expenses made on behalf of an insured toward an insured's cost share or co-pay responsibility.[137]

In 2018, in **Colorado,** the Executive Director of the Department of Health Care Policy and Financing issued an executive director rule requiring insurance carriers to disclose all compensation paid to them from drug manufacturers. That information is now shared publicly in the aggregate.

Affordability Boards

Twelve states have considered legislation to create a Prescription Drug Affordability Board and four states passed legislation.[138] Farthest along in implementation are Maryland and Maine.[139]

Maryland (HB 768, 2019) was the first state to pass legislation establishing a Prescription Drug Affordability Board. The board includes five members and looks at prescription drugs with costs that greatly impact Marylanders, including medications that impact the budgets of state, county, and local government programs and facilities.[140] The Board is an independent body with the authority to evaluate expensive drugs and recommend appropriate methods for addressing costs, including setting upper limits on what state residents would pay for them. Beginning in 2022, with approval of the Maryland General Assembly, the Prescription Drug Affordability Board may begin to set upper payment limits for prescription drugs purchased by state, county, or local governments. In 2023, the Board will recommend whether the General Assembly should pass legislation to expand upper payment limits to all purchases of prescription drugs throughout the state.

Maine (LD 1499, 2019) also passed legislation creating a Prescription Drug Affordability Board. The Board is tasked with establishing annual spending targets for prescription drugs purchased by public payors, and for drugs that may cause affordability challenges to enrollees in a public payer health plan. The Board must also help determine methods for the public payer to meet the spending targets and report its recommendations to the State Legislature.[141]

136 Pharmacy benefits managers; licensure and regulation., no. SB251 (2020). https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP1288
137 Pharmacy Benefits Managers; regulation and licensure; extensive revisions; provide, no. SB313 (2020). http://www.legis.ga.gov/legislation/en-US/Display/20192020/SB/313
138 Governor Chris Sununu Signs Prescription Drug Bill into Law, July 16, 2020, https://www.governor.nh.gov/news-and-media/governor-chris-sununu-signs-prescription-drug-bill-law; SSB 6088: RX Drug Affordability Board, https://www.healthcareforallwa.org/ssb_6088.
139 Reck, J. (2020, March 2). Q&A: How Maryland's First-in-the-Nation Rx Affordability Board Is Faring. The National Academy for State Health Policy Blog. https://www.nashp.org/qa-how-marylands-first-in-the-nation-rx-affordability-board-is-faring/
140 Health--Prescription Drug Affordability Board, no. HB0768 (2019). http://mgaleg.maryland.gov/mgawebsite/Legislation/Details/HB0768?ys=2019rs
141 Maine Prescription Drug Affordability Board, LD1499, https://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0461&item=3&snum=129

In **New Hampshire** (Governor Chris Sununu of New Hampshire signed the bipartisan bill HB 1280 (2020) into law in addition to other prescription affordability measures to establish a prescription drug affordability board. This board will evaluate drug prices and make recommendations about how much public payers will pay for high-cost prescriptions.[142]

The **Washington** Legislature passed legislation to establish a Prescription Drug Affordability Board in 2020. This bill would have set up an affordability board that would establish upper payment limits on medications for state payers. Due to budgetary constraints caused by COVID-19, the Governor vetoed it. Advocates anticipate that it will be reintroduced in 2021.[143]

142 Relative to copayments for insulin, establishing a wholesale prescription drug importation program, establishing a New Hampshire prescription drug affordability board, establishing the prescription drug competitive marketplace, relative to the pricing of generic prescription drugs, relative to prior authorization for prescription drug coverage, and requiring insurance coverage for epinephrine auto-injectors., no. HB1280 (2020). http://gencourt.state.nh.us/bill_status/bill_status.aspx?lsr=2032&sy=2020&sortoption=&txtsessionyear=2020&txtbillnumber=HB1280

143 Establishing a prescription drug affordability board, no. SB 6088 (2020). https://app.leg.wa.gov/billsummary?BillNumber=6088&Year=2019

Solutions for Colorado

The following section presents opportunities for Colorado to create or change state policies to address the cost drivers identified in this report. The recommendations below also consider the lessons learned from evolving policy in other states, as noted in the previous section.

Improve Prescription Drug Price Transparency

The state can tackle the industry's obscure pricing practices by building a foundation of insights through pricing transparency in standalone policy or in conjunction with other cost control policies. This could include:

- Disclosure of prescription drug price increases for generics, brand-name and specialty drugs when price increases are above a specific level
- Disclosure of the prescription drugs that are driving the highest volume (utilization), those driving the highest prices, those driving the highest overall impact to prescription drug benefit costs (combination of price and utilization), or those driving the highest rebates to PBMs/insurance carriers
- Review price differentials using averages for each of the major markets, i.e., individual, small group, large group, which would provide insights into the markups by PBMs and carriers to boost their own profits
- Disclosure of payments in any form made by manufacturers to insurance carriers/ PBMs (rebates, market share allowances, discounts, etc.), recognizing confidentiality considerations at the public level but providing the aggregated insights to policymakers
- Identifying when price increases for existing drugs match a price increase for a competitor's drug (aka shadow pricing)
- Comparing prices of new treatments to existing treatments in the same therapeutic class
- Medicaid policies that drive lower prescription drug costs which should be considered to drive similar savings in the commercial insurance and self-funded markets
- U.S. price comparisons to other countries

Transparency policy could also provide insights into the factors associated with the production cost or cost of goods sold to help state authorities identify the gap between the price to market and the cost to actually produce the drug, such as:

- Direct-to-consumer advertising and physician detailing payments and costs
- Rebate and other compensation paid to third party middlemen like insurance carriers or PBMs
- Research and development costs as well as the offsets from federal grants and grants from charitable organizations
- Acquisition cost of technology developed by third parties
- Cost to distribute
- Costs of ongoing safety and effectiveness research
- Allocation of manufacturer overhead (administration)
- Profit charge

In its entirety, this transparency information would provide the foundation for a multitude of new and effective policies that could drive down prescription drug prices to the betterment of Colorado consumers, employers, and public programs like Colorado Medicaid. That might include: establishing new pricing models, creating value-based contracts, passing through rebates to lower net costs for consumers and employers, enabling smaller employers to negotiate better pricing and rebate arrangements with their PBMs and carriers, indexing prices to other countries, importing drugs from other countries with lower prices, manufacturing drugs here in Colorado through public-private partnerships, addressing direct-to-consumer advertising and physician detailing, establishing expectations for manufacturer profits similar to insurance carrier Medical Loss Ratios, and setting upper payment limits. It all starts with transparency, which shines a light on the facts and opportunities to better control the largest contributor to rising health care costs – and that is prescription drug costs.

2020 Progress: Canadian Drug Importation Program Implementation

Drug importation from Canada has been a potential solution for pharmacies and presumably, states, since 2003, when Congress amended the Federal Food Drug and Cosmetic Act to allow for drug importation programs.[144] However, it was not until recent years that importation gained significant political traction at the national and state levels as a solution to widespread public concern with drug pricing. In the 2019 legislative session, the Colorado General Assembly passed SB 19-005, which was signed into law by Governor Polis.[145] This law tasked the Department with implementing a Canadian drug importation program. Subsequently, the Trump administration initiated the rulemaking process and released a final rule that went into effect on November 30.[146] Using this regulatory framework, Colorado intends to submit a formal application to the Food and Drug Administration (FDA) to begin importing drugs from Canada.

The Department estimates that Colorado will have an operational importation program by 2023. This timeline allows for a state procurement process to identify and contract with vendors to manage administrative and supply chain aspects of the program, the development of the application to the Food and Drug Administration (FDA), and federal review and approval of the program. The Department is actively working toward these goals.

2020 Opportunities: Expansion of Importation Programs to Include International Pricing and Additional Drug Classes

Prescription drug prices in the United States are nearly four times higher than average prices in other comparable countries.[147] As noted above, Colorado is already embarking on an importation program that focuses on Canada, which aligns with current federal statute.[148] However, the

144 Food Drug and Cosmetic Act: Importation of prescription drugs, 21 USC 384. Retrieved November 4, 2020, from https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)

145 Concerning wholesale importation of prescription pharmaceutical products from Canada for resale to Colorado residents, and, in connection therewith, making an appropriation, SB 19-005, Regular Session (2019). https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

146 Importation of Prescription Drugs, Department of Health and Human Services, Food and Drug Administration. Fed Reg Vol 85 No 191 62097 (October 1 2020), https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf

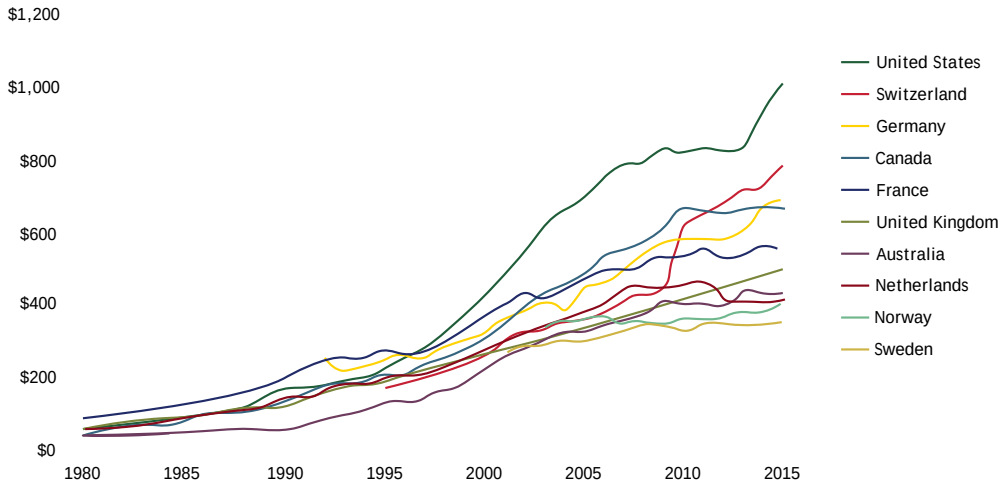
147 Ways and Means Committee Staff. (2019). *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices.* Committee on Ways and Means. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

148 Concerning wholesale importation of prescription pharmaceutical products from Canada for resale to Colorado residents, and, in connection therewith, making an appropriation, SB 19-005, Regular Session (2019). https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

expansion of importation programs to include countries in addition to Canada presents a strategic opportunity to increase potential savings from importation, while decreasing the pressure on our northern neighbors. Additionally, the expansion to additional eligible drug classes, such as biologics, would give states access to lower prices for some of the highest-cost drugs on the market. Both avenues require federal statutory changes; Colorado would benefit from state laws that parallel this expansion. Ultimately, the expansion of importation programs would enable greater savings over Canadian prices while also increasing drug supply alternatives to meet the high demands of U.S. consumers.

Importing drugs from other countries holds promise because the U.S. pays far higher prices on prescription drugs than other comparable countries. According to one study, U.S. drug prices were nearly four times higher when compared with similar countries.[149]

Figure 16. National Trends in Per Capita Pharmaceutical Spending, 1980-2015[150]



SOURCE: The Commonwealth Fund. Paying for Prescription Drugs Around the World.

To shed light on this specific savings opportunity associated with importing drugs from additional countries, the Department conducted a study of drug prices in Canada, France and Australia and compared those to Colorado's expenditures (see Appendix V). These selected comparative countries were aligned with U.S. quality metrics as indicated in the study, which found that when importing from Canada, Colorado consumers, employers, and other commercial payers could expect to save an average of 63% on the 50 drugs analyzed. Importing from France and Australia could deliver even higher savings at an average of 84% and 78% respectively, as illustrated in Figure 17.

149 Ways and Means Committee Staff. (2019). *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices.* Committee on Ways and Means. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

150 Sarnak, D. O., Squires, D., & Bishop, S. (2017). *Paying Prescription Drug Spending Why Is the U.S. an Outlier?* [Issue Brief]. The Commonwealth Fund. https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier

Figure 17. Drugs Eligible for Importation in Canada Expanded to France and Australia

Drug Name	Broad Drug Category	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada	Importation Price** from France	Percent Savings France	Importation Price** from Australia	Percent Savings Australia
Advair Diskus	Respiratory	$8.13	$2.19	73%	$0.77	91%	$0.60	93%
Afinitor	Cancer	$578.64	$269.70	53%	$126.82	78%	$55.45	90%
Alecensa	Cancer	$68.73	$45.86	33%	$33.36	51%	$31.01	55%
Atripla	HIV	$89.46	$42.25	53%	$30.08	66%	$10.75	88%
Augbagio	MS	$252.22	$55.42	78%	$37.62	85%	$23.45	91%
Biktarvy	HIV	$100.18	$42.65	57%	$33.11	67%	$31.33	69%
Breo Ellipta	Respiratory	$5.91	$2.98	50%	$1.54	74%	$1.46	75%
Brilinta	Cardiac	$6.40	$1.61	75%	$1.71	73%	$2.14	67%
Dovato	HIV	$79.07	$33.10	58%	$30.58	61%	$24.28	69%
Eliquis	Cardiac	$7.37	$1.74	76%	$1.54	79%	$1.33	82%
Enstilar	Psoriasis	$1,053.74	$91.59	91%	$56.51	95%	$70.15	93%
Entresto	Heart Failure	$8.78	$3.94	55%	$3.75	57%	$3.24	63%
Epi Pen	Anaphylaxis	$251.31	$88.09	65%	$51.33	80%	$70.15	72%
Epi Pen Jr	Anaphylaxis	$264.65	$88.09	67%	$51.33	81%	$70.15	73%
Farxiga	Diabetes	$15.93	$2.66	83%	$1.88	88%	$1.56	90%
Flovent Diskus	Respiratory	$189.15	$24.59	87%	$9.79	95%	$7.19	96%
Forteo	Osteoporosis	$3,906.62	$880.58	77%	$394.04	90%	$343.66	91%
Genvoya	HIV	$98.20	$47.63	51%	$38.26	61%	$33.35	66%
Gilenya	Multiple Sclerosis	$272.81	$92.62	66%	$81.27	70%	$76.74	72%
Glucagen	Hypoglycemia	$231.11	$83.85	64%	$22.82	90%	$51.85	78%
Ibrance	Cancer	$622.40	$276.13	56%	$178.42	71%	$203.23	67%
Imbruvica	Cancer	$144.42	$98.58	32%	$98.40	32%	$100.15	31%
Inlyta	Cancer	$266.53	$101.14	62%	$92.60	65%	$93.96	65%
Isentress	HIV	$26.63	$12.51	53%	$13.65	49%	$9.90	63%
Jakafi	Myelofibrosis	$242.04	$89.38	63%	$44.72	82%	$46.60	81%
Janumet	Diabetes	$7.19	$1.49	79%	$0.63	91%	$0.76	89%
Januvia	Diabetes	$14.65	$2.85	81%	$1.27	91%	$1.41	90%
Lamictal	Epilepsy	$12.24	$1.56	87%	$0.62	95%	$0.27	98%
Lumigan	Inflammation	$190.39	$29.39	85%	$27.09	86%	$32.14	83%
Nexavar	Cancer	$167.54	$50.03	70%	$42.91	74%	$46.94	72%
Odefsey	HIV	$90.38	$42.65	53%	$24.50	73%	$33.35	63%
Onglyza	Diabetes	$13.84	$2.50	82%	$1.40	90%	$1.57	89%
Pradaxa	Cardiac	$4.58	$1.74	62%	$1.40	69%	$1.13	75%
Spiriva Resmpimat	Respiratory	$9.92	$0.94	91%	$0.60	94%	$0.50	95%
Sprycel	Cancer	$470.80	$159.14	66%	$170.48	64%	$143.18	70%
Stiolto Respimat	Respiratory	$5.31	$1.10	79%	$1.05	80%	$1.28	76%
Sutent	Cancer	$664.90	$274.71	59%	$254.85	62%	$215.22	68%
Synthroid	Hypothyroidism	$1.20	$0.08	93%	$0.08	95%	$0.07	94%
Tagrisso	Cancer	$520.95	$320.46	38%	$309.38	41%	$271.78	48%
Tarceva	Cancer	$304.87	$87.00	71%	$86.78	72%	$36.12	88%
Tasigna	Cancer	$129.60	$29.66	77%	$34.20	74%	$32.14	75%
Tecfidera	MS	$134.25	$27.71	79%	$24.17	82%	$21.80	84%
Tivicay	HIV	$49.91	$20.12	60%	$27.32	45%	$22.01	56%
Trelegy	Respiratory	$9.21	$2.40	74%	$2.65	71%	$2.66	71%
Triumeq	HIV	$91.06	$44.12	52%	$38.26	58%	$28.89	68%
Truvada	HIV	$57.90	$28.39	51%	$16.84	71%	N/A***	N/A***
Xarelto	Cardiac	$14.63	$3.09	79%	$2.82	81%	$2.37	84%
Xeljanz	Arthritis, colitis	$72.34	$25.12	65%	$18.74	74%	$21.44	70%
Xigduo	Diabetes	$8.09	$1.33	84%	$0.94	88%	$0.82	90%
Xtandi	Cancer	$94.32	$30.83	67%	$42.35	55%	$31.47	67%

*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit from the All Payer Claims Database (APCD) increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.

**The importation price is the unit cost of the drug in each respective country, converted to US dollars, with a 45% markup for the supply chain.

***The Government of Australia only covers the generic version of Truvada.

Additionally, the Department analyzed 14 popular biologic drugs and found an average of 71% savings when imported from Canada, 77% from France, and 78% from Australia.

Figure 18. Biologic Drugs for Importation from Canada, France, and Australia

Drug Name	Broad Drug Category	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada	Importation Price** from France	Percent Savings France	Importation Price** from Australia	Percent Savings Australia
Avonex Syringe	Multiple Sclerosis	$1,736.07	$383.30	78%	$263.49	85%	$229.96	87%
Cimzia	Chronic inflammatory conditions	$2,246.38	$686.52	69%	$505.71	77%	$545.78	76%
Dupixent	Excema/Asthma	$769.96	$510.23	34%	$560.11	27%	$427.47	44%
Enbrel	Rheumatoid Arthritis	$638.71	$198.07	69%	$117.47	82%	$141.14	78%
Enbrel	Rheumatoid Arthritis	$1,295.37	$390.72	70%	$234.94	82%	$282.27	78%
Humalog	Diabetes	$19.58	$2.85	85%	$2.47	87%	$2.66	86%
Humalog KwikPen	Diabetes	$29.33	$3.73	87%	$3.34	89%	$2.98	90%
Humira	Chronic inflammatory conditions	$2,362.91	$776.74	67%	$490.89	79%	$620.56	74%
Lantus Solostar (Optisulin in Aus)	Diabetes	$25.27	$6.39	75%	$4.35	83%	$2.62	90%
Levemir Flex Pen	Diabetes	$29.42	$7.16	76%	$14.37	51%	$5.01	83%
Orencia	Chronic inflammatory conditions	$1,075.59	$374.87	65%	$315.32	71%	$256.48	76%
Rebif	Multiple Sclerosis	$1,329.14	$474.86	64%	$189.70	86%	$153.31	88%
Stelara	Chronic inflammatory conditions	$21,121.64	$4,689.00	78%	$3,653.79	83%	$4,182.21	80%
Trulicity	Diabetes	$374.23	$45.75	88%	$58.93	84%	$35.15	91%

*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.

**The importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

Accessing these increased savings requires federal and state statute changes. First, federal congressional action is needed to amend existing federal law at 21 U.S.C. § 384 to allow for (a) the expansion of importation from countries other than Canada and (b) the inclusion of biologics in the definition of drugs eligible for importation.[151] Second, the Colorado General Assembly would need to pass legislation to allow for the expansion of Colorado's importation program that would parallel changes in emerging federal policy. The Colorado General Assembly showed interest in passing SB 20-119, a bill that would have allowed for these program changes, in the truncated 2020 legislative session.

Drug importation is a valuable tool to address high prescription drug costs in Colorado. Expansion to include other countries as well as biologic drugs would only increase its impact. With the importation program's focus on the commercial market, Colorado has the opportunity to change the way Coloradans access the higher cost non-specialty brand name drugs in this state through a safe and effective model and distribution chain.

151 Importation of prescription drugs, Public Law 106-387, Public Law 108-173, 21 U.S.C. 384 (2011). https://www.govinfo.gov/app/details/USCODE-2011-title21/USCODE-2011-title21-chap9-subchapVIII-sec384

Looking to Medicaid as a Guide: Lessons from the Drug Importation Project

According to the Department's analysis, if drug importation programs were established, Colorado's Medicaid program would not see meaningful savings, while the commercial market and those covered by it would see very meaningful savings. While prescription drugs are the leading driver of rising health care costs in the commercial arena, Colorado Medicaid prescription drug expenses after the application of all rebates have been relatively flat on a per member basis over the past six years, as illustrated in the last column on the right in Figure 19.

Figure 19. Colorado Medicaid Pharmacy and Physician Administered Drug Expenditures and Rebates, Per Member Per Month (PMPM) 2014 - 2019

Calendar Year	Total Pharmacy & Physician Administered Drug Expenditure Amount	Total Pharmacy & Physician Administered Drug Spend, After Rebates	Total Drug Rebate Amount	Rebate Percentage of Total Expenditure Amount	Total Pharmacy & Physician Administered Drug Expenditure Amount, PMPM	Total Pharmacy & Physician Administered Drug Spend, After Rebates, PMPM
2014	$641,250,900	$401,444,356	$239,806,544	37.40%	$51.17	$32.04
2015	$841,710,698	$436,615,378	$405,095,320	48.13%	$56.47	$29.29
2016	$1,011,463,513	$523,133,928	$488,329,585	48.28%	$63.42	$32.80
2017	$1,093,440,876	$504,738,484	$588,702,391	53.84%	$67.60	$31.21
2018	$1,122,993,942	$445,861,992	$677,131,950	60.30%	$72.73	$28.88
2019	$1,146,383,302	$385,240,394	$761,142,908	66.40%	$77.78	$26.14

SOURCE: Colorado Medicaid (2020). CY 2017-2019 Drug Rebates are adjusted for an overcollection of drug rebates that occurred in CY 2017. The Department has been paying back the overcollection to drug manufacturers, and has adjusted the figures based on the approximate reimbursement by calendar year.

While Medicaid rebates are higher than rebates and other compensation paid to insurance carriers and PBMs for their commercial business, the chart shows the value of the rebate pass-through—in this case to the Colorado state budget and to the taxpayers who finance it.

Commercial carriers could choose to implement this same best practice of sharing rebates and all other compensation from drug manufacturers with consumers and employers. According to a 2020 study by CIVHC, the administrator of Colorado's All-Claims-Payer-Database, such payments could save consumers and employers as much as 22% on brand-name drugs. While this is less than the 60.18% average rebates in the Colorado Medicaid program over the last three calendar years, it would still provide meaningful savings to insured and self-funded employers, which could also be shared with employees through reductions in member co-pays or premium contributions as well.

Medicaid is more sheltered from the burden of rising drug prices compared to commercial payers. In addition to the many cost control initiatives the Department has implemented, this is a credit to federal protections in place for state Medicaid programs, such as:

- The Medicaid Drug Rebate Program requires that manufacturers offer their "best price" to Medicaid programs

- Medicaid rebates are increased when drug prices increase faster than inflation
- All rebates are passed through to the program at both the federal and state level (not kept by the PBM middleman)
- Supplemental rebates can be negotiated in excess of the mandated rebate in exchange for preferred formulary status.

When reviewing options for lowering prescription drug costs in the commercial market, policy makers should follow and learn from Medicaid policy.

Information and Tools for Prescribers

Health care providers could have the tools to help them prescribe more cost effectively; avoid addiction; promote health improvement programs versus just medications to get at the root of health; ease the administrative process; and employ evidence-based prescription practices to improve the health of their patients. The Department is implementing a tool that will do just that in 2021. The Prescriber Tool is a digital online tool that will be accessible to all prescribers in the state through electronic health record systems. This tool is intended to reduce opioid addiction risk, reduce prescription drug expenditures, and improve patient health. The Prescriber Tool will be implemented in two phases.

To ensure the tool will meet the needs of the industry for both commercial and Medicaid use, the Department created the original Request for Information to craft the Prescriber Tool in collaboration with the Colorado Hospital Association and independent hospitals, the Colorado Medical Society and physicians, the Colorado Association of Health Plans and its member health plans, Mercer (industry consultant), and Department subject matter experts.

Phase One

Opioid Module

Phase One consists of two parts. The first is the implementation of an opioid module that gives providers patient-specific opioid risk metrics and medication history to consider before they prescribe. The Department has contracted with OpiSafe as the vendor to provide the opioid risk metrics module for prescribers. The Department will be awarding 5,000 subsidized licenses to qualified Colorado Medicaid prescribers to facilitate quick adoption and use. Prescribers will need to apply for the license through an online survey process; if they meet the selection criteria, they will have free access to the tool for a full year. Prescribers who do not receive a subsidized license will need to purchase a license directly from OpiSafe in order to access the opioid module. This functionality will be operational in early 2021.

Affordability Module

The second part of Phase One is to implement a module that provides real-time patient-specific pharmacy benefit and price information for prescribed drugs. The information returned to prescribers will include patient co-pays, drug prices, covered therapeutic equivalent drugs, and utilization management policies such as prior authorization requirements. This information will help providers prescribe the most cost-effective drug available to generate the desired outcome. Insights into both Colorado Medicaid and commercial carriers and self-funded employer plans will help prescribers improve affordability results to the betterment of

Coloradan families, employers and the state budget. This functionality should be operational in late 2021.

Phase Two

Health Improvement Program

In Phase Two, the tool will return health improvement program information to providers, so they can prescribe or recommend a program to a patient, not just a medication, to get at the root of health issues. These programs might include tobacco cessation, diabetes management, maternity support, or social determinants of health supports such as the Supplemental Nutrition Assistance Program (SNAP) available through the Colorado Department of Human Services. This aspect of the tool can prove transformational, as we increase investments in health improvement and prevention while empowering Coloradans and physicians to better collaborate to improve patient health and outcomes. The timeline for this phase is still in development.

Leveraging the Prescriber Tool to Drive Value-Based Payments

While the Prescriber Tool has the potential to dramatically improve all prescribers' visibility into cost as part of the prescribing practice, it can also facilitate value-based payments to prescribers for both improving patient health (outcomes) and better controlling prescription drug costs and trends (affordability results). In this spirit, the Department has included an initial, value-based payment reward to hospitals for implementing the tool within the Hospital Transformation Program. This is a critical part of the rollout plan, as hospitals play an increasing role in the ownership of physician groups and the tools used to deliver care.

The Prescriber Tool is intended to enable the production of report cards that assist in provider education and coaching to address outlier behaviors in prescriber drug utilization patterns, which will further improve affordability results and patient health and well-being.

Partners That Are Assisting with the Prescriber Tool Rollout

The Office of eHealth Innovation is prioritizing its assistance with the rollout of the tool. All health plans serving Coloradans are encouraged to collaborate to load or provide access to their patient-specific reimbursements, plan designs, utilization review and prior authorization rules into the program. From a competitive perspective, carriers and PBMs that do not collaborate risk losing their competitive edge to other carriers and PBMs that better control prescription drug costs and outcomes through this innovative tool.

The Colorado Medical Society has offered to help with the Phase One testing of the tool as have a number of Federally Qualified Health Centers. The Department will also explore if there is an opportunity for prescription drug manufacturers and their representatives to take a larger role in our goal of reducing prescription drug costs through their support of the implementation and rollout of the Prescriber Tool.

Prescription Drug Monitoring Program (PDMP)

Many organizations trying to improve member health, address addiction, and control costs can benefit from access to the Prescription Drug Monitoring Program (PDMP). As an example, today, the Department of Health Care Policy & Financing can only identify the opioids an individual is taking from Colorado Medicaid claims data. The Department is unable to track opioids

purchased by covered Colorado Medicaid members who use cash or other sources to secure opioids. This creates an incomplete picture of the opioids a member is using, which makes it difficult to manage member health, evaluate prescribers and address addiction.

All claims for opioids are captured in the PDMP. Authorizing Colorado Medicaid access to the PDMP would allow physicians, pharmacists and clinical staff better clinical management of members and their use of opioids. This, in turn, can help improve health outcomes and prevent addiction, leading to a lower total cost of care and mitigating the devastating human toll of substance use disorders.

For Colorado Medicaid, this policy change would align with nationwide best practices as other states allow administrators access to the PDMP. The Department's lack of PDMP access is also out of line with CMS best practices. With better access to data through the PDMP, the state could also explore options such as a manufacturer fee on opioids to help fund treatment costs associated with opioid addiction. The Colorado Medical Society and the Colorado Hospital Association have also requested access to the PDMP to improve member health and affordability.

Ensure Employers Benefit from All Manufacturer Rebates and Compensation to Their Insurance Carriers/PBMs (Rebate Pass-Through)

Scott Gottlieb, former commissioner of the FDA, said at the Food and Drug Law Institute conference, "To take one example, one of the dynamics I've talked about before that's driving higher and higher list prices is the system of rebates between payers and manufacturers." Until we are able to negate the impact of rebates on the system at the federal level—including rebate impact on how pharmaceutical manufacturers choose to price drugs—it is important to consider ways to pass rebates and other manufacturer compensation along to employer payers and individual policyholders in the form of premium rate reductions. This would allow them to offset rising prescription drug costs in the same way that Medicaid does.

In Colorado, a study of the 2018 commercial rebates and other compensation paid by manufacturers to insurance carriers and their PBMs indicates that such payments to middlemen represented 22% of specialty drug spending and 18% of brand-name drug spending. The study also indicated that between 2016 and 2018, rebates increased by about 50%, rising from 11% to 16% of prescription drug spending (See Appendix IV). Requiring the pass through of all such compensation would directly reduce the net cost of prescription drugs to consumers and employers now and for years to come. With the dramatic increase of specialty drugs, this full pass through concept will continue to grow in importance. Full rebate and other compensation pass through would also follow a proven, Medicaid affordability policy.

This best practice policy would also battle misaligned financial incentives across the industry that are to the detriment of prescription drug affordability. Specifically, when rebates and other such compensation is not passed through by carriers and PBMs, they receive a financial benefit for the use of higher cost brand name drugs by their customers.

Laying the foundation for this opportunity, the Executive Director of the Department of Health Care Policy & Financing issued a rule in 2018 requiring the state's insurance carriers to disclose the rebates and all other compensation paid to them by prescription drug manufacturers. It is that Executive Director rule that is providing the insights into the current rebates received by carriers between 2016 and 2018.

Given that Colorado is a small employer state where rebates are often retained by insurance carriers and PBMs, and given the success of our individual market, policymakers can consider prescription drug policy that requires full pass-through of manufacturer rebates and all other compensation between manufacturers, insurance carriers and their PBMs to employers, municipalities, union trust funds, and individual policyholders and other such payers in the form of premium reductions or prescription drug claim offsets.

Figure 20. Commercial Payer Pharmacy Total Spend and Rebates by Drug Category[152]

Commercial Payer Pharmacy Total Spend and Rebates by Drug Category, 2016-2018									
Drug Category	2016			2017			2018		
	Total Spend	Rebate	% Rebate	Total Spend	Rebate	% Rebate	Total Spend	Rebate	% Rebate
Generic	$283M	$5.4M	2%	$271M	$6.2M	2%	$244M	$6.2M	3%
Brand	$425M	$70M	17%	$437M	$81M	19%	$465M	$100M	22%
Specialty	$340M	$43M	13%	$362M	$55M	15%	$400M	$72M	18%

Figure 21. Specialty Drug Percent Total Pharmacy Volume and Spend, 2018[153]

Specialty Drug Percent Total Pharmacy Volume and Spend, 2018		
Payer Type	% Total Prescription Volume	% Total Prescription Spend
Commercial	2%	49%
Medicaid	1%	44%
Medicare Advantage	1%	33%
Medicare FFS	1%	37%

*Note: Percent total volume and percent total spending was calculated based on monthly pharmacy claims submitted by payers to the CO APCD. Assignment of specialty drugs used Megallan RX Management™ guidelines.

Some have discussed policy that would pass along rebates to consumers at the point-of-sale. Policymakers should pause at this option; it can incentivize consumers for taking—and reward manufacturers for promoting—the higher cost brand-name drugs. Specifically, it can create comparatively higher patient cost sharing for lower cost, proven generic alternatives or even lower cost, proven brand-name drugs in the same therapy class, making higher cost drugs to employers appear even more attractive. Like manufacturer couponing, which reduces co-pays to members on high cost drugs, such practices can create misaligned affordability incentives and confusing messages for consumers. The preference could be to use manufacturer rebates and other compensation to offset the price (premiums) of individual and group policies, self-funded employer costs or overall member co-pays, or coinsurance and out-of-pocket costs in the employee benefit program.

152 Appendix VI: Center for Improving Value in Health Care (CIVHC). (2020) 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.
153 ibid

Explore Options on Manufacturer Couponing

As introduced above, some manufacturers provide "coupons" to consumers to offset their plan design co-pays, thereby encouraging consumers to try or continue to use specific prescription drug products. Most often, these coupons are employed by manufacturers to drive market share on new or more costly prescription drugs. Offered as a sole strategy or in combination with direct-to-consumer advertising and physician detailing practices, manufacturer coupons impede the intent of plan design member incentives or co-pays to use the lower cost drugs, be they generics or preferred brands. That is, a manufacturer coupon could fully offset the brand-name co-pay for a higher cost, new brand name-drug, which then the member is incented to use over a generic drug or a lower cost brand-name drug in the same class. This raises prescription drug costs for employers and other payers, and it increases insurance policy rates by driving unnecessary utilization of higher cost drugs. Given that manufacturers do not employ the use of coupons consistently across all drugs, there is an opportunity for robust dialogue on how to better control the adverse impacts of manufacturer coupons.

Tackling Physician Detailing: An Appointed Board That Frames Guidance for Prescribers

Physician detailing is a practice used by manufacturers to encourage physicians to prescribe their products. Many physicians are influenced by this practice. Recognizing this industry challenge, the State's Affordability Toolkit, in its pilot rollout to Grand Junction, asked participating physician group practice leaders as well as the Mesa County Health Leaders Consortium participants if they would benefit from a centralized, unbiased, expert panel or board that would frame and refine prescribing best practices and help educate physicians on such best practices with the goal of improving patient outcomes while better controlling prescription drug costs. The Consortium, including their physician leadership participants, agreed that this approach would benefit patients and employers from both a cost and health outcome perspective. The board could be comprised of members appointed by the Governor and General Assembly and include clinical experts, carriers and experts from state agencies such as the Department of Health Care Policy & Financing, the Division of Insurance, and the Department of Public Health and Environment.

Upon inquiry, the Colorado Medical Society has agreed that Coloradans, employers, and other payers could benefit from such a board. They have volunteered to actively engage in this effort to the benefit of patients, physicians, other prescribers and payers. Insurance carriers, which also have tremendous clinical expertise and have crafted best practices and clinical guidelines, would also provide great value in this process.

Clearly, the state can aggregate unbiased data to frame prescribing best practices to the benefit of all Coloradans, our employers, and public programs like Colorado Medicaid. There is an opportunity for the state of Colorado to create an unbiased entity that provides prescribers with guidance and best practices to improve patient outcomes and lower prescription drug costs. Such guidance would be available to physicians on a voluntary basis and could eventually be incorporated into next generation physician tools, such as the Prescriber Tool currently rolling out, or electronic health record (EHR) systems housed in prescriber offices.

Prescription Drug Affordability Board

As prescription drug costs continue to soar, the state has an opportunity to follow Maryland, Maine and other states by also creating a Prescription Drug Affordability Board (PDAB). This board would have the authority to evaluate expensive drugs and develop appropriate methods for addressing these costs for purchasers in municipalities, the State of Colorado employee benefit plan, and other state-based, taxpayer-supported programs that pay for them. The board could use specific criteria to identify which drugs are the best candidates for an affordability review and then impose an upper payment limit if the board determines that the drug has led to or will lead to an affordability challenge for Coloradans. Upper payment limits could employ evolving pricing models that more closely approximate the reimbursement rates in other countries to set benchmarks, targets, or price limits here in Colorado. While other states have challenged their affordability boards to explore the potential to set upper payment limits for commercial health plans, Colorado might prefer to add provisions that require value-based payments or contracts for high cost high cost specialty drugs or hold manufacturers accountable for behaviors that impede affordability, access, and quality.

Using the outcomes from Maryland, Maine and other states which have established similar boards, Colorado could set upper payment limits for prescription drugs for the benefit of all purchasers throughout the state, with the exception of Medicare and Medicaid.

Board members would be comprised of members appointed by the Governor and include experts in health care economics and clinical medicine. An advisory council could be created in service to the board and would include clinical experts, consumers, carriers and experts from the various agencies such as the Departments of Health Care Policy & Financing, Public Health & Environment, Human Services, Corrections, Personnel and Administration, Regulatory Agencies and Division of Insurance.

One option is to provide the board with appropriate access to agency prescription drug utilization and cost reporting. Access to the Center for Improving Value in Health Care (CIVHC) All Payer Claims Database reports and access to staff at the Department of Health Care Policy & Financing and other agency staff could maximize existing state repositories. Analytics would support its analysis, upper payment limit recommendations, and value-based contract content. Emerging specialty drugs and pending innovations entering the market would also be tracked and reviewed. The board could use this data to identify prescription drugs that are driving increased costs, new brand-name prescription drugs entering the market over a specific price, existing prescription drugs increasing in price over a specified amount, and prescriptions that are driving financial hardships to consumers, employers, or state programs, in order to determine appropriate upper payment limits and emerging cost control strategies.

Public and Private Partnerships to Improve Access to Prescription Drugs

The state or a non-profit partner could support the manufacturing of certain drugs with the goal of driving down prescription drug costs and prices.

In Colorado, we have already set precedent for this practice. Specifically, the state legislature through the Department of Public Health & Environment created a standing order (a blanket prescription for all residents) for the lifesaving overdose reversal drug, naloxone, decreasing access barriers.[154] The legislature also created a fund for the state to directly purchase the drug for a negotiated public health price at almost half the rate charged to retail pharmacies.[155]

Utah's health care leaders took a bold step to compete with drug manufacturers. Over 100 health care entities have come together to create their own drug manufacturing company. The goal is to combat arbitrary pricing and prevent local shortages of essential drugs.[156]

In California, legislation was passed to hire a drug manufacturer to make generic drugs specifically for California. The state will distribute and sell the generic drugs to prevent price gouging.[157]

The World Health Organization (WHO) recently invested in testing and approving a new generic insulin to combat rising insulin costs. The WHO previously used this approach to successfully increase global access to lifesaving drugs by driving down annual costs of HIV medications from $15,000 to $75.[158]

Colorado could produce its own drugs, mimic California and hire a specific manufacturer to do so, or join with Utah or other states to pursue related and bold initiatives to drive down prescription drug costs to the benefit of Coloradans, employers, state agencies, local municipalities, and the state budget.

Monitor Innovative, Evolving Ways to Price Prescription Drugs

The Institute for Clinical and Economic Review (ICER) uses a calculation that factors in a dollar amount associated with being healthy in order to estimate how a drug should be priced. The methodology uses the quality-adjusted life year (QALY), which places a dollar figure on a year of healthy life, to estimate how drugs should be priced, with consideration for how much a drug is restoring health to patients who are sick.[159]

With mounting political tension surrounding high drug prices in the U.S. and pressure to gain market share for new products, some drug manufacturers have moved toward aligning with ICER's QALY-based dollar estimate when evaluating the price of certain newer drugs. The methodology has resulted in significant cost reductions and price cuts on certain drugs that have recently entered the market. Countries like Canada, Britain, Ireland and the Netherlands have

154 Colorado Department of Public Health & Environment. (n.d.). Naloxone standing orders. Retrieved December 3, 2020, from https://cdphe.colorado.gov/prevention-and-wellness/injury-prevention/opioid-overdose-prevention/naloxone-standing-orders

155 Harm Reduction Substance Use Disorders, SB19-227 (2019). https://leg.colorado.gov/bills/sb19-227

156 McKellar, K. (2018, September 6). New Utah drug company to fight nation's "crazy" drug prices, shortages. Deseret News. https://www.deseret.com/2018/9/6/20652851/new-utah-drug-company-to-fight-nation-s-crazy-drug-prices-shortages

157 Dembosky, A. (2020, September 29). California Governor Signs A Bill To Allow State To Develop Generic Drugs. In All Things Considered. NPR. https://www.npr.org/2020/09/29/918317455/california-governor-signs-a-bill-to-allow-state-to-develop-generic-drugs

158 McNeil, Jr., D. G. (2019, November 14). To Drive Down Insulin Prices, W.H.O. Will Certify Generic Versions. The New York Times. https://www.nytimes.com/2019/11/13/health/insulin-prices-generic-who.html

159 Cost-Effectiveness, the QALY, and the evLYG. (n.d.). Institute for Clinical and Economic Review. Retrieved December 17, 2020, from https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/

used these types of calculations to leverage drug prices with manufacturers and to determine which drugs their government-funded health programs should cover.[160]

While U.S. insurers may be limited in drug price negotiations with manufacturers due to a fundamental obligation to pay for necessary treatments regardless of cost, use of cost-per-QALY reporting such as that conducted by ICER can provide valuable benefits. This includes helping payers leverage bigger discounts from drug makers, determining limitations to coverage for certain drugs, or indicating preferential coverage of alternative treatments with better estimated value.[161] Responding to community concerns that QALYs can be discriminatory against people with disabilities by implying that life with a disability, illness, or injury does not have as much value in the calculations,[162] ICER plans to modify their approach to incorporate the metric Equal Value of Life Years Gained (evLYG). This metric "evenly measures any gains in length of life, regardless of the treatment's ability to improve patients' quality of life."[163] A newly-created Affordability Board would have the opportunity to utilize such an innovative method to ensure that inclusivity is woven into affordability initiatives.

When Gilead Sciences initially priced remdesivir, a COVID-19 therapy, financial analysts estimated that the market would bear a price of $10,000 for a single, ten-day course of treatment.[164] The Institute for Clinical and Economic Review (ICER) analyzed the price and transparently shared their pricing analysis with the public. The result was a lower price to market of $5,700 for a single course of treatment.[165] ICER's estimate dropped again in response to additional trials and the World Health Organization (WHO) updated clinical care guidance.[166]

Hospital Drug Acquisition Cost and Pricing and Site of Service Opportunities to Reduce Employer and Consumer Prices

Hospitals have a number of levers that impact the cost of drugs administered to patients. A hospital may contract with a specialty pharmacy or wholesaler to acquire the drug at a particular price and then charge a health plan (and therefore its employer and individual clients) a higher price. Rather than charging these higher prices to commercial health plans, hospitals accessing lower prices could make strategic decisions to pass those savings along to health plans, thereby reducing the financial impact of high cost drugs to employers and consumers.

Potential policy options to address this issue include transparency into hospital prescription drug prices versus costs as well as limiting hospital markup. Additionally, if a Prescription Drug Affordability Board is created, the board may consider setting an upper payment limit on the

160 Roland, D. (2019, November 4). Obscure Model Puts a Price on Good Health—and Drives Down Drug Costs. Wall Street Journal. https://www.wsj.com/articles/obscure-model-puts-a-price-on-good-healthand-drives-down-drug-costs-11572885123

161 *Cost-Effectiveness, the QALY, and the evLYG*. (n.d.). Institute for Clinical and Economic Review. Retrieved December 17, 2020, from https://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg/

162 Pettitt, D. A., Raza, S., Naughton, B., Roscoe, A., Ramakrishnan, A., Ali, A., ... & Brindley, D. A. (2016). *The limitations of QALY: a literature review. Journal of Stem Cell Research and Therapy, 6(4).*

163 ICER. (2018). *The QALY: Rewarding the Care That Most Improves Patients' Lives.* Institute for Clinical and Economic Review. https://icer.org/wp-content/uploads/2020/11/QALY_evLYG_FINAL.pdf

164 Humer, C. (2020, September 11). Big Pharma wages stealth war on drug price watchdog. Reuters. https://www.reuters.com/article/us-usa-drugpricing-lobbying-special-repo-idUSKBN2621IQ

165 ibid

166 Campbell, J. D., Whittington, M. D., & Rind, D. M. (2020). *Alternative Pricing Models for Remdesivir and Other Potential Treatments for COVID-19; Updated Report*. Institute for Clinical and Economic Review. https://icerreview.org/topic/covid-19/

prices charged to health plans by hospitals who are able to access lower 340B prices. Safeguards must be instituted to make sure carriers pass along these same savings to their insured and self-insured clients rather than retaining these savings in the form of profits.

Site of Service Opportunities to Reduce Employer and Consumer Costs

The site of care used to dispense drug therapies also impacts the cost to the health plan and therefore consumers and employers. Hospital prices charged to commercial payers are higher than physician offices or home infusion sites.[167] As Figure 10 on page 26 illustrates, these higher prices charged by hospitals can be dramatic—over 200% higher than the prices charged by alternative providers. Until hospitals lower their prices, a best practice for insurance carriers, government programs and other payers is to ensure the intervention and redirection of drug therapy administration to the most cost-effective site of care. Employers should make sure their PBMs, plan administrators, and insurance carriers are contracted (required) to do just that.

Value-Based Contracts to Improve the ROI on High Cost Specialty Drugs

Value-based Contracts (VBCs) are used in a variety of contexts including negotiated agreements between manufacturers and payers such as Medicaid or commercial insurance carriers. They can be structured to financially reward or penalize manufacturers for clinical or health outcomes performance compared to their clinical promises, with the goal of further motivating manufacturers to achieve desired outcomes in exchange for their high prices. Such arrangements may have the impact of disincentivizing the use of high cost drugs for off-label treatments where the clinical outcomes are less proven.

Historically, VBCs have been employed with Multiple Sclerosis, Hepatitis-C specialty drug therapies and other high cost drugs where there is benefit to both sides—the carrier or PBM and the manufacturer. That is, the insurance carrier, which also has insights into medical claims and outcomes, can provide meaningful insights and statistics to the drug manufacturer into the performance of the drug on various demographics and consideration of other patient conditions or comorbidities. This exchange of information can also be accounted for through value-based contracting.

There is also an opportunity for the proposed Prescription Drug Affordability Board to consider the application of VBCs in conjunction with the upper payment limit configuration to further hold manufacturers accountable for their clinical promises. Or, in collaboration with the Department of Health Care Policy & Financing in the administrative oversight of the All Payer Claims Database, the Affordability Board could explore data sharing with manufacturers to further the impact of VBCs to drive down prices on higher cost drugs. VBCs are even more appropriate today with a manufacturer focus on rare disease innovation, which is bringing products to market with less robust clinical performance data. This focus on innovation has resulted in higher cost drugs entering the market without the improved clinical effectiveness one would expect compared to existing therapies. VBCs may be able to address this industry challenge, which is driving up prices without improved clinical results.

167 Winn, A. N., Keating, N. L., Trogdon, J. G., Basch, E. M., & Dusetzina, S. B. (2018). Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. *JAMA Oncology,* 4(4), 580. https://doi.org/10.1001/jamaoncol.2017.5544

Employer Best Practices for Drug Utilization Review, Contract Reimbursements and Fees

The purpose of this section is to give employers suggestions of best practices in prescription drug cost control. This section will enable employers to compare best prices to the prescription drug prices and administrative fees they pay, providing a target for better negotiations with insurance carriers and PBMs. It also provides insights into effective utilization review programs that can better control rising costs. Closing gaps to best practices will help employers control their prescription drug benefit costs more effectively.

Utilization management is made up of several different programs to assess different health care needs, including drug utilization review (DUR), step therapy (ST), prior authorizations (PA) and case management for members on multiple drugs or high cost drug therapies. Employers can work with their brokers and consultants to review their plans to explore the inclusion of the below program components where applicable and appropriate.

Drug Utilization Review. Insurance carriers and PBMs use drug utilization review (DUR) tools to optimize patient outcomes and reduce waste, error, unnecessary drug use and costs. Drug utilization review (DUR) is defined as an authorized and structured ongoing review of prescribing, dispensing and use of medication.[168] DUR encompasses a review against predetermined criteria that results in changes to drug therapy when these criteria are not met. It involves a comprehensive review of a patient's prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes. DUR is classified in three categories:

- Prospective: evaluation of a patient's drug therapy before medication is dispensed
- Concurrent: ongoing monitoring of drug therapy during the course of treatment
- Retrospective: review of drug therapy after the patient has received the medication

DUR also affords the managed care pharmacist the opportunity to identify trends in prescribing within groups of patients whether by drug-specific criteria or disease state, such as those with asthma, diabetes or high blood pressure. Pharmacists can then, in collaboration with prescribers and other members of the health care team, initiate action to improve drug therapy for patients.

Prior Authorizations. Prior authorizations are a mechanism that requires the prescriber to obtain approval for a medication before a health plan will pay for it. The prescriber often must confirm that certain clinical or safety criteria are met or demonstrate that the drug is medically necessary for that patient. When used appropriately, prior authorization programs are both a safety and cost-saving measure. Some PBMs do not charge for PAs, while others charge hundreds of dollars for each PA. Given the emergence of high cost specialty drugs, the impact of a thoughtful and appropriately priced PA process will help to ensure appropriate utilization, member quality care, and affordability. This step should also employ a review of the site of service. As noted in Figure 10 on page 26, the site of service such as home infusion, physician office, or outpatient hospital has a significant impact on price, which can be in the 200% range, with home infusion and physician offices being the more cost-effective settings.

168 AMCP. (2019, July 18). *Drug Utilization Review.* Managed Care Pharmacy 101. https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/drug-utilization-review

Step Therapy. Step therapy helps to lower costs by promoting the use of safer and/or less expensive medications first, then allowing the patient to "step up" to a different drug if needed to achieve desired results. Step therapy is often performed as a type of prior authorization.[169] It can be an effective tool in the battle to ensure appropriate drug therapy given manufacturer investment in physician detailing and direct-to-consumer marketing.

Automatic Refill Policy. Overall, automatic refills contribute to unnecessary and wasteful billing practices and increase pharmacy spending. Employers and consultants should examine the process for refills, ensuring that the consumer consents to the refill, where appropriate.

In 2019, MassHealth (Massachusetts' Medicaid program) filed lawsuits against several pharmacies to resolve allegations that it improperly billed the state's Medicaid program by $5.86 million through automatic refilling of prescriptions that were not requested by MassHealth patients or their caregivers.[170]

Employers should work with their brokers and consultants to ensure their hired vendors have active and appropriate programs to ensure proper cost control while protecting access and improving the quality of care. Carriers and PBMs will offer varying levels of programs. A thorough review of the options is recommended.

Preferred Drug Pricing for Employers

Employers have an opportunity to review their contracts with their carrier or PBM to ensure that they are receiving the lowest prices, highest rebates, and lowest administrative fees. The chart below can be used to help employers – or their representatives - negotiate improved pricing with their contracted PBM or carrier. Employers should note that the benchmarks below will vary significantly based on their size, which is why we recommend employers band together to negotiate pricing. Pricing can also be impacted by specialty and mail order drug utilization, the formulary, the size of the pharmacy network, and the utilization management programs in place. The information in Figures 22 and 23 has been provided by Mercer, a global consulting firm. It illustrates the dramatic difference in market pricing.

Figure 22. Typical Discounts for Commercial Contracts relative to Average Wholesale Price (AWP) for Brand and Generic Drugs

Members	Retail Brand Discount	Retail Generic Discount	Mail Order Brand	Mail Order Generic
<10k	AWP-16 to 19%	AWP-72 to 76%	AWP-20 to 25%	AWP-76 to 87%
10k to 100k	AWP-18 to 21%	AWP-74 to 84%	AWP-24 to 26%	AWP-78 to 89%
>100k	AWP-18 to 22%	AWP-83 to 85%	AWP-24 to 27%	AWP-85 to 89%

SOURCE: Mercer

169 Blue Cross/Blue Shield. (n.d.). *What is step therapy?* [Frequently Asked Questions]. Retrieved December 3, 2020, from https://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/pharmacy/what-is-step-therapy.html

170 Office of Attorney General Maura Healey. (2019). *Colorado-based Pharmacy to Pay $1 Million for Operating an Unauthorized Automatic Refill Program* [Press Release]. Massachusetts Attorney General. https://www.mass.gov/news/colorado-based-pharmacy-to-pay-1-million-for-operating-an-unauthorized-automatic-refill

Figure 23. Typical Discounts for Commercial Contracts relative to Average Wholesale Price (AWP) for Specialty Drugs

Members	Overall Specialty Discount*	Retail Rebates**	Mail Order Rebates**	Specialty Pharmacy Rebates**
<10k	AWP- 13.5% to 20%	$70 to $180/ brand claim	$250 to $575/ brand claim	$580 to $1900/ brand claim
10k to 100k	AWP-17% to 22%	$75 to $180/ brand claim	$315 to $655/ brand claim	$970 to $2300/ brand claim
>100k	AWP- 20% to 22%	$120 to $180/ brand claim	$355 to $665/ brand claim	$1320 to $2300/ brand claim

Administrative fee: $1 to $4.25 per claim***

*The overall specialty discount assumes an open specialty arrangement where members can obtain specialty drugs through the retail delivery channel.

**Rebates assume an incentive plan design with at least $15 differential between the preferred and non- preferred brand co-payments and an open specialty arrangement where members can obtain specialty drugs through the retail delivery channel.

***The administrative fees represent those charged in transparent pricing arrangements, as many traditional pricing arrangements include an administrative fee of $0.00.

SOURCE: Mercer

As noted in the rebate section, rebates are increasing each year. It is therefore important for employers and their representatives to negotiate the pass-through of all rebates. This rebate pass-through will be concurrent with a higher administration fee paid by the employer, often called Transparent Pricing. Those insurance carriers indicating that rebates are being passed along in the form of lower medical administration costs should be asked for the full disclosure of the value of manufacturer rebates and all other manufacturer compensation. Often, such agreements allow the PBM or insurance carrier to withhold rebates far in excess of the lower offsets or reductions applied to the employer's administration fees.

Carriers and PBMs also often own the mail order pharmacy serving members. The pricing of the prescription drugs received via the mail order drug pharmacy can vary significantly for employers, increasing profits to the carrier or PBM, accordingly. Employers are encouraged to push for preferred mail order drug pricing, recognizing this pricing variation. It is also critical for employers to negotiate guarantees on the generic utilization rate, also called the generic dispense rate (GDR), in collaboration with a full rebate pass-through provision or a rebate guarantee, which can be quoted on rebatable prescriptions or all prescriptions. Employers will want equal pressure on the carrier or PBM to dispense generics which don't traditionally provide rebates while also rebates through to the employer to create the lowest net cost of the prescription drug benefit.

The Department is rolling out the Health Care Affordability Toolkit across the state. It includes providing data, tools and engagement resources for employers and other community leaders to improve how they execute on these practices.

Federal Solutions to Lower Prescription Drug Costs

Reducing the cost of prescription drugs has garnered bipartisan support and action at the federal level in recent years, which includes executive orders, administrative actions by the Department of Health & Human Services (HHS) and the introduction of legislation in Congress. However, given the impending leadership changes in Washington, action on drug pricing will be an area to watch closely.

During the Trump administration, proposed federal changes focus on Medicare and include negotiating drug prices, modifying benefit design, capping increases at inflation rates, benchmarking U.S. prices to international pricing, modifying payments and rebates, and other changes. Most recently, President Trump has sought to address high drug prices through a series of executive orders that tasked HHS with finalizing several pieces of drug pricing regulation. In September 2020, HHS finalized the Drug Importation Rule, setting forth a regulatory framework to allow states to implement wholesale drug importation programs once approved by the FDA. Additionally, HHS finalized the Most Favored Nation Model Interim Final Rule, described below, and the Rebate Rule, which, once in effect, will require that rebates are passed through to consumers at the pharmacy counter.

In the 116th Congress, both the U.S. House and Senate have considered legislation that addresses pricing transparency, patent law and rebates; however, to date, no bills have yet become law. As the new Congress is sworn in in early 2021, following progress in this space will be integral to a path forward on drug pricing.

The incoming Biden administration has set forth an ambitious health care agenda that includes proposed actions on drug pricing. Detailed proposals are not yet available, but areas of in terest include:

- Allowing Medicare to negotiate lower prices with drug corporations.
- Limiting launch prices for drugs in Medicare that face no competition by establishing an independent review board that will have the authority to recommend reasonable prices based on prices in other countries.
- Limiting price increases for all brand and biotech and certain generic drugs to the general inflation rate and imposing a tax penalty on drug manufacturers for price increases higher than general inflation.
- Eliminating the tax deduction for pharmaceutical corporations' drug advertising spending.
- Improving the supply of quality generic drugs by expediting the development of safe generics and the entrance of generics into the market.

Reform Patent and Exclusivity Regulations

Both patents and exclusivity regulations were meant to reward innovation and give innovators temporary market exclusivity to recoup their research and development costs.[171] Indeed, whenever discussion arises concerning reform of patents and exclusivity, manufacturers insist that reform will deter innovation. As reviewed earlier in this report, pharmaceutical companies use the patent system to effectively extend the period of exclusivity beyond what the law intended. This allows the patent holder to drive revenues and return on investment far above the original patent intention and without market competition or price transparency or price controls.

It is time for federal policymakers to consider such legislation to better align the period of patent protection to the recoupment of investment in today's market plus a reasonable return on investment specific to new drugs coming to market. Federal policymakers could also explore policy changes that allow for patents only for true innovation, while curtailing the extension of patents for minimal changes to an existing product. Some policymakers suggest it is time to implement a "one and done" approach that awards one patent for one drug.

Regulate Prices by Connecting U.S. Prices to International Prices

If reforms to regulating prices or setting prices are considered, one methodology may be to require U.S. prices be aligned or benchmarked to prices in other countries. In October 2018, HHS announced its plans to explore an International Pricing Index Model for Medicare Part B Drugs.[172,173] However, an updated version of the proposal was issued by the Trump administration on November 20, 2020 as the Most Favored Nation Interim Final Rule.

On November 20, 2020, HHS announced the Most Favored Nation Model, which will test the idea of ensuring Medicare pays no more than the lowest price charged in identified countries for certain Part B covered drugs and biologicals with the highest Medicare Part B spending.[174] The test will operate for seven years with the first performance year starting on January 1, 2021. On December 4, 2020, the Biotechnology Innovation Organization announced they were filing a lawsuit to block implementation. Their primary argument is that the administration did not follow administrative procedures when enacting the proposal.[175]

In general, this model will face opposition from the pharmaceutical industry because they claim it will stifle innovation and reduce access to drugs. This initiative has also received some opposition from hospitals and other providers because it would deny them access to rebates and discounts, such as those they receive under the 340B program.[176]

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171 Food and Drug Administration. (2020, February 5). *Frequently Asked Questions on Patents and Exclusivity.* FDA. https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity

172 Health and Human Services. (2018). *HHS Advances Payment Model to Lower Drug Costs for Patients* [Press Release]. Health and Human Services. https://doi.org/10/25/hhs-advances-payment-model-to-lower-drug-costs-for-patients.html

173 Centers for Medicare & Medicaid Services (n.d.). P*rescription Drug Coverage.* Retrieved December 3, 2020, from https://www.medicare.gov/coverage/prescription-drugs-outpatient

174 Centers for Medicare & Medicaid Services. (2020). *Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period* [Fact Sheet]. CMS. https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule

175 Florko, N. (2020, December 4). BIO files lawsuit to block Trump international drug pricing policy. STAT. https://www.statnews.com/2020/12/04/bio-to-file-lawsuit-today-to-block-trump-international-drug-pricing-policy/

176 Firth, S. (2018, October 26). Reactions Mixed to Part B Drug Pricing Plan. *Medpage Today.* https://www.medpagetoday.com/publichealthpolicy/medicare/75967

Emerging Federal & International Policy: The German Prescription Drug Pricing Model and Potential U.S. Cost Savings

In Germany, net prices for infused medications were 60% lower than that of the U.S. in 2018, primarily due to their marketing negotiation structure.[177] Federal policymakers are reviewing the German model to potentially address the complexities of the U.S. system while ensuring competition and reducing prescription drug costs.[178]

The German Pharmaceutical Marketing Restructuring Act (AMNOG), passed in 2002, introduced marketing negotiation measures, which triggered a 24.5% decrease in 57 anti-cancer drugs by 2017 and saved $1 billion in 2015 alone.[179,180] AMNOG allows manufacturers to set prices for a drug's first market-year, during which its therapeutic benefits are evaluated by a nonprofit, a nongovernmental research body, hospitals, insurers and research institutions. Prices are negotiated with manufacturers after the clinical evidence and standard of care outcomes have been reviewed. All German health plans participate in the price negotiations with pharmaceutical manufacturers. In a July 2020 analysis, *Health Affairs* "did not find evidence that manufacturers responded by setting higher launch prices."[181]

The German and American health care systems are similar in that both systems utilize competing, private health plans to deliver care to beneficiaries. Adopting a model to allow the U.S. to have more control over pharmaceutical prices is gaining traction in the federal space and was most recently mentioned by the incoming Biden administration as an emerging priority.

Redesign the FDA Approval Process to Include Cost Considerations

France, Germany, Sweden, and the United Kingdom[182] currently factor a drug's price into their drug approval process, which serves as an effective pricing control measure. In the U.S., however, drug pricing is not considered part of the FDA approval process, nor can a maximum cost be used for consideration of coverage for certain payers, like state Medicaid programs. Therefore, a discussion about the framework and implementation of a drug price ceiling or limit is needed. Over 40% of new drug approvals are for drugs that treat rare disease, while financial and exclusivity incentives are allowing Orphan Drugs to become blockbusters.[183] The FDA and Congress should consider restricting could the conditions used to determine which companies and potential products receive the financial incentives for development. Changes could also be made so that incentives are paid back, or measures are added to ensure public programs receive significant discounts as a trade-off for financial incentives.

177 Robinson, J. C., Ex, P., & Panteli, D. (2020). *Drug Price Moderation in Germany: Lessons for U.S. Reform Efforts* [Issue Brief]. Commonwealth Fund. https://doi.org/https://doi.org/10.26099/d3g0-mx46

178 Sagonowsky, E. (2020, October 20). Biden looks to Germany for answers on how to tackle high U.S. drug prices: analyst. *Fierce Pharma*. https://www.fiercepharma.com/pharma/biden-looks-to-germany-for-answers-how-to-tackle-high-u-s-drug-prices-analyst

179 Lauenroth, V. D., Kesselheim, A. S., Sarpatwari, A., & Stern, A. D. (2020). Lessons From The Impact Of Price Regulation On The Pricing Of Anticancer Drugs In Germany. Health Affairs, 39(7), 1185–1193. https://doi.org/10.1377/hlthaff.2019.01122

180 Lauterbach, K., McDonough, J. E., & Seeley, E. (2016, December 29). Germany's Model For Drug Price Regulation Could Work In The US | Health Affairs Blog. *Health Affairs Blog*. https://www.healthaffairs.org/do/10.1377/hblog20161229.058150/full/

181 Lauenroth, Victoria, Kesselheim, Aaron, Ameet Sarpatwari, and Ariel D. Stern. (2020) Lessons From The Impact Of Price Regulation On The Pricing Of Anticancer Drugs In Germany. Health Affairs. Vol. 39, No. 7: Food, Income, Work & More. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2019.01122

182 Gross, D. J., Ratner, J., Perez, J., & Glavin, S. L. (1994). International pharmaceutical spending controls: France, Germany, Sweden, and the United Kingdom. *Health care financing review*, 15(3), 127–140.

183 Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*, 5(3), 590–647. https://doi.org/10.1093/jlb/lsy022

Limit Direct-to-Consumer Advertising

Limiting or significantly regulating direct-to-consumer (DTC) advertising of pharmaceutical drugs at the federal level is severely needed. Billions are invested by drug manufacturers into promotional marketing, which drives up the price of the drug as well as the patient demand and therefore the utilization of profitable, higher cost brand-name drugs.[184] The Trump administration attempted to provide some pricing transparency by requiring drug makers to put pricing information in their advertisements. This regulation was blocked by a federal judge in July 2019, who determined the regulation violated free speech.[185] Further exploration into federal policies that limit or mitigate these promotional advertisements should be explored, recognizing this most recent federal decision.

Expedite Generic Drug Approvals

Generics introduce competition. The sooner they can come to market, the faster drug prices come down. In 2017, the FDA announced plans to expedite medication reviews for generic drugs on a list of several hundred branded drugs with no listed patents or exclusivities and no approved generic drug application. The goal was to incentivize the rapid conversion from branded to generic drugs.[186] From August to December 2018, the FDA approved the first five generic drugs through this new expedited approval pathway.[187]

In 2019, the FDA Commissioner at that time, Dr. Scott Gottlieb, outlined plans for additional policy steps the FDA would take to reduce barriers to generic drug development and foster generic drug competition. Among those are plans for issuing guidance documents for developing complex generic drugs, plans to optimize the approval process for complex generic drugs by developing more advanced analytical tools and in vitro tests, and steps to enhance overall efficiency of the generic drug application submission process.[188]

184 Wilkes, M. S., Bell, R. A., & Kravitz, R. L. (2000). Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications. *Health Affairs*, 19(2), 110–128. https://doi.org/10.1377/hlthaff.19.2.110

185 Armour, S. (2019, July 9). Trump Rule Requiring Drug Prices in TV Ads Blocked. *Wall Street Journal*. https://www.wsj.com/articles/trump-rule-requiring-drug-prices-in-tv-ads-blocked-11562634281

186 Office of the Commissioner. (2019). *Statement on a new effort to improve transparency and predictability for generic drug applicants to help increase timely access to high-quality, lower cost generic drugs [Press Release]*. https://www.fda.gov/news-events/press-announcements/statement-new-effort-improve-transparency-and-predictability-generic-drug-applicants-help-increase

187 Office of the Commissioner. (2019). *Statement from FDA Commissioner Scott Gottlieb, M.D., on new policy to improve access and foster price competition for drugs that face inadequate generic competition* [Press Release]. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-price-competition

188 Office of the Commissioner. (2019). *Statement from FDA Commissioner Scott Gottlieb, M.D., on new policy to improve access and foster price competition for drugs that face inadequate generic competition* [Press Release]. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-price-competition

Conclusion

According to a national poll from the West Health Institute, a nonpartisan, nonprofit health care research organization, 78% of Americans said addressing health care costs was their highest priority.[189] The overwhelming majority of Americans also favor government action to bring down the price of prescription drugs.[190] Given that prescription drugs are often the first line of offense and defense against illness, injury, and chronic conditions, our ability to control their costs more effectively is critical to the overall affordability of health care.

As this report has illustrated, there is little transparency around the cost to develop and manufacture drugs or why prices fluctuate so wildly, even for generic drugs. Business practices across manufacturers are driving prices up and are not aligned with the free market competition that typically benefits consumers and purchasers.

This report has articulated a series of opportunities for the state to address these cost drivers through actions, such as:

- **Establishing a Prescription Drug Affordability Board** that uses price transparency and other cost and price insights to establish upper payment limits for drug transactions in Colorado
- **Prescription drug price transparency,** such as disclosures related to price increases or the build-up costs incorporated into pricing models. This might include advertising or profit margins
- **Expanding state importation policy** to support the potential expansion of federal regulations for drug importation from other countries, including the importation of biologics as an eligible drug class
- Investing in and expanding access to physician tools, like **the Prescriber Tool and Prescription Drug Monitoring Program,** that fuel more cost-effective prescribing practices while improving patient health and outcomes
- **Requiring rebates and other compensation flowing** from drug manufacturers to insurance carriers and PBMs to be passed through to employers and consumers
- Implementing **innovative reimbursement methodologies** that focus on affordability, patient outcomes and quality of life including **value-based contracts** to hold the industry accountable for their clinical promises
- **Public-private partnerships** that support hospitals or public entities in direct price negotiations, purchasing, or even manufacturing of drugs to meet local needs
- **Empowering and educating employers to negotiate contracts** that maximize the prescription drug pricing discounts, improve utilization management controls and maximize rebate pass throughs that serve to offset the cost of the prescription drug benefit
- Creating a board or other resources that provide **prescription drug prescribing best practices based on evidence-based medicine,** thereby battling the influence of physician marketing (physician detailing)

189 *High Prices, Broken Promises.* (2018). [Press Release]. NORC. https://www.norc.org/NewsEventsPublications/PressReleases/Pages/high-prices-broken-promises.aspx

190 Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 1). KFF Health Tracking Poll – February 2019: Prescription Drugs. *KFF*. https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

If the Biden Administration were to prioritize federal reform that reduces the cost of prescription drugs, these could include:

- **Expanding drug importation** to include other countries beyond Canada and the importation of biologics as an eligible drug class
- **Reforming patent and exclusivity laws** and regulations that prevent competition while expediting approvals for generic drugs to enter the market
- Looking to **international drug pricing models** and connecting U.S. prices to other countries
- Adding **price and cost consideration** to the FDA approval process
- **Limiting direct-to-consumer advertising**

These policies would help to mitigate the unsustainable cost increases that are affecting individuals and families, employers and tax-funded programs like Medicaid.

The innovation, research and development of life-saving drugs is extraordinary. Pharmaceuticals propel a better quality of life for millions, expand the lifespans for those who were once hopeless, prevent life-threatening disease or disease progression, and cure illnesses that were previously debilitating. The emerging COVID-19 vaccine alone will save millions of lives while helping economies around the world recover.

By improving affordability, we can help ensure that Coloradans can access these breakthroughs in modern medicine. The Department will be hosting events to invite stakeholders to actively participate in the dialogue that will help drive prescription drug affordability policy and the state and federal level as well as best practices to the benefit of Coloradans, employers, the state budget, and taxpayer-supported programs like Medicaid. We invite your active engagement to achieve our shared goals.

Appendices

Appendix I. Definitions

For the purposes of this report, the terms utilized herein have the following FDA definitions:[191]

Average Manufacturer Price (AMP)

The AMP is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts. The AMP is statutorily defined, and its calculation is based on actual sales transactions. Drug manufacturers must report AMP data for all Medicaid-covered drugs to the Centers for Medicare & Medicaid Services (CMS) quarterly as a requirement of the Medicaid drug rebate program.

Biologics and Biosimilars

Biologics are medicines that are isolated from a variety of natural sources – human, animal or microorganism – and may be produced by biotechnology methods and other cutting- edge technologies. Biosimilars are biological products that are highly similar to and have no meaningful differences from an existing FDA-approved reference biologic. Biosimilars may be therapeutically substituted for a biologic, though a biosimilar is not a replicant of the biologic in the way that a generic drug is a replicant of a brand-name drug.

Brand-Name Drug

A brand-name drug is a drug marketed under a proprietary, trademark-protected name.

Colorado Prescription Drug Monitoring Program (PDMP)

The Colorado Prescription Drug Monitoring Program (PDMP) is a tool for prescribers and pharmacists to help reduce prescription drug misuse, abuse, and diversion. Pharmacies upload prescription data to the PDMP database for controlled medications listed in Schedules II to V that are dispensed to Colorado patients. The database helps prescribers make more informed decisions when considering prescribing or dispensing a controlled substance to a patient. The PDMP is managed by the Colorado Division of Regulatory Agencies (DORA).

Drug

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary
- A substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease
- A substance (other than food) intended to affect the structure or any function of the body
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process)

191 All definitions are from the FDA glossary: *Drugs@FDA Glossary of Terms.* (2017, November 14). Food and Drug Administration. https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

Drug Sample

A drug sample is a prescription drug that is not intended to be sold. They are generally provided by manufacturers directly to prescribers as a starter supply for patients and sometimes used in cases where patients cannot afford medications.

Formulary

A formulary is the list of prescription drugs that a non-government health insurer will cover; it assigns particular products to one of several tiers (typically two to four in commercial formularies) with different member cost sharing. Formularies are generally developed by PBMs, which negotiate contracted prescription drug prices and rebates with pharmaceutical manufacturers on behalf of their clients, which may be health insurers.

Generic Drug

A generic drug is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use. Before approving a generic drug product, the Food and Drug Administration (FDA) requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand-name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand-name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand-name product.

Insurance Carrier

An insurance carrier is a company that is licensed to sell insurance plans and policies.

Label

The FDA-approved label is a summary for the safe and effective use of the drug, including whatthe drug is approved for, safety warnings, side effects, and instructions for use in specialty populations.

Manufacturer

A manufacturer is any entity that is responsible for the research, development, manufacture, packaging, labelling, marketing, and pricing of a drug.

Per Member Per Month (PMPM)

Per member per month is the cost or number of units of something divided by member months. It is often used to describe premiums or payments to providers but can also refer to the revenue or cost for each enrolled member each month.

Pharmacy Benefit Managers (PBMs)

PBMs are third-party administrators of prescription drug programs for health insurers, self-insured employers, and union health plans. Government health programs also make use of PBMs, typically to process pharmacy claims and contract with manufacturers.

Physician Detailing

Pharmaceutical detailing is a 1:1 marketing technique used by pharmaceutical companies to educate a physician about a vendor's products in hopes that the physician will prescribe the company's products more often.

Prescription Drug Product

A drug product that requires a prescriber's order.

Rebate

A rebate is the return of part of the purchase price by the seller to the payer or purchaser. The role of rebates is different between Medicaid and commercial plans. In Medicaid, rebates offset the federal and state costs. For commercial plans, the rebates are paid by the manufacturers to the PBMs to encourage utilization of a product.

Specialty Drugs

Specialty drugs are generally considered to be those drugs and biologics that are complex to manufacture, can be complex to administer, may require special patient monitoring and are high cost.

Third Party Administrator

A third-party administrator (TPA) is an organization that handles certain administrative responsibilities, such as claims administration, for other organizations.

Wholesale Acquisition Cost (WAC)

The WAC is the list price set by the manufacturer. Generally, it is the price of a drug before any rebates, discounts, allowances or other price concessions are offered by the supplier of the product.

Wholesale Distributor

A wholesale distributor is an entity engaged in wholesale distribution of prescription drugs. The distributor assists in moving the drug from the manufacturer to the pharmacy or dispensing outlet.

Appendix II. Federal Legislative Action

House of Representatives Legislation

The 116th U.S. Congress has introduced competing bills to lower American prescription drug costs. H.R. 3 would require CMS to negotiate prices for certain drugs. Specifically, CMS must negotiate maximum prices for insulin products and at least 25 single source, brand-name drugs that do not have generic competition and that are among the 125 drugs that account for the greatest national spending, or the 125 drugs that account for the greatest spending under the Medicare prescription drug benefit and Medicare Advantage. Those negotiated prices must be offered under Medicare and Medicare Advantage, and may also be offered under private health insurance unless the insurer opts out. The negotiated maximum price may not exceed (1) 120% of the average price in Australia, Canada, France, Germany, Japan and the United Kingdom; or (2) if such information is not available, 85% of the U.S. average manufacturer price. Drug manufacturers that fail to comply with the bill's negotiation requirements are subject to civil and tax penalties.

The House bill also makes a series of additional changes to Medicare prescription drug coverage and pricing. Among other things, the bill (1) requires drug manufacturers to issue rebates to the CMS for covered drugs that cost $100 or more and for which the average manufacturer price increases faster than inflation; and (2) reduces the annual out-of-pocket spending threshold, and eliminates beneficiary cost-sharing above this threshold, under the Medicare prescription drug benefit.[192]

Senate Legislation

In the Senate, the bipartisan, S. 2543 Prescription Drug Pricing Reduction Act[193] has been introduced and aims to overhaul parts of Medicare and Medicaid prescription drug benefits. For Medicare, the proposal aims to modernize and improve the successful Part D program by simplifying the program's design through protecting beneficiaries with high costs by providing an on out-of-pocket spending cap; improving incentives to increase negotiation among prescription drug plans and manufacturers; protecting the program from manufacturer drug price increases; and benefiting patients and taxpayers through lower government spending, premiums, and out-of-pocket costs. The legislation aims to increase transparency into pharmacy benefit manager (PBM) practices and manufacturer drug pricing decisions and enhance innovations by improving how Medicare calculates Part B prescription drug payment amounts to lower spending and beneficiary out-of-pocket costs; and eliminates excess Part B drug payments that drive up beneficiary and program costs.

For Medicaid, the Senate legislation proposes to increase transparency to make manufacturers more accountable to federal taxpayers by providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to drug price and rebate data for the purposes of monitoring, analysis, and making program recommendations. It would allow Medicaid to pay for gene therapies for rare diseases through new risk-sharing value-based agreements and apply pressure on manufacturers to lower list prices and report more accurate calculations of their rebate obligations; and prevent spread pricing and gaming in the Medicaid program by PBMs to provide the best deal possible.

192 Elijah E. Cummings Lower Drug Costs Now Act, no. HR 3 (2019). https://www.congress.gov/bill/116th-congress/house-bill/3
193 Prescription Drug Pricing Reduction Act of 2019, no. S.2543 (2019). https://www.congress.gov/bill/116th-congress/senate-bill/2543/all-info

The proposal aims to improve drug manufacturers' reporting of average sales prices (ASP) which would help set accurate payment rates by requiring manufacturers that do not have a Medicaid drug rebate agreement to report average sale price information to the HHS Secretary that would then be used to help establish Medicare payment rates. The proposal would also require prescription drug manufacturers to exclude the value of coupons provided to privately insured individuals from each drug's average sales price. Also, the proposal would establish a wholesale acquisition cost add-on payment of no greater than 3% when the average sale price is unavailable for new drugs; for biosimilars a payment rate would be established that would be the lesser of the biosimilar's WAC plus 3% or ASP plus 6% of the reference biological product.

The proposal aims to redesign benefits for Medicare Part D by simplifying the design and realigning financial incentives to better manage spending for high cost drugs. It would streamline the benefit between the deductible and catastrophic out of pocket threshold and eliminate the coverage gap and cap enrollee cost sharing above the catastrophic out of pocket threshold at $3,100. In addition, modifications to Part D would shift federal reinsurance to Part D plan sponsors in the catastrophic coverage period, sunset the existing manufacturer discount program in the coverage gap, and institute a new manufacturer discount program in the catastrophic portion of the benefit, which would require 20% discounts on brand-name drugs.

In terms of transparency, the bill proposes providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment Access Commission with access to certain drug payment information including certain rebate information for the purposes of monitoring, analysis, and making program recommendations. It would also require public disclosure of drug discounts and other pharmacy benefit manager provisions to be made public and require Part D and Medicare Advantage plans to conduct audits of PBM contract terms and direct and indirect remuneration data to account for the true net cost of covered Part D Drugs. It would also require manufacturers to pay a rebate for Part D drugs for which the list price, based on the WAC, increases faster than inflation.

Enhanced technology is also part of the proposal, like

- increasing the use of real-time benefit check tools to lower beneficiary costs
- improving provisions of Medicare parts A and B claims data to prescription drug plans
- establishing pharmacy quality metrics in Part D
- encouraging biosimilar uptake through star rating measures
- permanently authorizing a successful pilot on retroactive Part D coverage for low-income beneficiaries
- creating a Medicare and Medicaid prescription drug pricing dashboard

Appendix III. Total Prescription Revenues in Billions

Largest 15 U.S. Pharmacies, by Total Prescription Revenues, 2018[194]

Company	Stock Ticker	Estimated 2018 Prescription Revenues (billions)	Share of 2018 Prescription Revenues	Changes in Revenues vs. 2017	Primary Dispensing Format
CVS Health Corporation Retail Pharmacy Pharmacy Services1	CVS	 $64.2 $38.6	 15.1% 9.1%	 +7.8% -0.1%	Chain drugstore/LTC pharmacy Mail/Specialty pharmacy
Walgreens Boots Alliance2	WBA	$74.4	17.5%	+15.6%	Chain drugstore/Mail/ Specialty pharmacy
Cigna/Express Scripts, Inc.3	CI	$46.5	11.0%	-1.8%	Mail/Specialty pharmacy
UnitedHealth Group (OptumRx)	UNH	$25.9	6.1%	+23.4%	Mail/Specialty pharmacy
Walmart Stores, Inc.4	WMT	$20.9	4.9%	+2.1%	Mass merchant with pharmacy
The Kroger Company5	KR	$13.4	3.2%	+4.7%	Supermarket with pharmacy
Rite Aid Corporation6	RAD	$11.1	2.6%	-29.4%	Chain drugstore
Humana Pharmacy Solutions	HUM	$6.3	1.5%	+0.6%	Mail/Specialty pharmacy
Albertsons Companies6	Private	$5.0	1.2%	-0.3%	Supermarket with pharmacy
Diplomat Pharmacy7	DPLO	$4.8	1.1%	+6.7%	Mail/Specialty pharmacy
Costco Wholesale Corporation	COST	$2.6	0.6%	+1.7%	Mass merchant with pharmacy
PharMerica	Private8	$2.4	0.6%	+4.3%	Long-term care pharmacy
Publix	Private	$2.2	0.5%	+4.7%	Supermarket with pharmacy
Ahold Delhaize	ADRNY	$2.1	0.5%	-1.2%	Supermarket with pharmacy
H-E-B	Private	$1.8	0.4%	+4.6%	Supermarket with pharmacy
Subtotal Top 15		$322.3	76.1%		Supermarket with pharmacy
Total Pharmacy Industry prescription Revenues		$423.7	100%		

LTC= long-term care. Totals may not sum due to rounding. Includes revenues from all pharmacy dispensing formats. Excludes estimated infusion services covered by medical benefit. Revenues reflect calendar year 2018, which may not correspond to fiscal year reporting.

1. Includes Retail Pharmacy USA segment (which includes Alliance Rx Walgreens Prime) and pro forma full year revenues from 2018 acquisitions.
2. Includes Retail Pharmacy USA segment (which includes Alliance Rx Walgreens Prime) and pro forma full year revenues from 2018 acquisitions.
3. In 2018, Cigna acquired Express Scripts, Includes pro forma dispensing revenues and growth rates of both companies.
4. Includes Walmart and Sam's Club stores.
5. Includes retail pharmacies and Kroger Specialty Pharmacy (which Kroger reports separately in its financial reports).
6. Includes estimated revenues from EnvisionMail and EnvisionSpecialty, the mail and specialty pharmacies of EnvisionRx. These were formerly known as Orchard Pharmaceutical Services.
7. Includes specialty pharmacy dispensing revenues plus estimated mail pharmacy dispensing revenues of CastiaRx.
8. In 2017, PharMerica was acquired by investment firm KKR and Walgreens Boots Alliance. Its common stock stopped trading in December 2017.

194 Fein, A. J. (2019). *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. Drug Channels Institute*. https://drugchannelsinstitute.com/products/industry_report/pharmacy/

Appendix IV. Colorado Prescription Drug Spending and The Impact Of Drug Rebates (CIVHC Report)

CENTER FOR IMPROVING
VALUE IN HEALTH CARE

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

Released January 2021

Contents

Executive Summary

Access to affordable prescription drugs is necessary for a healthy population, and with drug costs on the rise, it is important to investigate ways to lower prescription drug costs. Analyses of 2018 claims from the Colorado All Payer Claims Database (CO APCD) shows Colorado spent nearly $4 billion, or 13% of total health care spending ($23 billion), on prescription drugs alone. This is an increase of over $300 million since 2016.

Understanding the total amount health insurance companies spend upfront on prescription drugs is important, but does not paint the full picture of spending. Tracking drug spending is complicated because health insurance companies and pharmacy benefit managers receive rebates, discounts, and other compensations from drug manufacturers as incentives for making certain drugs available.

In 2019, health insurance payers submitted drug rebate and concession information for 2016, 2017 and 2018 to the CO APCD for the first time. Analysis of rebate data across all years and all payers shows that nearly $3 billion was collected in prescription drug rebates, representing 26% of total spending. While rebates can reduce overall prescription drug spending for payers, they also contribute to long-term growth in prescription drug spending by incentivizing the use of higher cost specialty and brand name drugs. It is also unclear if these savings for commercial insurance companies are passed on to consumers or to employer purchasers through reductions in premiums or prescription drug costs.

This drug rebate analysis is the first in Colorado to provide prescription drug spending and rebate information across Medicaid, Medicare fee-for-service and Medicare Advantage, and commercial health insurance payers.

Key findings include:

- Total prescription drug spending grew 15% from 2016 to 2018, but only grew 9% when considering rebates received by health plans.
- For all payers combined, the amount they received in rebates rose from $850 million dollars in 2016 to $1.12 billion in 2018, an increase of 32%.
- In 2018, rebates as a percentage of total drug spending varied considerably by payer type (Medicaid 55%; Medicare Fee-for-Service 18%; Medicare Advantage 17%; Commercial plans 16%.
- For commercial payers, prescription drug rebates went up from $119 million in 2016 to $179 million in 2018 – an increase of $60 million (50%). Rebates as a percentage of commercial prescription drug spending also increased substantially, from 11% to 16% from 2016 to 2018.
- While prescription drug spending for commercial payers before rebates increased by 6% from 2016-2018, total net spending including rebates remained flat.
- In 2018, across all payers, 42% of all brand name drug spending, 27% of all specialty drug spending, and 4% of all generic drug spending was received back in rebates.
- Total spending for high cost specialty drugs increased by 25% ($1.14B to $1.51B) from 2016-2018 across all payers, and percent of rebates received for specialty drugs increased significantly for Medicaid (46% to 54%) and commercial payers (13% to 18%).

This report demonstrates that rebates complicate an already complex process of tracking the total cost of prescription drugs across payers. Results show that prescription drug rebates reduce drug spending by payers in the short-term. However, rebates could be incentivizing increased use of high cost drugs, resulting in a negative impact on health care costs long-term. To better understand the impact of rebates, more transparency is needed on how drug rebates impact the use of prescription drugs.

Introduction

Prescription drug costs are the fastest growing health care expense in the United States.[1] The main driver of the increase in total health care spending is high prescription drug prices and, particularly, the introduction and rapid growth in prices for specialty drugs.

Tracking total drug spending is complicated because health insurance companies and pharmacy benefit managers receive rebates, discounts, and other compensations from drug manufacturers as incentives for making certain drugs available. Manufacturer rebates and other compensations are typically considered confidential and play a role in influencing drug purchasing across all payers. Compensation includes discounts, fees, educational grants for the provision of utilization data to manufacturers for marketing and related purposes, market share incentives, commissions and manufacturer administrative fees.

Prior to the 2018 Colorado state regulations requiring payers to report rebates and other compensations, measuring actual net prescription drug spending in Colorado was a challenge.

Note: For the purposes of brevity, the term prescription drug "rebates, discounts, coupons and other compensation" will be referenced in this report as "rebates."

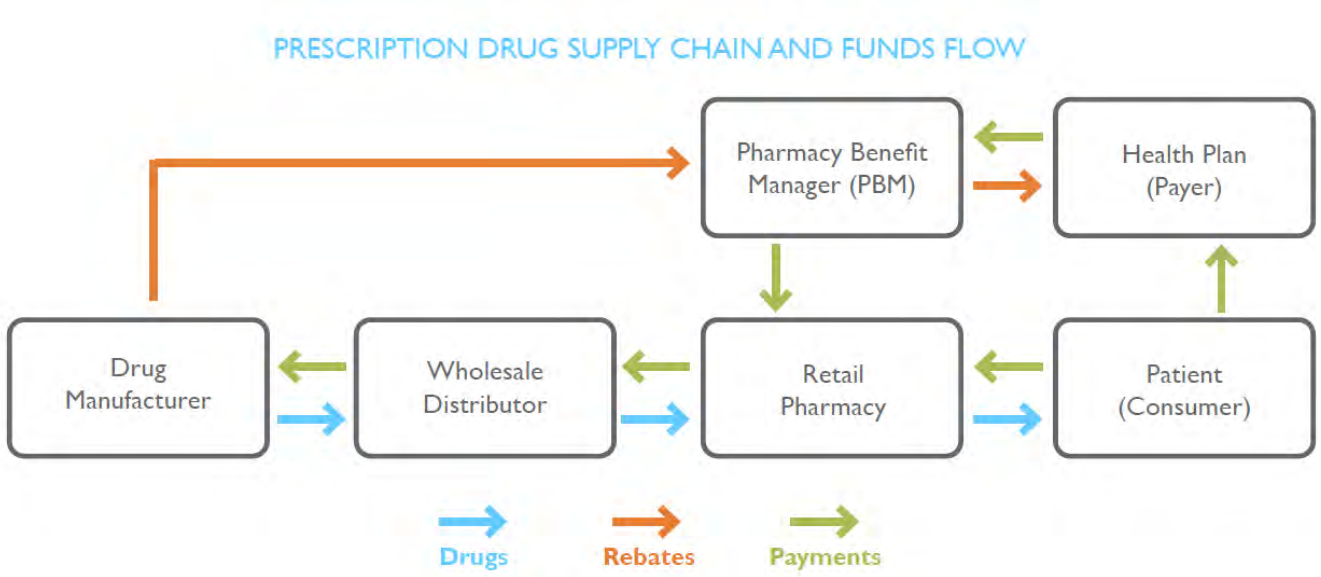
Prescription Drug Supply Chain and Funds Flow

The information below provides a simplified explanation of the prescription drug supply chain and the flow of drugs, payments and rebates.

What is a Pharmacy Benefit Manager?

A pharmacy benefit manager (PBM) is a company that manages prescription drug benefits on behalf of health insurers and self-funded employers. Health plans often contract with PBMs to negotiate discounts from retail pharmacies, maintain the drug formulary (the list of drugs covered by the health plan and their associated co-pays) and pay claims for drugs dispensed to consumers by retail pharmacies.

PBMs operate in the middle of the distribution chain for prescription drugs. They use their purchasing power to negotiate rebates and discounts from drug manufacturers.



What are Drug Rebates and How Do They Work?

Drug manufacturers sell drugs to wholesalers that sell them to retail outlets like a local pharmacy. The price at the pharmacy is the manufacturer's price that is marked up by the wholesaler and then by the retailer. Health plans, through their PBM, negotiate discounts from these retail outlets.[2]

For some drugs, manufacturers pay rebates to the PBM or health plan to make them "preferred drugs" in the health plan formulary. Rebates are paid separately to the PBM or health plan after consumers purchase the drugs. In effect, rebates reduce the cost of drugs to the PBM or health plan. However, rebates may produce a net increase in prescription drug spending if rebates lead to increased utilization of higher cost drugs. They could also contribute to higher total health care spending if the savings are not passed through to the consumer or employer who purchased the health plan.

How rebates are used by payers and PBMs is not fully transparent. It is not clear whether rebates are retained by PBMs and commercial health plans or whether they are used to reduce premiums and out-of-pocket costs for employers and consumers.[2,3] If passed through, consumers can receive indirect benefits from rebates. Otherwise they may not, because consumer out-of-pocket costs (i.e., copayment, coinsurance) are based on the negotiated price of a drug, not the price after rebates.[2]

In some cases, manufacturers will issue coupons for specific drugs that commercially-insured patients can use to reduce their out-of-pocket expenses. These point-of-sale rebates, which are banned for Medicare Part D and Medicaid insured patients, are typically offered for high cost drugs to make them more affordable to individuals. Although coupons reduce patient out-of-pocket costs, they can encourage use of higher cost drugs and can have the effect of increasing premiums, lowering health plan profits or increasing consumer out-of-pocket expenses for other drugs.[2]

U.S. Prescription Drug Rebates

National studies of the size of rebates shows differences by payer type. Medicaid receives the largest rebate as a percentage of prescription drug spending, roughly 50%-52%. Medicare Part D receives 18-22% of total spending back in rebates and commercial insurance payers receive 12%.[2,4]

Medicaid receives the largest percentage in part because of the federal Medicaid Drug Rebate Program which requires manufacturers to provide rebates to help offset Medicaid pharmacy costs.[2,6] State Medicaid programs, such as Health First Colorado, are funded through both state and federal dollars, so the federal government is able to oversee these regulations.

Medicare Part D is unable to negotiate drug prices due to federal regulations. Medicare Advantage plans are different from Medicare Fee-For-Service (FFS) Part D coverage in that they are administered by commercial health insurance companies. Commercial payers receive lower rebates as a percentage of prescription drug spending than both Medicaid and Medicare Part D. Commercial payer rebates are lower because they typically cover more drugs than public insurers, and because manufacturers can make coupons available to commercial patients directly. Having more drugs covered and offering direct to consumer coupons helps increase the use of drugs without having to provide as many rebates to PBMs or commercial health plans.[2]

The rebates Medicaid and Medicare FFS receive are reported publicly and are used to reduce government spending and, in the case of Medicare, reduce premiums.[2,3] It is not clear how commercial health insurance payers use rebates and whether any of the savings are passed along to employers and consumers through reductions in premiums or prescription drug coverage costs.

Colorado Drug Rebate Data Sources

Drug rebate information in Colorado was previously unavailable until a regulatory change to the Data Submission Guide, enacted in October 2018, required health insurance payers in Colorado to submit rebate and other compensation information to the Center for Improving Value in Health Care (CIVHC), administrator of the Colorado All Payer Claims Database (CO APCD).[5]

Payers began reporting in the fall of 2019 and submitted information for drug rebates and total spending for 2016, 2017 and 2018. Drug rebate files were submitted based on data from the payer's PBM, which included drug rebates and other compensations paid by manufacturers to the PBM. Commercial payers reported receiving 97% of the rebate dollars back from the PBMs.

The quality of the results summarized in this report are entirely dependent on the completeness and validity of the payer-submitted data. Each payer used their own definition of specialty, brand and generic drugs when reporting rebates and spending at the drug category level.

In order to validate the information, CIVHC evaluated each submission and compared reported member months and total prescription drug spending in the drug rebate files to the claim information submitted by the payers on a monthly basis to the CO APCD. Discrepancies were communicated to payers, which in many cases resulted in payers revising their submission.

This report references "all payers" which refers to all Colorado payers that reported rebates to the CO APCD. Two commercial payers did not submit a rebate file and are not included in the analysis. These two payers represent a relatively small percentage of insured lives in the state and the impact of the missing data is unlikely to have a material impact on the prescription drug spending and rebate amounts reported. Details regarding data submission methods and caveats are presented in the Appendix.

Colorado Prescription Drug Rebate Findings

Estimating prescription drug spending minus rebates provides information about the impact rebates may have on the amount that payers ultimately spend on prescription drugs. This is especially important for evaluating the potential impact of rebates for Colorado's commercial health plans, which unlike rebates for Medicaid and Medicare, are not publicly reported.

According to the drug rebate submissions, $1.12 billion in rebates was received across all payers in Colorado in 2018. From 2016 to 2018, total prescription drug spending without rebates grew from $3.4 billion to $3.9 billion, a 15% increase. Prescription drug rebates grew 32% during this period, from $850 million in 2016 to $1.12 billion in 2018. Rebates represented 29% of total prescription drug spending across all payers in 2018.

Total prescription drug spending net of rebates grew nearly 9% from 2016 to 2018, as opposed to 15% without accounting for rebates. These findings indicate that rebates provided by manufacturers significantly reduce the overall growth of prescription drug spending for Colorado payers in the short-term.

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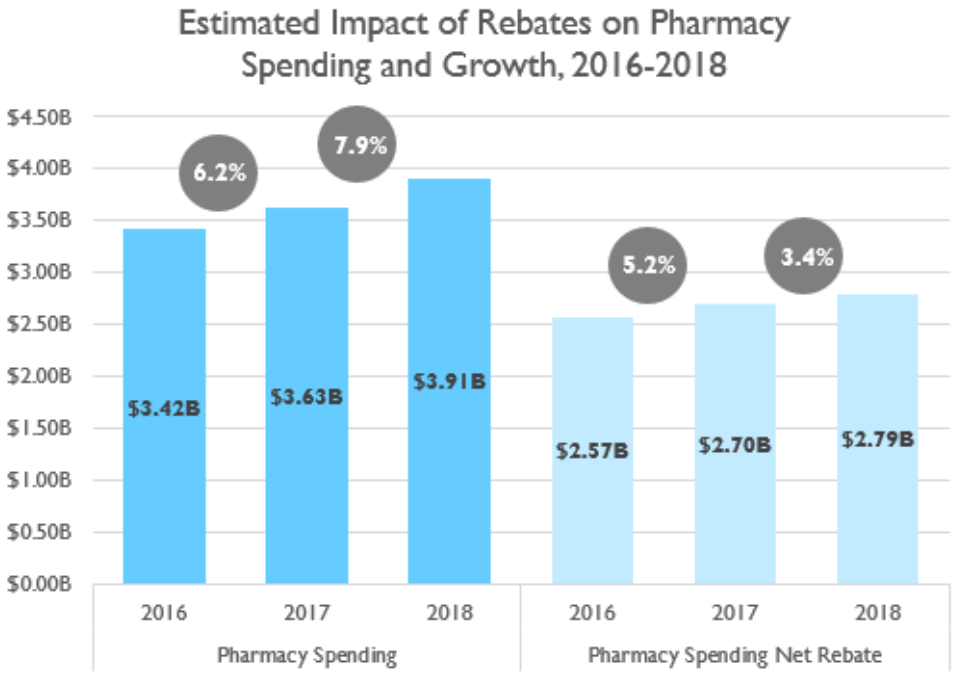
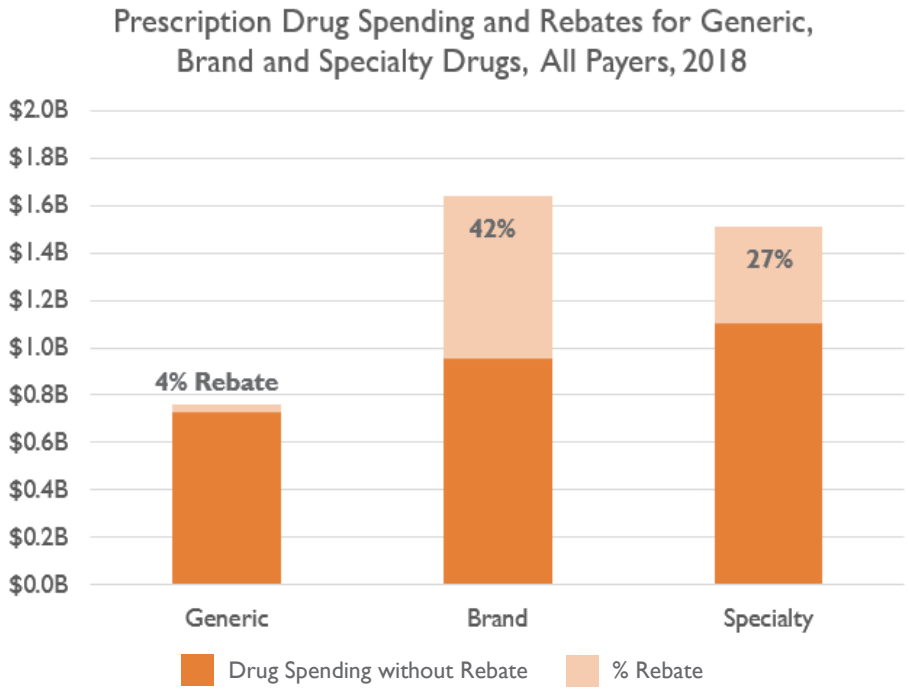
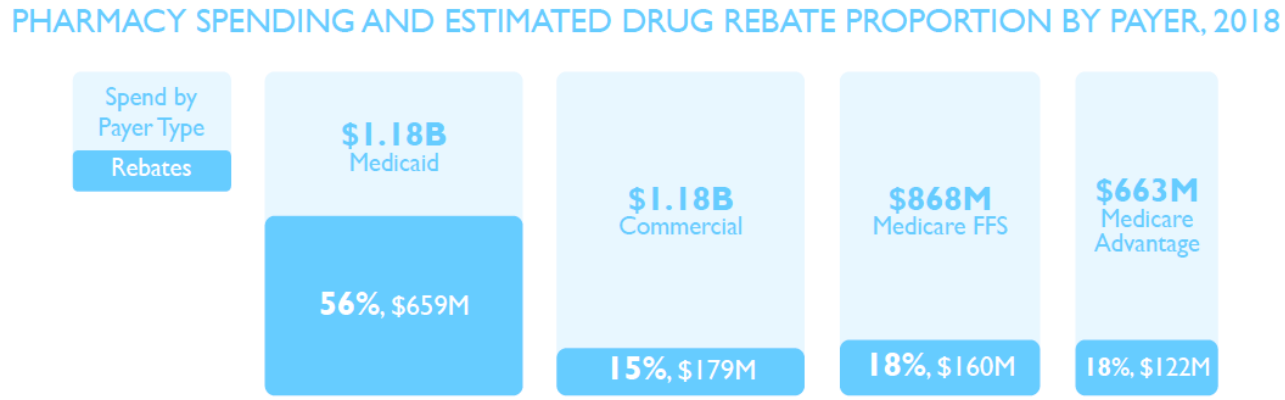


*Note: Multiple graphics in this report were adapted based on the CHIA Annual Report of Performance of the Massachusetts Health Care System.[4] Total prescription drug spending and spending net of rebates do not equal the sum of these figures across the four payer types because some spending could not be assigned to a payer type. Percentages represent percent change year over year.

In 2018, across all payers, prescription drug spending was highest for brand drugs ($1.6 billion), followed by specialty drugs ($1.5 billion) and generics ($759 million). Rebates as a percentage of drug spending by category type were highest for brand name drugs (42%), then specialty (27%) and generic drugs (4%).



Because the legal and market dynamics involved in negotiating rebates with drug manufacturers differs between payer types, the following pages summarize rebates separately for commercial payers and public payers – Medicaid, Medicare FFS and Medicare Advantage. Results show that prescription drug rebates as a percentage of total prescription drug spending varied by payer type and were similar to rebate percentages reported across the U.S.[2,4]



Drug Category Spending

Prescription drugs can be classified as generic, brand name, or specialty. Brand name drugs are protected by patent law that can extend for up to 20 years and are generally more expensive than generic drugs. Generics are manufactured with the same ingredients as brand name drugs, but can only be produced and sold after the patent expires. Generic drugs are the same dosage, safety, and strength, but are almost always less expensive than brand name drugs, as they bring competition to the market.

Specialty drugs are a subcategory of brand name drugs. There is no standard definition or list of specialty drugs, but they usually treat complex and rare conditions and diseases and require special handling, storage, administration, and patient monitoring. Specialty drugs are most notably different than generic and non-specialty brand name drugs in that they are very expensive and often the only drug of their kind to treat certain conditions.

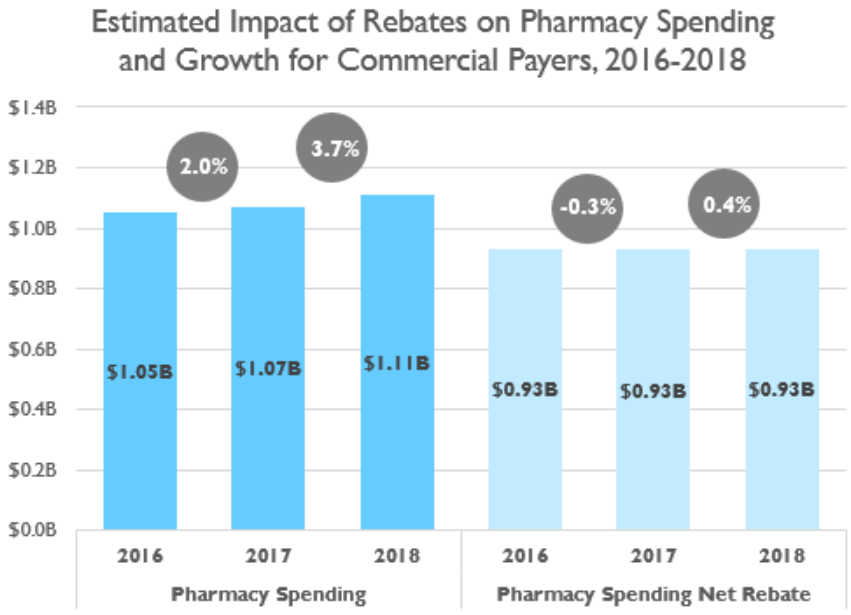
Using pharmacy claims data submitted to the CO APCD, and the list of specialty drugs used by Magellan Rx Management™, CIVHC estimates that across all payers and prior to rebates, specialty drugs represent only 1-2% of drug claims volume, but account for 37-49% of total drug spending.

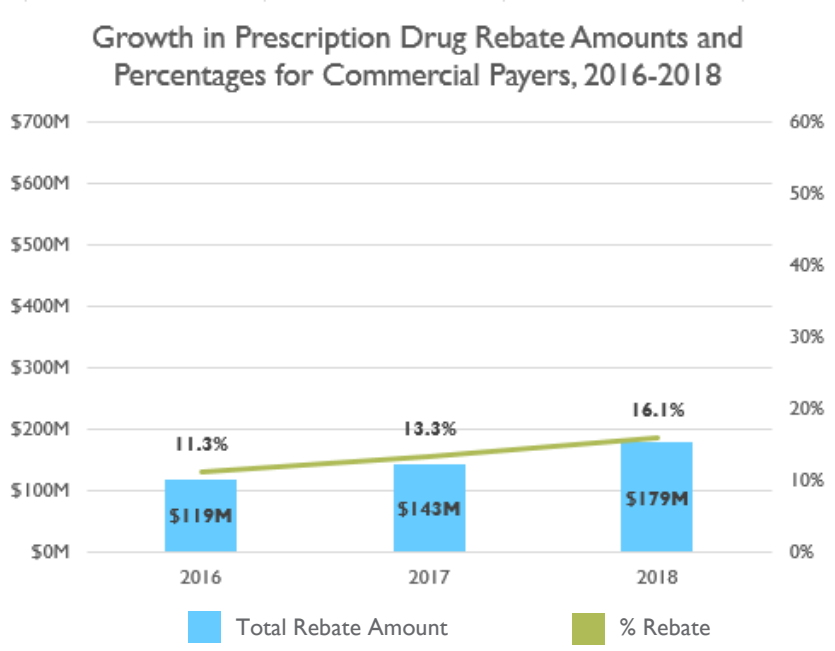
Specialty Drug Percent Total Pharmacy Volume and Spend, 2018		
Payer Type	**% Total Prescription Volume**	**% Total Prescription Spend**
Commercial	2%	49%
Medicaid	1%	44%
Medicare Advantage	1%	33%
Medicare FFS	1%	37%

*Note: Volume of claims by drug category was not included in the drug rebate file submissions in 2019. As a result, percent total volume and percent total spending in the table above was calculated based on monthly pharmacy claims submitted by payers to the CO APCD. Assignment of specialty drugs used Magellan Rx Management™ guidelines. Specialty drug spending and rebate information throughout the rest of the report was calculated using the drug rebate file submissions.

Prescription Drug Rebate Findings – Commercial Payers

For commercial payers, total prescription drug spending grew from $1.05 billion in 2016 to $1.11 billion in 2018, a 5.8% increase. In contrast, growth in spending net of rebates was negligible (0.10%) between 2016 and 2018.

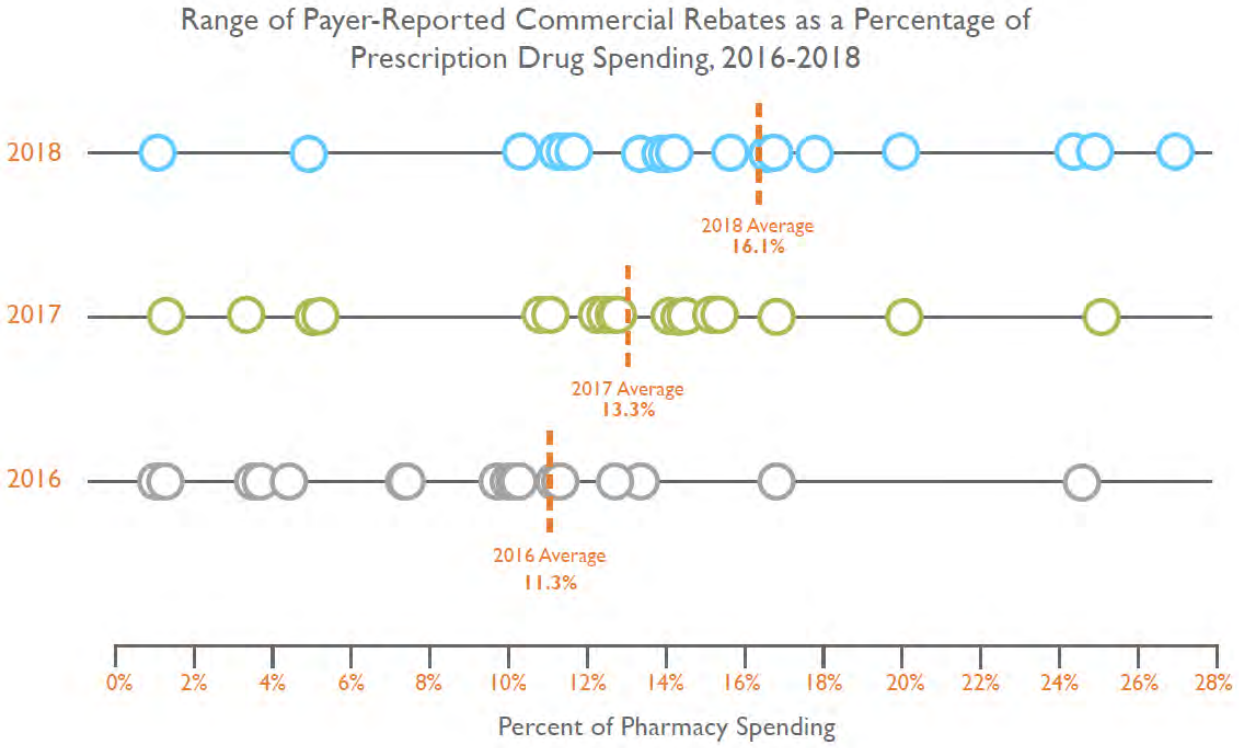




Prescription drug rebates for commercial payers went up from $119 million in 2016 to $179 million in 2018 – an increase over three years of $60 million (50%). Rebates as a percentage of prescription drug spending also increased substantially, from 11% to 16% between 2016 and 2018.

Variation in Rebates by Commercial Payer

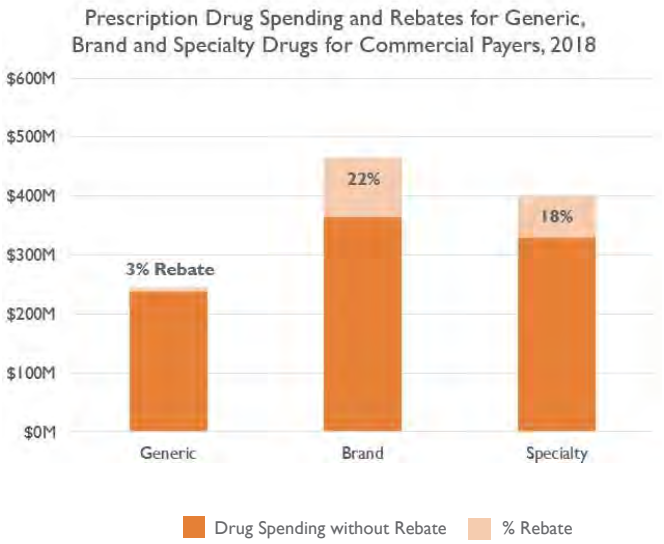
For commercial plans, prescription drug rebates as a percentage of total prescription drug spending varied dramatically by individual commercial payer for each reported year. The lowest percentage was less than 2% and the highest was approximately 27%.

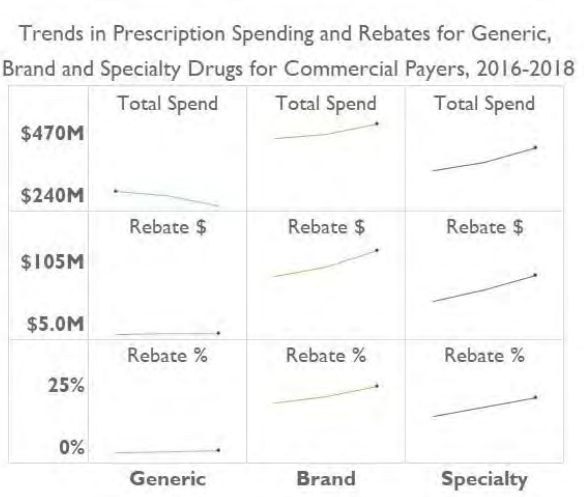


When isolating the analysis to only the six largest commercial payers in Colorado, the average percentage rebate is similar to the "all payer" results. This is because the large commercial payers account for the majority of drug rebates and prescription drug spending.

Spending and Rebates for Specialty, Brand and Generic Drugs

For commercial payers, in 2018, both total drug spending and percent rebates was the highest for brand name drugs ($465M and 22%), although specialty drugs also had significant spending and percent rebates ($400M and 18%).





Trends in generic, brand name, and specialty drug spending, illustrated in the table below, show that the increases in total rebate dollars and rebates as a percent of total spending for brand and specialty drugs align very closely with total spending increases from 2016-2018.

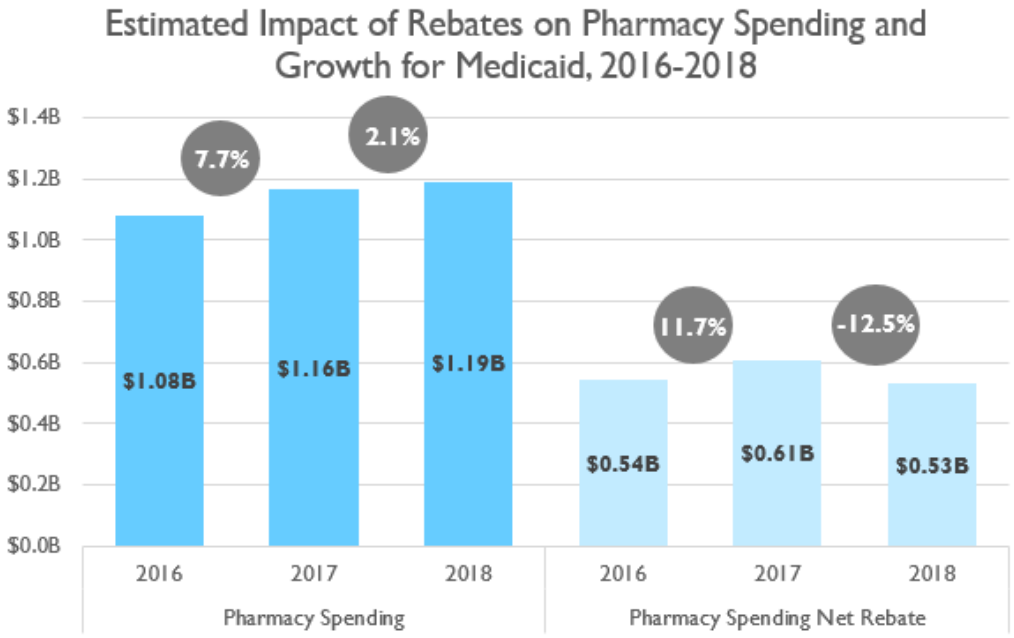
Commercial Payer Pharmacy Total Spend and Rebates by Drug Category, 2016-2018

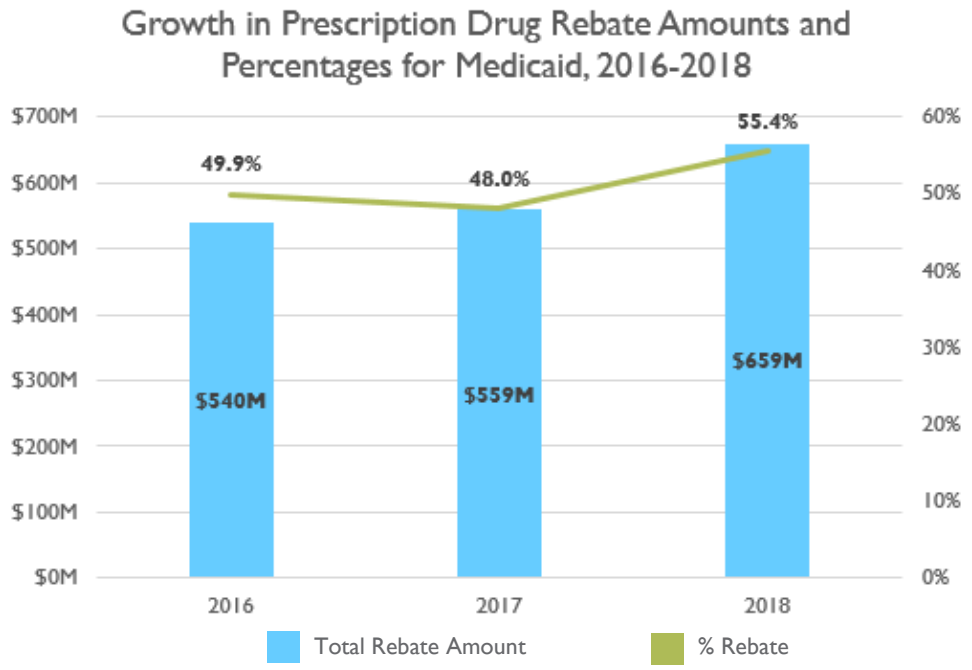
Drug Category	2016			2017			2018		
	Total Spend	Rebate	% Rebate	Total Spend	Rebate	% Rebate	Total Spend	Rebate	% Rebate
Generic	$283M	$5.4M	2%	$271M	$6.2M	2%	$244M	$6.2M	3%
Brand	$425M	$70M	17%	$437M	$81M	19%	$465M	$100M	22%
Specialty	$340M	$43M	13%	$362M	$55M	15%	$400M	$72M	18%

Rebates for brand and specialty drugs grew $59 million from 2016 to 2018, and total spending increased $100 million. This finding suggests that while rebates help offset the costs of these higher price drugs, they may incentivize increased use, raising overall health care costs over time. In contrast, total spending without rebates for generic drugs fell from 2016-2018 and rebates for these generic drugs were minimal during the evaluation period compared to brand and specialty drugs.

Prescription Drug Rebate Findings – Medicaid and Medicare

Medicaid pharmacy spending increased 9% from 2016 to 2018 ($1.08 billion to $1.19 billion). Compared to Medicare and commercial payers, the estimated impact of rebates on spending growth was largest for Medicaid, with total spending actually decreasing when considering rebates.

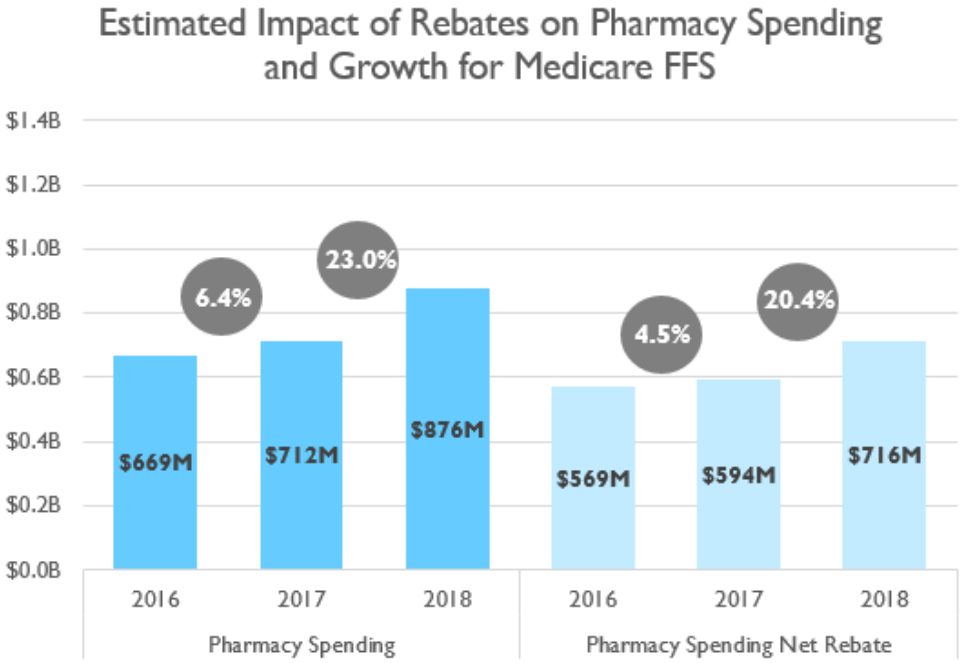


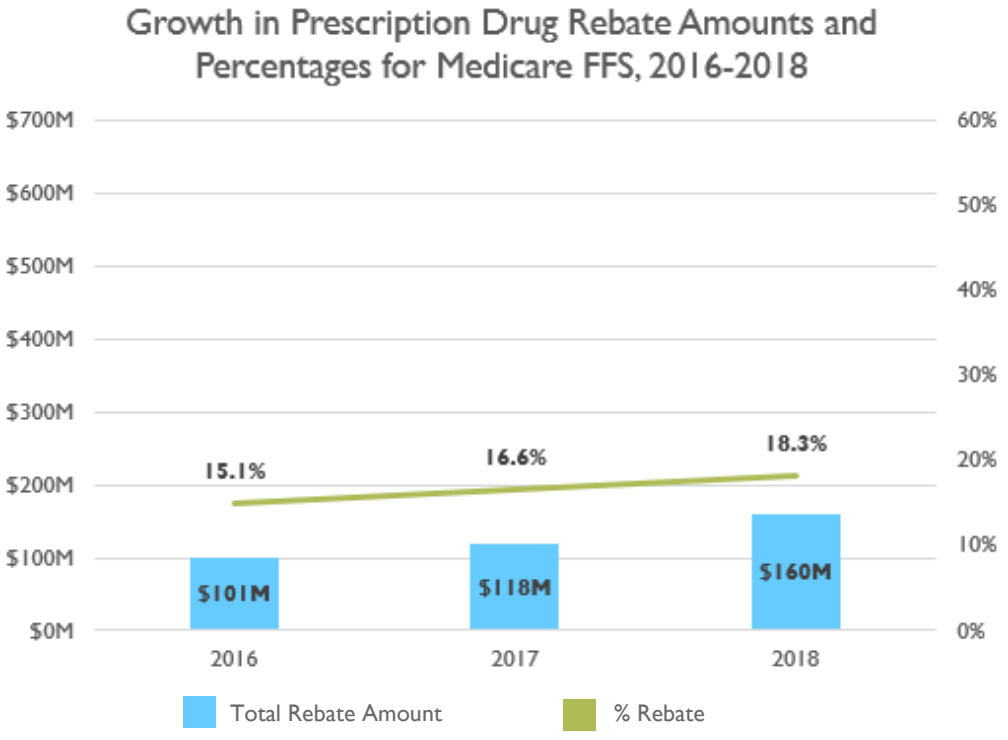


As mentioned above, Medicaid drug rebates are the highest among the four payer types due in large part to federal pricing policy such as the Medicaid Drug Rebate Program, and supplemental rebates

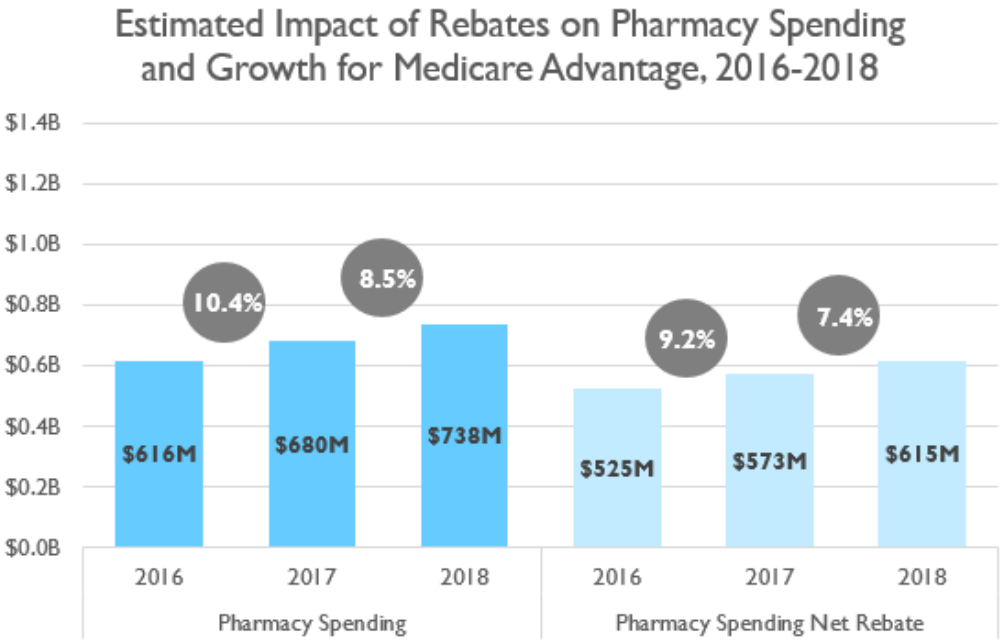
negotiated based on formulary status.[6] Prescription drug rebates increased for Medicaid over the three years by $120 million (22%), and rebates as a percentage of prescription drug spending increased from 50% in 2017 to 55% in 2018.

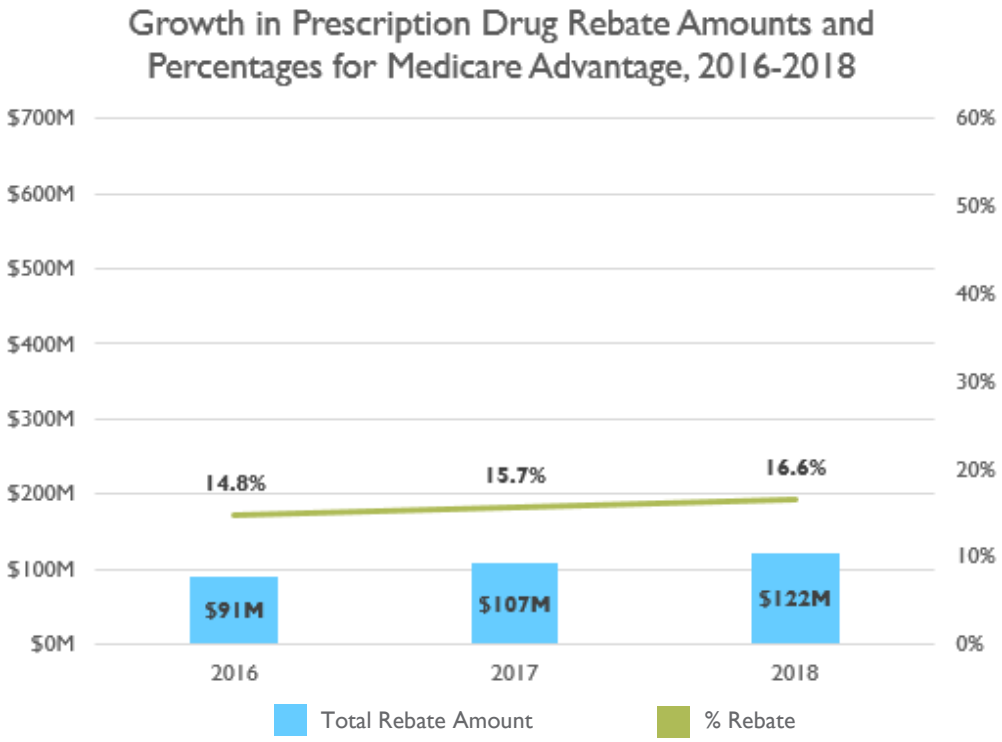
The growth in prescription drug spending from 2016 to 2018 for Medicare FFS (31%) and Medicare Advantage (20%) was larger than that of the other payers. However, the impact of rebates on reducing total spending growth was smallest for the Medicare plans. Growth in spending when considering rebates was only slightly lower than growth in total spending without rebates for both Medicare FFS and Medicare Advantage.





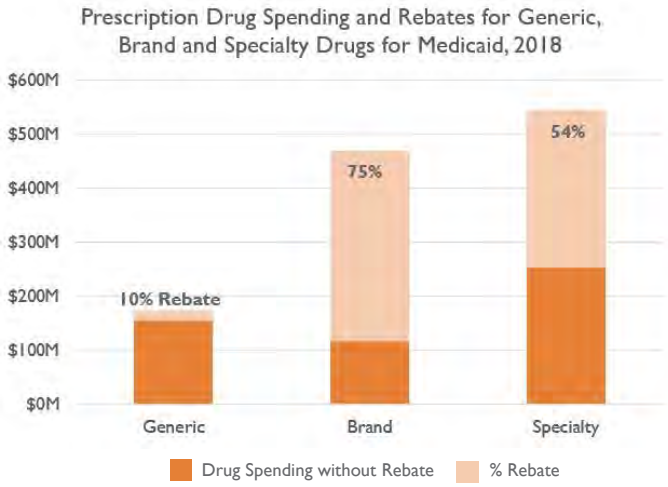
Prescription drug rebates for Medicare FFS increased over the three-year period by $60 million (59%) and rebates as a percentage of total drug spending showed an increase from 15% in 2016 to 18% in 2018. Rebates for Medicare Advantage increased $31 million (34%) and rebates as a percentage of spending increased from 15% in 2016 to 17% in 2018.

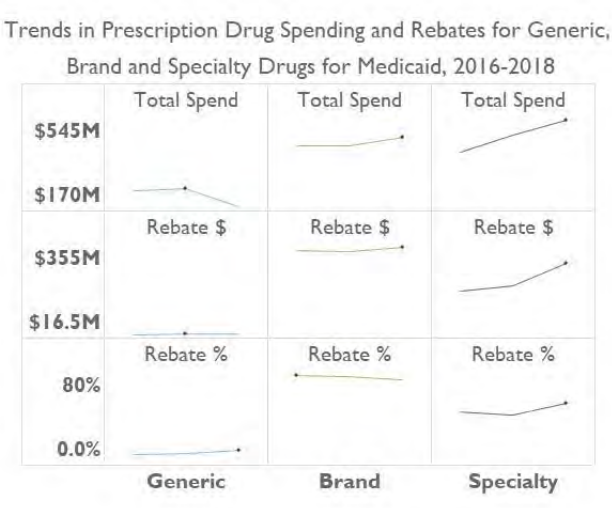




Spending and Rebates for Specialty, Brand and Generic Drugs

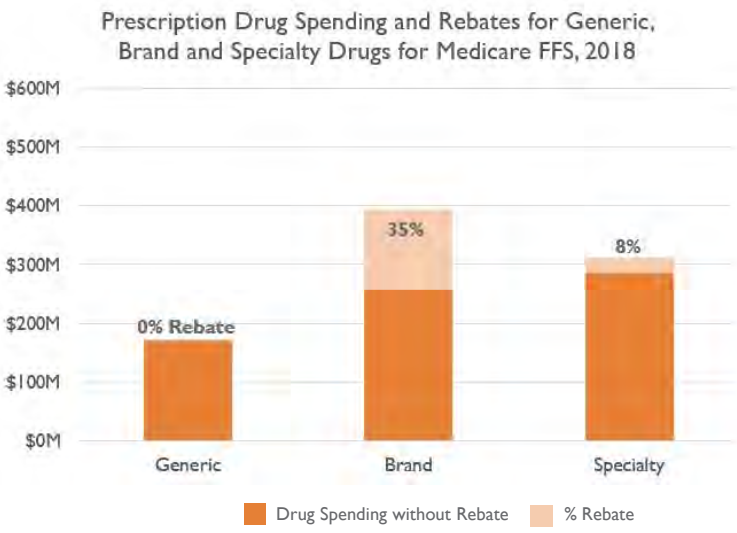
For Medicaid, prescription drug spending was highest for brand drugs in 2016, and highest for specialty drugs in 2017 and 2018. Rebates as a percentage of total spend were highest for brand name drugs across all three years with 75% of total brand drug spending reflecting rebates in 2018.

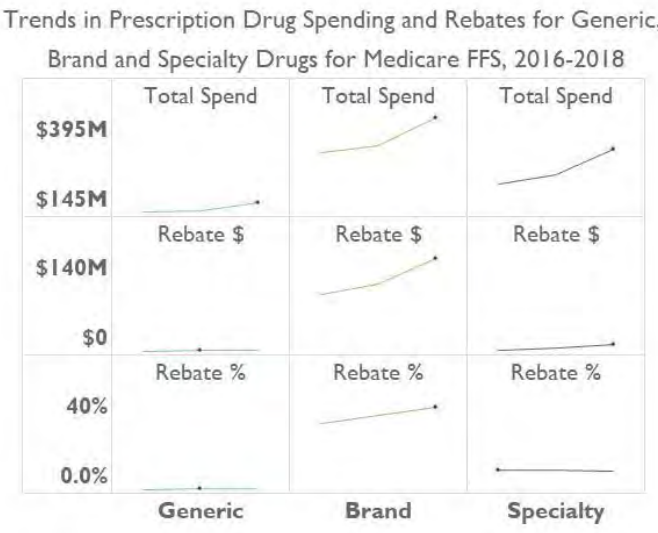


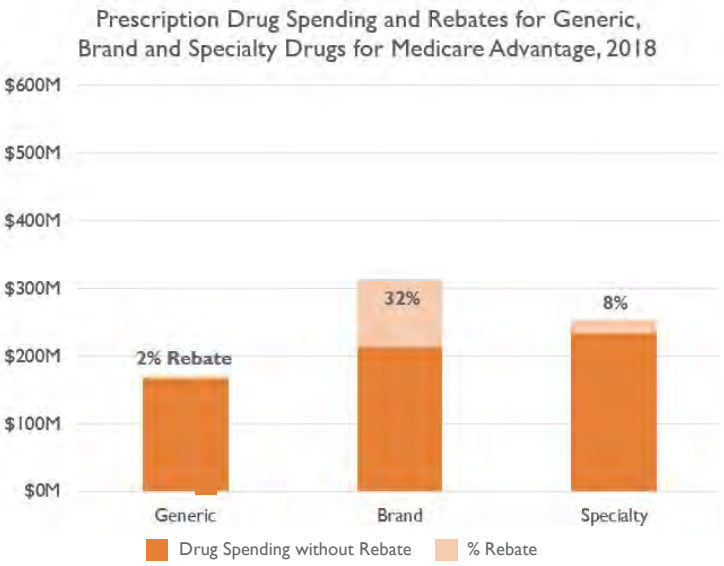


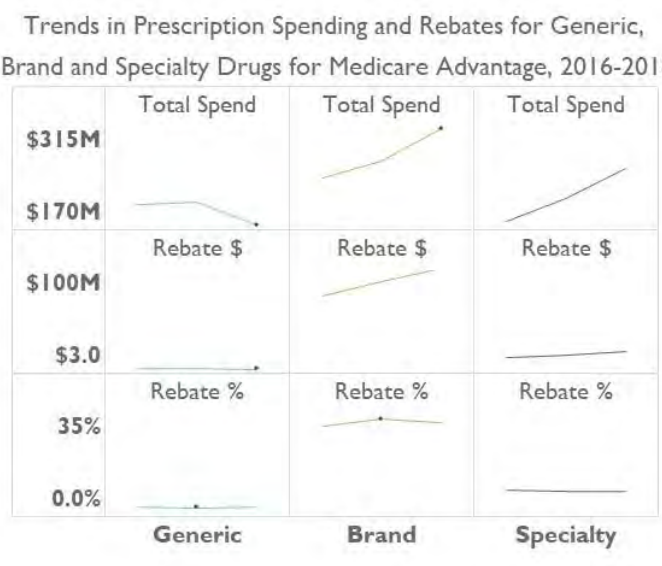
From 2016 to 2018, spending for brand name drugs grew from $433 million to $468 million, and rebate percentages remained relatively stable (78% in 2016 and 74% in 2018). Both spending as well as rebates for specialty drugs grew dramatically just as they did with commercial payers. Spending for generic drugs fell and rebate percentages for these drugs remained very small. As with commercial payers, increases in the amount paid in rebates correlated with increases in spending for both specialty and brand name drugs, and growth in spending exceeded the growth in rebates for these drugs by $56 million.

For Medicare FFS and Medicare Advantage, both prescription drug spending and rebate percentages were highest for brand name drugs. Rebate percentages for generic drugs were negligible (.0001% in 2018).









From 2016 to 2018, both total spending and rebate percentages for brand name drugs for Medicare FFS plans increased. Spending for specialty drugs grew dramatically for Medicare Advantage and Medicare FFS, which is consistent with the findings for commercial payers and Medicaid. However, unlike Medicaid and commercial, rebate percentages for specialty drugs were low and did not change. Spending for generic drugs was relatively small and rebates were mostly unchanged.

Similar to commercial and Medicaid, the increase in amount paid in rebates correlates with the increase in spending for both specialty and brand name drugs. The growth in spending exceeded the growth in rebates for these drugs by $123 million and $120 million for Medicare FFS and Medicare Advantage, respectively.

Conclusions and Next Steps

This analysis demonstrates that rebates complicate an already complex process of tracking the total cost of prescription drugs across payers. Results show that prescription drug rebates are substantial and reduce both the size and growth of overall drug spending by payers in the short-term. However, health insurance companies and PBMs receive significant rebates and concessions for specialty drugs and brand name drugs which may be incentivizing their increased use and contributing to rising pharmacy costs long-term.

It is important to note that some specialty drugs are the only drug available for certain conditions. This puts patients, families and payers in a situation where they have no other option but to pay exorbitant prices for these drugs. However, specialty drugs and brand drugs must be carefully evaluated and when available, less expensive and equally effective alternative drugs and treatments should be considered to increase affordability and reduce overall spending.

Medicaid and Medicare use rebates to reduce total spending of tax payer dollars, but it is unclear how commercial payers use rebates and whether the dollars are passed through to employers and consumers. If not, employers and those on the individual market are paying significantly for increasingly expensive drugs, while PBMs and health plans are benefitting from rebate dollars.

Without more transparency about how drug rebates are being used by PBMs and health plans as well as information about how they influence the use and prices of expensive drugs, it is impossible to evaluate the full impact of rebates. Critical questions include:

- Do commercial health plans pass savings on to employers and, and if so how (for example, via premium decreases or more generous drug benefits)?
- Are rebates driving up utilization of specialty and brand name drugs?
- Do rebates drive up the price of specialty and brand name drugs so that manufacturers can recover the costs of the rebates?
- Are rebate costs initially factored into drug prices and manufacturer profits, creating a false narrative of "savings"?

Price transparency is also needed to understand the impact of rebates on the price of individual drugs, particularly higher cost specialty and brand name drugs. These drugs showed increases in both the total rebate amount as well as total spend, and the growth in spending when considering rebates was also substantial. Rebate and price transparency at the individual drug level can help determine whether manufacturers increased prices for certain drugs in an effort to offset the financial impact of rebates.

What Can Be Done

A number of opportunities exist across stakeholder groups to reduce drug spend and to ensure that rebates are helping consumers and employers save money on prescription drug costs, including:

- **Employers:** Request rebate dollars to be provided back to the employer to offset increases in prescription drug spending, and design benefit plans to limit the use of specialty drugs when alternatives exist.
- **Policy Makers:** Seek greater transparency around drug pricing and how rebates and other compensations are being used.
- **Researchers:** Study the pros and cons of drug rebates and their impact on utilization and prices of specialty and brand name drugs, and how this affects spending and clinical outcomes.
- **Consumers:** Ask health providers about alternative drug options, including generics, that may provide the same results at a lower cost.

Appendix: Prescription Drug Rebate Data Collection and Caveats

Data Submission Methodology

Beginning in September 2019, health in insurance payers in Colorado were required to submit prescription drug rebate information to CIVHC on an annual basis.[5] The first submissions included rebate data for three years: 2016, 2017 and 2018.

CIVHC modeled data submission requirements and instructions after a program administered by the Center for Health Information and Analysis (CHIA) in Massachusetts[4], and communicated these requirements to payers through calls, individual payer meetings, e-mails and the Prescription Drug Rebate Data Submission Manual.

Payer-submitted files of prescription drug rebate data included the following information (refer to the manual above for details):

- **Insurance product type** (e.g., used to classify members and prescription drug spending into payer type: Commercial, Medicaid, Medicare Advantage and Medicare FFS)
- **Member count and member months** with prescription drug coverage
- **Prescription drug spending excluding rebates.** Spending include all incurred claim allowed payment amounts to pharmacies for prescription drugs, biological products, or vaccines as defined by the payer's prescription drug benefit, including member cost-sharing.
    - Total
    - By type of drug – specialty, non-specialty brand and non-specialty generic
- **Prescription drug rebate amounts.** Includes prescription drug rebates, compensation, remuneration, and any other price concessions provided by pharmaceutical manufacturers and conferred to the payer regardless of whether paid as regular aggregate amounts, on a claim-by-claim basis at the point-of-sale as part of retrospective financial reconciliations, or by any other method.

  Compensation includes discounts, fees, educational grants for the provision of utilization data to manufacturers for marketing and related purposes, market share incentives, commissions and manufacturer administrative fees.

  This amount includes the total amount of prescription drug rebates and compensation provided by pharmaceutical manufacturers, regardless of whether they are conferred to the payer directly by the manufacturer, a PBM, or any other entity.
    - Total
    - By type of drug – specialty, non-specialty brand and non-specialty generic

With the submitted drug rebate files, payers were required to return an attestation, signed by a chief executive, that the results were "as complete and as accurate as possible and submitted according to the guidelines detailed in the Submission Manuals."

Drug rebate files submitted were based on data from the payer's pharmacy benefit manager (PBM), which included drug rebates and other compensations paid by manufacturers to the PBM. Commercial payers reported receiving 97% of the total rebate dollar amounts from their PBMs.

Data Submission Caveats

CIVHC attempted to validate payer-submitted drug rebate files by comparing member, member month and total prescription drug spending with those derived from CO APCD prescription drug data. Discrepancies were communicated to payers, which in many cases resulted in payers revising their submission.

Submissions from two of thirty payers (6.7%) were not received. However, total prescription drug spending for these payers represent a small portion of expenditures for all commercial payers (approximately 1%). The impact of these missed submissions does not have a material effect on reported prescription drug spending and rebate amounts.

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4. Center for Health Information and Analysis. Performance of the Massachusetts Health Care System Annual Report 2018. https://www.mass.gov/doc/chia-annual-report-september-2018/download Accessed March 6, 2019.
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6. Prescription Drugs, retrieved from Medicaid.gov. https://www.medicaid.gov/medicaid/prescription-drugs/index.html/. Accessed January 7, 2021.
7. Reynolds I and Chester A. The prescription drug landscape, explored. The Pew Charitable Trusts; 2019. https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf Accessed June 17, 2019

Appendix V. Drug Importation and International Pricing Report

Drug Importation in Colorado

International Pricing Report

December 2020

COLORADO
Department of Health Care Policy & Financing

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I. Executive Summary

Prescription drug costs are the fastest-growing consumer health care expense in the U.S., a trend that is unlikely to change in the coming years without disruption to the industry.[1] [2] Just in 2020, more than 200 drug manufacturers have raised prices on 645 brand-name drugs with an average price increase of 5.9 percent through August 2020 and the highest increase reached 230 percent.[3]

The cost burden of prescriptions is not just taking a toll on the financial wellbeing of Colorado families, employers, and the government, it also has the tragic effect of people foregoing their medications because they can't afford them. In the most recent Colorado Health Access Survey (CHAS), one in five Coloradans reported foregoing their prescription drugs due to cost.[4] Because of these facts, saving people money on healthcare is one of Governor Polis' top priorities, and prescription drug importation is a promising initiative the state is pursing to bring down costs for Coloradans and their employers.

Importing drugs from other countries holds promise because the U.S. pays far higher prices on prescription drugs than other comparable countries. According to one study, U.S. drug prices were nearly four times higher when compared with similar countries.[5]

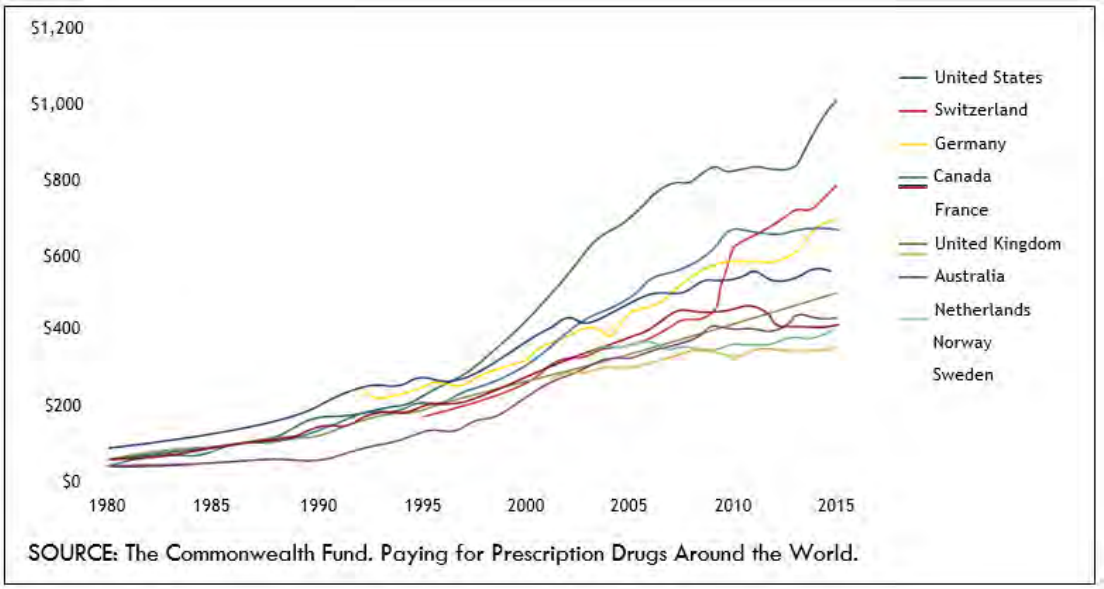
[1] Center for Sustainable Health Spending. (2017). *Health Sector Economic Indicators: Insights from Monthly National Price Indices Through June 2017*. Altarum Institute. https://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_Aug_2017.pdf

[2] Hanna, C., & Uccello, C. E. (2018). *Prescription Drug Spending in the U.S. HealthCare System*. American Academy of Actuaries. https://www.actuary.org/content/prescription-drug-spending-us-health-care-system

[3] Tedford, E. (2020, September 4). Drug manufacturers raise prices for 645 brands in 2020 so far. *DMD America Inc*. https://www.einpresswire.com/article/525209354/drug-manufacturers-raise-prices-for-645-brands-in-2020-so-far

[4] *2019 Colorado health access survey: Health insurance coverage*. (2020). Colorado Health Institute. https://www.coloradohealthinstitute.org/research/2019-colorado-health-access-survey-health-insurance-coverage

[5] Ways and Means Committee Staff. (2019). *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*. Committee on Ways and Means. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf



Drug importation can bring Colorado prices for many drugs more in line with global prices to the benefit of Coloradans and employers.

The Department of Health Care Policy and Financing has produced this report to illustrate the savings available through importation and to outline the current and pending steps to make that vision a reality. Highlights of the report are provided below.

- Prescription drug prices in the United States are nearly four times higher than they are in other comparable countries.[6]
- Lowering health care costs, and particularly prescription drug costs, in Colorado is a priority of Governor Jared Polis.
- One strong lever to address high drug prices in the state is the implementation of a Canadian importation program.
- The State's Canadian importation program, when fully implemented, could result in an average of 61 percent savings on 167 drugs initially analyzed for importation.[7]
- If changes were made to federal statutes to expand state-led importation programs to allow for importation from countries in addition to Canada, Colorado could access even lower drug prices—and an increase in access to drug supplies—to the benefit of consumers, employers, and tax subsidized plans like municipalities and the state's employee benefit plan.
- The Department of Health Care Policy and Financing (the Department) conducted a study of cost savings on 50 drugs from expanding importation to other countries and

[6] Ways and Means Committee Staff. (2019). *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices*. Committee on Ways and Means. https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf

[7] Department of Health Care Policy and Financing staff, (2020). *Colorado Drug Importation Program--Draft Application*. Colorado Department of Health Care Policy and Financing. https://www.colorado.gov/pacific/sites/default/files/Colorado%20Draft%20SIP%20%20-%20Version%203-9-2020.pdf

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compared pricing in Canada, France and Australia to Colorado's commercially insured expenditures. If importing from Canada, Colorado's consumers, employers, and non-Medicaid payers could expect to save an average of 63 percent on the 50 drugs analyzed. Importing from France and Australia could deliver even higher savings at an average of 84 percent and 78 percent, respectively.

- Additionally, the Department analyzed 14 popular biologic drugs. If federal statutes were amended to allow for the importation of biologic drugs, the state could import high cost drugs like Humira and branded insulins, with an average of 71 percent savings when imported from Canada, 77 percent from France, and 78 percent from Australia.
- Accessing these increased savings requires federal and state statute changes. The Colorado General Assembly showed interest in passing SB20-119 in the truncated 2020 legislative session. This bill would have allowed the Department to import drugs from countries other than Canada, should the federal government amend existing statute to allow.

II. Introduction

Drug importation from Canada has been legal in the U.S. since 2003, when Congress amended the federal Food Drug and Cosmetic Act[8] to allow for drug importation programs. However, it was not until recent years that importation gained significant political traction at the national and state levels as a solution to address widespread public concern with drug pricing.

In the 2019 legislative session, the Colorado General Assembly passed SB 19-005,[9] which was subsequently signed into law by Governor Polis. This law tasked the Department of Health Care Policy and Financing with implementing a Canadian drug importation program. Subsequently, the Trump administration initiated the rulemaking process and released a final rule[10] in September and was effective November 30, 2020. Using this regulatory framework, Colorado intends to submit a formal application to the Food and Drug Administration (FDA) to begin importing drugs from Canada.

The Department estimates that the state will have an operational importation program by 2022 or 2023. This timeline allows for: (a) a state procurement process to identify and contract with vendors to manage administrative and supply chain aspects of the program, (b) development of the application to the Food and Drug Administration (FDA) to approve the program, and (c) federal review and approval of the program.

[8] Federal Food Drug and Cosmetic Act: Importation of prescription drugs, 21 USC 384. Retrieved November 4, 2020, from https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim

[9] Concerning wholesale importation of prescription pharmaceutical products from Canada for resale to Colorado residents, and, in connection therewith, making an appropriation, SB 19-005, Regular Session (2019). https://leg.colorado.gov/sites/default/files/2019a_005_signed.pdf

[10] Importation of Prescription Drugs, Department of Health and Human Services, Food and Drug Administration. Fed Reg Vol 85 No 191 62097 (October 1 2020), https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf

Based on a comprehensive analysis of 167 drugs by the Department, Colorado's proposed Canadian importation program would save an average of 61 percent on the drugs we seek to import for consumers, employers and other payers in the commercial market.[11] Analysis shows that savings could be even steeper if Colorado expanded its importation program to include prescription drugs from countries other than Canada, and if the program were expanded to include the importation of biologic drugs, such as Humira and branded insulins.

The state of Colorado is exploring the opportunity to expand the drug importation program in the event that the federal government amends the current statute to allow Colorado to import from other countries. An expanded importation program would lower prices even more while reducing the pressure on the Canadian supply chain to meet the entirety of the U.S. demand. Canada has signaled that their current supply may not be enough to meet the U.S. demand for imported drugs given the growing number of U.S. states interested in pursuing importation strategy. Most recently, Health Canada, the governmental department that oversees Canadian federal health policy, released an Interim Order[12] that prohibits Canadian distributors from exporting drugs that would lead to a shortage, or exacerbate an existing shortage.

To accommodate Canada's concerns regarding drug supply for their own nation, Colorado's Canadian importation proposal does not seek to import any prescription drugs in short supply in Canada. We would further ensure that all our selected Canadian partners are in compliance with Health Canada's Interim Order. To ensure quality of imported medications, the Department would also only seek to import drugs from those countries that meet current good manufacturing practice standards set forth by the FDA, including countries with either mutual recognition agreements[13] or cooperative arrangements[14] already in place. Imported drugs will be limited to FDA-approved drugs received from FDA-approved manufacturers.

Ultimately, the importation program would also be able to capitalize on lower costs for biologic drugs available from other countries. "Biologic" describes a diverse category of therapeutic pharmaceuticals that are often "produced through biotechnology in a living system, such as a microorganism, plant cell or animal cell."[15] These drugs often carry a high price tag.

For example, Humira is a biologic drug that is used to treat rheumatoid arthritis and other autoimmune diseases. Humira is the top-selling biologic in the U.S.[16] In 2019 alone,

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[11] "Colorado Drug Importation Program--Draft Application", Department of Health Care Policy and Financing, https://www.colorado.gov/pacific/sites/default/files/Colorado%20Draft%20SIP%20%20-%20Version%203-9-2020.pdf

[12] Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply), Health Canada. Retrieved December 1, 2020. https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html

[13] Food and Drug Administration & European Union. (2020, May 8). *Mutual recognition agreement (MRA)*. International Agreements; FDA. https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra

[14] Food and Drug Administration. (2020, October 13). *Cooperative arrangements*. Cooperative Agreements; Food and Drug Administration. https://www.fda.gov/international-programs/international-arrangements/cooperative-arrangements

[15] *Biological Product Definitions*. (n.d.). Food and Drug Administration. Retrieved November 5, 2020, from https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf

[16] Stone, K. (2020, June 23). Top 10 Biologic Drugs in the United States. *Verywell Health*. https://www.verywellhealth.com/top-biologic-drugs-2663233

consumers, employers, and commercial payers in the state of Colorado[17] spent almost $76 million on Humira.[18] Importing Humira from Canada could save Coloradan consumers, employers, and others covered by commercial payers $52.9 million annually, a savings of 67%. Like with other pharmaceuticals, importing biologic drugs would not compromise safety or quality. There are already strong standards in place from the FDA to ensure the safe distribution of biologic drugs. At the same time, about 70% of biologic drugs sold in the U.S. are already made overseas, sourced from 439 foreign FDA-registered licensed facilities.[19]

Together, these importation program expansions, if allowed to move forward, will result in significant cost savings and improved access to essential prescription drugs for all Coloradans.

III. Methodology

For this analysis, the Department used data from Colorado's All Payer Claims Database (APCD), which collects pricing data from the commercial insurance market as well as public payers. The data used for this study does not include Medicaid or Medicare data. The Department's initial analysis shows that Medicaid would see little to no savings from an importation program due to the deep discounts the program receives.

The Department selected prescription drugs for the analysis based on whether the drug was higher cost, highly utilized in Colorado, and eligible for importation in federal and state statute. The analysis began with over 200 drugs, but eventually the list was narrowed to 50 drugs from common drug categories for which pricing was available in each of our sample countries. Additionally, the Department verified that none of the drugs were currently experiencing a shortage in Canada prior to their inclusion in the analysis.

[17] For our analysis, the analysts used data from Colorado's All Payer Claims Database (APCD) which accounts for 100 percent of fully insured Coloradans and 65 percent of self-funded lives (according to the Center for Improving Value in Health Care (CIVHC) and other sources). To account for the 35 percent of self-funded lives not included in the data, the analysts assumed similar utilization rates to APCD claims but a lower cost per claim of 10 percent to account for the stronger negotiating power of larger self-funded employers. This number does not include Medicaid expenditures.

[18] The total cost for Humira in Colorado was estimated using the 2019 APCD data for commercial utilization and self-funded estimates for cost/unit and total units.

[19] *Regulated products and facilities* (FDA at a Glance). (2019). Food and Drug Administration. https://www.fda.gov/media/131874/download

To identify the importation price for each sample country, the Department used online resources to identify resources for pricing of each drug in Canada, France and Australia. In each case, these are prescription drug formularies developed by the government of each country. As these formularies are more recent than our data set, we increased the 2019 cost per unit for each Colorado drug by 3.7 percent to account for the 2020 increase of drug prices, as referenced by the Centers for Medicare and Medicaid Services.[20] To reach an importation price for each drug, the Department compared this estimated cost per unit to comparable unit costs in each test country. The Department converted the foreign price to U.S. dollar, and increased the price by 45 percent to account for a supply chain markup to maintain the profit margins across the distribution continuum. The percent savings for each sample country was calculated using the difference between Colorado's 2020 unit cost and each sample country's importation price divided by the 2020 Colorado unit cost.

IV. Savings from International Importation

Based on the Department's study, drugs imported Canada would generate a savings of 63 percent for Colorado consumers, employers and other commercially insured and self-funded payers. France and Australia's importation pricing, when compared to Colorado prices, deliver higher savings at an average of 84 percent and 78 percent, respectively. This analysis demonstrates that expanding the breadth of an importation program to include countries other than Canada would lead to savings.

The full list used in this analysis is below. Further in this report, the Department focuses on different drug classes where savings are particularly deep across our sample countries.

[20] *Regulated products and facilities* (FDA at a Glance). (2019). Food and Drug Administration. https://www.fda.gov/media/131874/download

Drugs Eligible for Importation in Canada Expanded to France and Australia								
Drug Name	Broad Drug Category	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada	Importation Price** from France	Percent Savings France	Importation Price** from Australia	Percent Savings Australia
Advair Diskus	Respiratory	$8.13	$2.19	73%	$0.77	91%	$0.60	93%
Afinitor	Cancer	$578.64	$269.70	53%	$126.82	78%	$55.45	90%
Alecensa	Cancer	$68.73	$45.86	33%	$33.36	51%	$31.01	55%
Atripla	HIV	$89.46	$42.25	53%	$30.08	66%	$10.75	88%
Augbagio	MS	$252.22	$55.42	78%	$37.62	85%	$23.45	91%
Biktarvy	HIV	$100.18	$42.65	57%	$33.11	67%	$31.33	69%
Breo Ellipta	Respiratory	$5.91	$2.98	50%	$1.54	74%	$1.46	75%
Brilinta	Cardiac	$6.40	$1.61	75%	$1.71	73%	$2.14	67%
Dovato	HIV	$79.07	$33.10	58%	$30.58	61%	$24.28	69%
Eliquis	Cardiac	$7.37	$1.74	76%	$1.54	79%	$1.33	82%
Enstilar	Psoriasis	$1,053.74	$91.59	91%	$56.51	95%	$70.15	93%
Entresto	Heart Failure	$8.78	$3.94	55%	$3.75	57%	$3.24	63%
Epi Pen	Anaphylaxis	$251.31	$88.09	65%	$51.33	80%	$70.15	72%
Epi Pen Jr	Anaphylaxis	$264.65	$88.09	67%	$51.33	81%	$70.15	73%
Farxiga	Diabetes	$15.93	$2.66	83%	$1.88	88%	$1.56	90%
Flovent Diskus	Respiratory	$189.15	$24.59	87%	$9.79	95%	$7.19	96%
Forteo	Osteoporosis	$3,906.62	$880.58	77%	$394.04	90%	$343.66	91%
Genvoya	HIV	$98.20	$47.63	51%	$38.26	61%	$33.35	66%
Gilenya	Multiple Sclerosis	$272.81	$92.62	66%	$81.27	70%	$76.74	72%
Glucagen	Hypoglycemia	$231.11	$83.85	64%	$22.82	90%	$51.85	78%
Ibrance	Cancer	$622.40	$276.13	56%	$178.42	71%	$203.23	67%
Imbruvica	Cancer	$144.42	$98.58	32%	$98.40	32%	$100.15	31%
Inlyta	Cancer	$266.53	$101.14	62%	$92.60	65%	$93.96	65%
Isentress	HIV	$26.63	$12.51	53%	$13.65	49%	$9.90	63%
Jakafi	Myelofibrosis	$242.04	$89.38	63%	$44.72	82%	$46.60	81%
Janumet	Diabetes	$7.19	$1.49	79%	$0.63	91%	$0.76	89%
Januvia	Diabetes	$14.65	$2.85	81%	$1.27	91%	$1.41	90%
Lamictal	Epilepsy	$12.24	$1.56	87%	$0.62	95%	$0.27	98%
Lumigan	Inflammation	$190.39	$29.39	85%	$27.09	86%	$32.14	83%
Nexavar	Cancer	$167.54	$50.03	70%	$42.91	74%	$46.94	72%
Odefsey	HIV	$90.38	$42.65	53%	$24.50	73%	$33.35	63%
Onglyza	Diabetes	$13.84	$2.50	82%	$1.40	90%	$1.57	89%
Pradaxa	Cardiac	$4.58	$1.74	62%	$1.40	69%	$1.13	75%
Spiriva Respimat	Respiratory	$9.92	$0.94	91%	$0.60	94%	$0.50	95%
Sprycel	Cancer	$470.80	$159.14	66%	$170.48	64%	$143.18	70%
Stiolto Respimat	Respiratory	$5.31	$1.10	79%	$1.05	80%	$1.28	76%
Sutent	Cancer	$664.90	$274.71	59%	$254.85	62%	$215.22	68%
Synthroid	Hypothyroidism	$1.20	$0.08	93%	$0.08	95%	$0.07	94%
Tagrisso	Cancer	$520.95	$320.46	38%	$309.38	41%	$271.78	48%
Tarceva	Cancer	$304.87	$87.00	71%	$86.78	72%	$36.12	88%
Tasigna	Cancer	$129.60	$29.66	77%	$34.20	74%	$32.14	75%
Tecfidera	MS	$134.25	$27.71	79%	$24.17	82%	$21.80	84%
Tivicay	HIV	$49.91	$20.12	60%	$27.32	45%	$22.01	56%
Trelegy	Respiratory	$9.21	$2.40	74%	$2.65	71%	$2.66	71%
Triumeq	HIV	$91.06	$44.12	52%	$38.26	58%	$28.89	68%
Truvada	HIV	$57.90	$28.39	51%	$16.84	71%	N/A***	N/A***
Xarelto	Cardiac	$14.63	$3.09	79%	$2.82	81%	$2.37	84%
Xeljanz	Arthritis, colitis	$72.34	$25.12	65%	$18.74	74%	$21.44	70%
Xigduo	Diabetes	$8.09	$1.33	84%	$0.94	88%	$0.82	90%
Xtandi	Cancer	$94.32	$30.83	67%	$42.35	55%	$31.47	67%

*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit from the All Payor Claims Database (APCD) increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.

**The Importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

***The Government of Australia only covers the generic version of Truvada.

Certain drug classes eligible for importation, such as HIV drugs, are particularly well positioned for deep savings to the benefit of Coloradans and our employers, as illustrated by the table below. In 2019, Colorado[21] commercially insured payers spent over $124 million[22] on these drugs—an amount expected to rise. Improving the affordability of HIV drugs would also improve patient compliance,[23] which directly improves patient outcomes, lowers complications and reduces medical costs across the system.

HIV Drugs Eligible for Importation in Canada Expanded to France and Australia

Drug Name	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada	Importation Price** from France	Percent Savings France	Importation Price** from Australia	Percent Savings Australia
Atripla	$89.46	$42.25	53%	$30.08	66%	$10.75	88%
Biktarvy	$100.18	$42.65	57%	$33.11	67%	$31.33	69%
Dovato	$79.07	$33.10	58%	$30.58	61%	$24.28	69%
Genvoya	$98.20	$47.63	51%	$38.26	61%	$33.35	66%
Isentress	$26.63	$12.51	53%	$13.65	49%	$9.90	63%
Odefsey	$90.38	$42.65	53%	$24.50	73%	$33.35	63%
Tivicay	$49.91	$20.12	60%	$27.32	45%	$22.01	56%
Triumeq	$91.06	$44.12	52%	$38.26	58%	$28.89	68%
Truvada	$57.90	$28.39	51%	$16.84	71%	N/A***	N/A***

*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit from the All Payor Claims Database (APCD) increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.

**The importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

***The Government of Australia only covers the generic version of Truvada.

Truvada is one of the leading HIV drugs on the market, taken once per day for both prevention and treatment. In 2019, Colorado's commercially insured health plans and patients spent $35 million on Truvada. Other countries access this drug at a fraction of the price. In fact, in all three of the researched countries, a generic version of Truvada has been available for some time; however, in the U.S. a generic version was only recently approved in September 2020. While the price of brand Truvada is expected to decrease in the U.S. due to the presence of the generic version, it will take time to reach the pricing levels in our test sample countries. In fact, the initial offering price of generic Truvada in the U.S. is only 16% less than the brand name price.[24] Since there is now an approved generic version available in

[21] For the analysis, the analysts used data from Colorado's All Payer Claims Database (APCD) which accounts for 100 percent of fully insured Coloradans and 65 percent of self funded lives (according to the Center for Improving Value in Health Care (CIVHC) and other sources). To account for the 35 percent of self funded lives not included in the data, the analysts assumed similar utilization rates to APCD claims but a lower cost per claim of 10 percent to account for the stronger negotiating power of larger self-funded employers. This number does not include Medicaid expenditures.

[22] The total cost for the selected list of HIV drugs in Colorado was estimated using the 2019 APCD data for commercial utilization and self-funded estimates for cost/unit and total units.

[23] Silverman, E. (2020, September 16). The cost of Gilead's HIV prevention pill thwarted widespread use, study finds. *STAT*. https://www.statnews.com/pharmalot/2020/09/16/gilead-hiv-aids-medicare-medicaid/

[24] The percent difference was calculated using the estimated 2020 brand name cost and the released cost of $48.51: Highleyman, L. (2020, October 2). First generic Truvada now available in the United States. *POZ*. https://www.poz.com/article/first-generic-truvada-now-available-united-states

the U.S., Colorado could import it from abroad and realize the significant savings immediately. Should an international importation program come to fruition, Colorado could take advantage of the significant cost difference of generic Truvada in other countries. As illustrated below, the generic version of Truvada in Australia is 93% less expensive, even with a markup for the supply chain, than what is available in Colorado.

Example: Generic Truvada Cost Comparison by Country				
Price	**Cost Per Tablet**	**2019 Tablets Dispensed*** **	**Estimated 2020 Cost**	**Percent Savings over Brand**
2020 Brand Name Cost Truvada*	$57.90	631036	$36,536,984	N/A
Generic Truvada Estimated US Cost+	$48.51		$30,611,556	16%
Price	**Cost Per Tablet**	**2019 Tablets Dispensed*** **	**Estimated 2020 Cost**	**Percent Savings over Generic Price**
Canadian Importation Price**	$7.94	631036	$5,010,426	84%
French Importation Price**	$7.92		$4,997,805	84%
Australian Importation Price**	$3.22		$2,031,936	93%
*Colorado's 2020 cost per tablet is the 2019 Colorado cost per tablet of Truvada increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services. +Price for Generic Truvada is the Wholesale Acquisition Cost as of October 2nd, 2020 **The Importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain. ***Total number of brand name Truvada tablets dispensed in Colorado in 2019				

V. Savings from the Importation of Biologic Drugs

The federal rule[25] that outlines the regulatory framework for importation includes eight drug categories that are excluded[26] from importation. Many of these exclusions are due to the nature of the drugs in question. Most are drugs that are not available for purchase at a pharmacy, are physician-administered, or have additional safety requirements.

[25] Importation of Prescription Drugs, Department of Health and Human Services, Food and Drug Administration. Fed Reg Vol 85 No 191 62097 (October 1 2020), https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf

[26] Drug excluded from importation are controlled substances, infusions (drugs given in an office or infusion center), intravenous (drugs given through a vein), drugs inhaled for surgery, risk evaluation and mitigation strategy (REMS) (drugs requiring extra safety protocols), intraocular (drugs administered through the eye), intrathecal (drugs administered through the spine), and biologics, such as insulin or Humira.

However, many common biologic drugs are available at local pharmacies and subject to no more additional safety protocols than non-biologic prescription drugs approved for importation. Eliminating the exclusion for biologic drugs, such as insulins or drugs like Humira, would allow for even greater savings.

Based on the Department's analysis, commercially insured and self-funded employers, and their covered members in Colorado are paying as much as 78 percent more for Humira than purchasers in other countries. The following table illustrates the savings that could be realized through the importation of biologics from the three evaluated countries. If Colorado could import these selected biologic drugs[27] from Canada for example, Colorado[28] commercially covered consumers, employers and other payers could save over $146 million annually—71 percent.

Biologic Drugs for Importation from Canada, France, and Australia

Drug Name	Broad Drug Category	2020 Colorado Cost*	Importation Price** from Canada	Percent Savings Canada	Importation Price** from France	Percent Savings France	Importation Price** from Australia	Percent Savings Australia
Avonex Syringe	Multiple Sclerosis	$1,736.07	$383.30	78%	$263.49	85%	$229.96	87%
Cimzia	Chronic inflammatory conditions	$2,246.38	$686.52	69%	$505.71	77%	$545.78	76%
Dupixent	Excema/Asthma	$769.96	$510.23	34%	$560.11	27%	$427.47	44%
Enbrel	Rheumatoid Arthritis	$638.71	$198.07	69%	$117.47	82%	$141.14	78%
Enbrel	Rheumatoid Arthritis	$1,295.37	$390.72	70%	$234.94	82%	$282.27	78%
Humalog	Diabetes	$19.58	$2.85	85%	$2.47	87%	$2.66	86%
Humalog KwikPen	Diabetes	$29.33	$3.73	87%	$3.34	89%	$2.98	90%
Humira	Chronic inflammatory conditions	$2,362.91	$776.74	67%	$490.89	79%	$620.56	74%
Lantus Solostar (Optisulin in Aus)	Diabetes	$25.27	$6.39	75%	$4.35	83%	$2.62	90%
Levemir Flex Pen	Diabetes	$29.42	$7.16	76%	$14.37	51%	$5.01	83%
Orencia	Chronic inflammatory conditions	$1,075.59	$374.87	65%	$315.32	71%	$256.48	76%
Rebif	Multiple Sclerosis	$1,329.14	$474.86	64%	$189.70	86%	$153.31	88%
Stelara	Chronic inflammatory conditions	$21,121.64	$4,689.00	78%	$3,653.79	83%	$4,182.21	80%
Trulicity	Diabetes	$374.23	$45.75	88%	$58.93	84%	$35.15	91%

*Colorado's 2020 cost per unit is the 2019 Colorado cost per unit increased by 3.7% to account for annual average increase in drug prices, as estimated by the Centers for Medicare and Medicaid Services.

**The importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

VI. Accessing Importation Savings

Accessing lower prescription drug prices through importation and bringing meaningful relief to Coloradans requires several changes to different levels of legislation. First and foremost, statutory changes are needed at the federal level to allow states to import drugs from other

[27] The total cost for the selected list of biologic drugs in Colorado was estimated using the 2019 APCD data for commercial utilization and self-funded estimates for cost/unit and total units. The estimated total cost of this selected list is $217,237,215.

[28] For our analysis, we used data from Colorado's All Payer Claims Database (APCD) which accounts for 100 percent of fully insured Coloradans and 65 percent of self-funded lives (according to the Center for Improving Value in Health Care (CIVHC) and other sources). To account for the 35 percent of self-funded lives not included in the data, we assumed similar utilization rates to APCD claims but a lower cost per claim of 10 percent to account for the stronger negotiating power of larger self-funded employers. This number does not include Medicaid expenditures.

countries in addition to Canada. 21 USC 384[29], as it currently stands, specifically allows for the importation of drugs into the U.S. from Canada only, and bars the importation of biologic drugs. Colorado can work with our federal bipartisan congressional delegation to drive for amendments to this portion of U.S. law. Momentum is building for drug pricing reforms, given the impact of the rising cost of prescription drugs to the overall affordability of healthcare.

In Colorado, the state legislature has shown interest in passing SB 20-119, which could have expanded the Canadian importation program to include other countries. The bill was tabled in the truncated 2020 legislation session but creates an opportunity for the upcoming 2021 session. This bill, as previously introduced in the 2020 legislative session, proposed to mirror changes to federal law enabling importation from other countries and for importable drug classes. This would enable Colorado to keep pace with federal legislation, ensuring Colorado's continued leadership in this important area of prescription drug affordability.

VII. Look to Medicaid as a Guide – A Lesson from the Importation Project

According to the Department's analysis, if drug importation programs were established, Colorado's Medicaid program would not see meaningful savings, while the commercial market and those covered by it would see very meaningful savings. This is an important learning that has come out of the Drug Importation workstream.

The analysis highlights that Medicaid is more sheltered from the burden of rising drug prices and sheltered from the full effect of high cost specialty drugs compared to commercial payers. This is a credit to federal protections in place, such as:

- The Medicaid Drug Rebate Program requires that manufacturers offer their "best price" to Medicaid programs
- Medicaid rebates are increased when drug prices increase faster than inflation
- All rebates are passed through to the program at both the federal and state level (not kept by the Pharmacy Benefit Manager (PBM) middleman)
- Supplemental rebates can be negotiated in excess of the mandated rebate in exchange for preferred formulary status.

When reviewing options for lowering prescription drug costs in the commercial market, Medicaid protections and policies can be used as a guide to aid policy makers in their design of new programs and models to address this challenging issue in the commercial market. Drug importation, and the expansion of this innovative program, is one of the levers available to bring more immediate relief to consumers in Colorado and across the nation by bringing prescription drug costs to the commercial market that are more in line with Medicaid and other countries.

Drug importation is a valuable tool to address high prescription drug costs in Colorado and its expansion to include other countries as well as biologic drugs would only increase its impact.

[29] Importation of prescription drugs, 21 USC 384 § Title 21: Food and Drugs. Retrieved November 5, 2020, from https://www.govinfo.gov/app/details/USCODE-2014-title21/USCODE-2014-title21-chap9-subchapVIII-sec384

With the importation program's focus on the commercial market, Colorado can change the way Coloradans access the higher cost, non-specialty brand name drugs in this state through a safe and effective model and distribution chain. To expand the importation program, the state of Colorado and other stakeholders must engage with federal partners to pursue the necessary federal statutory changes.

VIII. Conclusion and Next Steps

According to a national poll from the West Health Institute, a nonpartisan, nonprofit health care research organization[30], 78% of Americans said addressing health care costs was their highest priority. The overwhelming majority of Americans also favor government action to bring down the price of prescription drugs.[31] Given that prescription drugs are the top driver of rising health care costs and often the first line of offense and defense against illness, injury, and chronic conditions, our ability to control their costs more effectively is critical to the overall affordability of health care.

Importation presents one of the highest opportunities for savings on common, high volume, branded drugs that treat chronic conditions. Savings that average between 61% to more than 80% from other countries is incredibly meaningful to Coloradan families, our employers and taxpayer supported programs like the State employee health benefit plan. That's why Governor Polis and his administration have prioritized it, and why the Department of Health Care Policy and Financing is so focused on making drug importation a reality by 2023.

The Department looks forward to working with stakeholders through the next steps in the importation process. This will be a continued focus on our Canadian importation program through the release of an Invitation to Negotiate (ITN) to identify our supply chain partners and continued stakeholder engagement to structure the program to bring the most savings to Colorado consumers, employers and commercial payers. We look forward to continued discussions.

For more information on the Department's Importation work, or to engage in the stakeholder process, please visit https://www.colorado.gov/hcpf/drug-importation. *We appreciate your partnership.*

[30] *High Prices, Broken Promises*. (2018). [Press Release]. NORC. https://www.norc.org/NewsEventsPublications/PressReleases/Pages/high-prices-broken-promises.aspx
[31] "KFF Health Tracking Poll (conducted February 14-24, 2019)," Kaiser Family Foundation, http://files.kff.org/attachment/Topline-KFF-Health- Tracking-Poll-February-2019.

Appendices

Appendix 1: A Price Analysis of Fifty Selected Drugs for Importation from Canada, France, and Australia

Drug Name	Strength	Drug Indication	2020 Colorado Unit Cost*	Total 2019 CO Utilization by Unit**	2020 Colorado Total Cost Per Drug based on estimated 2019 Utilization	Importation Price*** from Canada	Percent Savings Canada	Canadian Importation Total Cost	Importation Price*** from France	Percent Savings France	French Importation Total Cost	Importation Price*** from Australia	Percent Savings Australia	Australian Importation Total Cost
Advair Diskus	250/50mcg	Respiratory	$8.13	2441680	$19,851,054.67	$2.19	73%	$5,351,369	$0.77	91%	$1,876,489.90	$0.60	93%	$1,468,289.69
Afinitor	10mg	Cancer	$578.64	4008	$2,319,438.67	$269.70	53%	$1,081,082	$126.82	78%	$508,350.37	$55.45	90%	$222,256.53
Alecensa	150mg	Cancer	$68.73	37504	$2,577,762.75	$45.86	33%	$1,719,806	$33.36	51%	$1,251,314.01	$31.01	55%	$1,162,890.00
Atripla	600/200/300mg	HIV	$89.46	17701	$1,583,572.88	$42.25	53%	$747,801	$30.08	66%	$532,437.19	$10.75	88%	$190,343.14
Augbagio	14mg	Multiple Sclerosis	$252.22	41606	$10,493,916.85	$55.42	78%	$2,305,687	$37.62	85%	$1,565,434.20	$23.45	91%	$975,595.59
Biktarvy	50/200/25mg	HIV	$100.18	291993	$29,253,160.01	$42.65	57%	$12,454,856	$33.11	67%	$9,667,249.49	$31.33	69%	$9,148,258.80
Breo Ellipta	100/25mcg	Respiratory	$5.91	529175	$3,127,899.46	$2.98	50%	$1,576,809	$1.54	74%	$814,876.31	$1.46	75%	$773,441.92
Brilinta	90mg	Cardiac	$6.40	220605	$1,411,494.37	$1.61	75%	$355,064	$1.71	73%	$377,455.05	$2.14	67%	$472,138.69
Dovato	50/300mg	HIV	$79.07	5953	$470,735.48	$33.10	58%	$197,075	$30.58	61%	$182,025.78	$24.28	69%	$144,566.79
Eliquis	5mg	Cardiac	$7.37	1362445	$10,045,401.62	$1.74	76%	$2,370,654	$1.54	79%	$2,098,028.90	$1.33	82%	$1,806,438.44
Enstilar	0.005/0.064%	Psoriasis	$1,053.74	533	$561,382.94	$91.59	91%	$48,795	$56.51	95%	$30,108.25	$70.15	93%	$37,370.77
Entresto	97/103mg	Heart Failure	$8.78	69008	$606,123.23	$3.94	55%	$271,667	$3.75	57%	$258,578.78	$3.24	63%	$223,337.14
Epi Pen	0.3/0.3mL	Anaphylaxis	$251.31	485	$122,001.61	$88.09	65%	$42,764	$51.33	80%	$24,919.14	$70.15	72%	$34,053.90
Epi Pen Jr	0.15/0.15mL	Anaphylaxis	$264.65	594	$157,163.03	$88.09	67%	$52,310	$51.33	81%	$30,482.12	$70.15	73%	$41,656.15
Farxiga	10mg	Diabetes	$15.93	138711	$2,209,426.58	$2.66	83%	$369,577	$1.88	88%	$261,067.19	$1.56	90%	$215,772.64
Flovent Diskus	100mcg	Respiratory	$189.15	814	$153,885.64	$24.59	87%	$20,004	$9.79	95%	$7,962.34	$7.19	96%	$5,852.13
Forteo	250mcg	Osteoporosis	$3,906.62	3618	$14,134,179.71	$880.58	77%	$3,185,950	$394.04	90%	$1,425,651.69	$343.66	91%	$1,243,378.71
Genvoya	150/150/200/10mg	HIV	$98.20	309041	$30,348,983.11	$47.63	51%	$14,720,473	$38.26	61%	$11,823,259.38	$33.35	66%	$10,305,066.98
Gilenya	0.5mg	Multiple Sclerosis	$272.81	87012	$23,738,040.02	$92.62	66%	$8,058,769	$81.27	70%	$7,071,668.39	$76.74	72%	$6,677,673.64
Glucagen	1mg	Hypoglycemia	$231.11	175	$40,486.18	$83.85	64%	$14,689	$22.82	90%	$3,998.54	$51.85	78%	$9,082.45
Ibrance	125mg	Cancer	$622.40	14367	$8,941,743.53	$276.13	56%	$3,967,052	$178.42	71%	$2,563,337.14	$203.23	67%	$2,919,657.55
Imbruvica	140mg	Cancer	$144.42	20629	$2,979,262.98	$98.58	32%	$2,033,619	$98.40	32%	$2,029,859.06	$100.15	31%	$2,065,986.36
Inlyta	5mg	Cancer	$266.53	2678	$713,832.25	$101.14	62%	$270,871	$92.60	65%	$248,003.77	$93.96	65%	$251,648.01
Isentress	400mg	HIV	$26.63	90027	$2,397,435.46	$12.51	53%	$1,125,901	$13.65	49%	$1,229,209.90	$9.90	63%	$891,008.78
Jakafi	5mg	Myelofibrosis	$242.04	4343	$1,051,040.46	$89.38	63%	$388,148	$44.72	82%	$194,183.51	$46.60	81%	$202,378.56
Janumet	50/1000mg	Diabetes	$7.19	179671	$1,291,190.36	$1.49	79%	$267,688	$0.63	91%	$113,744.40	$0.76	89%	$136,930.96
Januvia	100mg	Diabetes	$14.65	309766	$4,538,949.44	$2.85	81%	$881,827	$1.27	91%	$392,207.74	$1.41	90%	$436,584.88
Lamictal	100mg	Epilepsy	$12.24	55207	$675,544.85	$1.56	87%	$85,914	$0.62	95%	$34,005.25	$0.27	98%	$14,985.36
Lumigan	0.01%	Inflammation	$190.39	11791	$2,244,891.07	$29.39	85%	$346,528	$27.09	86%	$319,423.01	$32.14	83%	$378,930.87
Nexavar	200mg	Cancer	$167.54	4564	$764,593.18	$50.03	70%	$228,343	$42.91	74%	$195,837.28	$46.94	72%	$214,212.41
Odefsey	200/25/25mg	HIV	$90.38	73987	$6,687,335.50	$42.65	53%	$3,155,905	$24.50	73%	$1,812,801.12	$33.35	63%	$2,467,132.90
Onglyza	5mg	Diabetes	$13.84	59934	$829,722.23	$2.50	82%	$149,910	$1.40	90%	$84,088.49	$1.57	89%	$93,856.52
Pradaxa	150mg	Cardiac	$4.58	937397	$4,296,594.57	$1.74	62%	$1,631,070	$1.40	69%	$1,315,186.10	$1.13	75%	$1,056,933.35
Spiriva Resmpimat	2.5mcg	Respiratory	$9.92	420183	$4,169,936.58	$0.94	91%	$395,261	$0.60	94%	$251,626.75	$0.50	95%	$210,562.24
Sprycel	100mg	Cancer	$470.80	15321	$7,213,204.80	$159.14	66%	$2,438,255	$170.48	64%	$2,612,025.32	$143.18	70%	$2,193,764.30
Stiolto Respimat	2,5mcg	Respiratory	$5.31	112950	$599,776.88	$1.10	79%	$124,675	$1.05	80%	$119,142.73	$1.28	76%	$144,647.62
Sutent	50mg	Cancer	$664.90	748	$497,511.61	$274.71	59%	$205,552	$254.85	62%	$190,693.11	$215.22	68%	$161,037.99
Synthroid	75mcg	Hypothyroidism	$1.20	457998	$550,934.84	$0.08	93%	$38,252	$0.06	95%	$28,994.47	$0.07	94%	$33,470.49
Tagrisso	80mg	Cancer	$520.95	12839	$6,688,418.60	$320.46	38%	$4,114,379	$309.38	41%	$3,972,154.31	$271.78	48%	$3,489,428.91
Tarceva	150mg	Cancer	$304.87	1203	$366,615.05	$87.00	71%	$104,621	$86.78	72%	$104,358.60	$36.12	88%	$43,438.58
Tasigna	150mg	Cancer	$129.60	18155	$2,353,012.20	$29.66	77%	$538,503	$34.20	74%	$620,965.83	$32.14	75%	$583,599.74
Tecfidera	240mg	Multiple Sclerosis	$134.25	151098	$20,284,938.44	$27.71	79%	$4,186,774	$24.17	82%	$3,651,722.78	$21.80	84%	$3,293,747.69
Tivicay	50mg	HIV	$49.91	185860	$9,276,447.33	$20.12	60%	$3,739,281	$27.32	45%	$5,078,576.41	$22.01	56%	$4,090,328.33
Trelegy	100/62.5/25 mcg	Respiratory	$9.21	139251	$1,282,301.05	$2.40	74%	$333,663	$2.65	71%	$369,300.57	$2.66	71%	$370,713.97
Triumeq	600/50/300mg	HIV	$91.06	138552	$12,616,377.90	$44.12	52%	$6,112,328	$38.26	58%	$5,300,706.57	$28.89	68%	$4,002,410.35
Truvada	200/300mg	HIV	$57.90	631036	$36,534,263.90	$28.39	51%	$17,912,534	$16.84	71%	$10,624,269.66	$0.00	100%	$0.00
Xarelto	20mg	Cardiac	$14.63	876005	$12,817,762.54	$3.09	79%	$2,705,541	$2.82	81%	$2,473,092.76	$2.37	84%	$2,076,026.09
Xeljanz	5mg	Arthritis, colitis	$72.34	56573	$4,092,536.37	$25.12	65%	$1,420,963	$18.74	74%	$1,059,916.00	$21.44	70%	$1,213,132.56
Xigduo	5/1000mg	Diabetes	$8.09	34553	$279,484.90	$1.33	84%	$46,031	$0.94	88%	$32,516.04	$0.82	90%	$28,497.88
Xtandi	40mg	Cancer	$94.32	48704	$4,593,552.63	$30.83	67%	$1,501,319	$42.35	55%	$2,062,492.84	$31.47	67%	$1,532,537.05
				Colorado Total Cost	**$314,835,320.32**	**Canada Total Cost**		**$115,395,906.48**	**France Total Cost**		**$49,084,441.54**	**Australia Total Cost**		**$69,755,054.40**
						Average Percent Savings** Canada**		**63%**	**Average Percent Savings**** France**		**84%**	**Average Percent Savings**** Australia**		**78%**

All prices in this spreadsheet, for purposes of display, have been rounded to the nearest hundredth.

*Prices were obtained from the Colorado All Payer Claims Database (APCD) using unit price data from all participating health plans in 2019. The unit price per drug was then increased by 3.7% to account for an annual price increase as projected by the Centers for Medicare and Medicaid Services.

**Total units utilized in 2019 is an esimate developed by the Department. APCD data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources), therefore leaving 35% of the self funded market's utilization unaccounted for. In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to fully-insured claims and and combined the units together to calculate an estimated total utilization.

***The Importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

****The Average Percent Savings was calculated using the difference between Colorado's 2020 total cost and each test country's total importation cost price divided by Colorado's 2020 total cost.

Appendix 2: A Price Analysis of Selected Biologics for Importation from Canada, France and Australia

Drug Name	Strength	Drug Indication	2020 Colorado Cost*	Total 2019 CO Utilization by Unit**	2020 Colorado Total Cost Per Drug based on estimated 2019 Utilization	Importation Price*** from Canada	Percent Savings Canada	Canadian Importation Total Cost	Importation Price*** from France	Percent Savings France	French Importation Total Cost	Importation Price from Australia	Percent Savings Australia	Australian Importation Total Cost
Avonex Syringe	30mcg/0.5mL	Multiple Sclerosis	$1,736.07	2096	$3,639,289.37	$383.30	78%	$803,502.94	$263.49	85%	$552,356.39	$229.96	87%	$482,063.55
Cimzia	200mg/mL	Chronic inflammatory conditions	$2,246.38	3625	$8,144,078.22	$686.52	69%	$2,488,919.86	$505.71	77%	$1,833,432.12	$545.78	76%	$1,978,682.09
Dupixent	300mg/2mL	Excema/Asthma	$769.96	17069	$13,142,193.38	$510.23	34%	$8,708,932.62	$560.11	27%	$9,560,356.99	$427.47	44%	$7,296,323.15
Enbrel	25mg/0.5mL	Rheumatoid Arthritis	$638.71	2464	$1,574,073.86	$198.07	69%	$488,147.06	$117.47	82%	$289,497.11	$141.14	78%	$347,822.02
Enbrel	50mg/mL	Rheumatoid Arthritis	$1,295.37	9522	$12,334,917.84	$390.72	70%	$3,720,559.39	$234.94	82%	$2,237,149.92	$282.27	78%	$2,687,842.79
Humalog	100U/mL	Diabetes	$19.58	1280861	$25,077,410.63	$2.85	85%	$3,645,313.91	$2.47	87%	$3,164,602.36	$2.66	86%	$3,405,476.31
Humalog KwikPen	100U/mL	Diabetes	$29.33	366905	$10,759,984.51	$3.73	87%	$1,368,335.03	$3.34	89%	$1,224,159.78	$2.98	90%	$1,095,148.27
Humira	40mg/0.8mL	Chronic inflammatory conditions	$2,362.91	33341	$78,782,885.57	$776.74	67%	$25,897,537.37	$490.89	79%	$16,366,868.46	$620.56	74%	$20,690,446.56
Lantus Solostar (Optisulin in Aus)	100U/mL	Diabetes	$25.27	244356	$6,175,284.42	$6.39	75%	$1,561,116.00	$4.35	83%	$1,063,628.08	$2.62	90%	$641,419.08
Levemir Flex Pen	100U/mL	Diabetes	$29.42	221255	$6,509,259.39	$7.16	76%	$1,583,086.49	$14.37	51%	$3,179,968.24	$5.01	83%	$1,107,884.42
Orencia	125mg/mL	Chronic inflammatory conditions	$1,075.59	4916	$5,287,112.96	$374.87	65%	$1,842,693.64	$315.32	71%	$1,549,954.77	$256.48	76%	$1,260,729.44
Rebif	44mcg/0.5mL	Multiple Sclerosis	$1,329.14	5064	$6,730,814.07	$474.86	64%	$2,404,713.71	$189.70	86%	$960,623.49	$153.31	88%	$776,354.48
Stelara	45mg/0.5mL	Chronic inflammatory conditions	$21,121.64	787	$16,619,478.63	$4,689.00	78%	$3,689,518.07	$3,653.79	83%	$2,874,969.96	$4,182.21	80%	$3,290,753.96
Trulicity	1.5mg/0.5mL	Diabetes	$374.23	28742	$10,756,249.81	$45.75	88%	$1,314,985.87	$58.93	84%	$1,693,684.30	$35.15	91%	$1,010,290.70
				Colorado Total Cos	$205,533,032.66	Canada Total Cost		$59,517,361.97	France Total Cost		$46,551,251.97	Australia Total Cost		$45,589,173.26
						Average Percent Savings****Canada		71%	Average Percent Savings****France		77%	Average Percent Savings****Australia		78%

All prices in this spreadsheet, for purposes of display, have been rounded to the nearest hundredth.

*Prices were obtained from the Colorado All Payer Claims Database (APCD) using unit price data from all participating health plans in 2019. The unit price per drug was then increased by 3.7% to account for an annual price increase as projected by the Centers for Medicare and Medicaid Services.

**Total units utilized in 2019 is an esimate developed by the Department. APCD data includes 100 percent of fully-insured and 65 percent of self-funded lives (according to CIVHC and other sources), therefore leaving 35% of the self funded market's utilization unaccounted for. In order to derive a cost savings estimate for the self-funded lives not included in CIVHC data, we assumed similar utilization rates to fully-insured claims and and combined the units together to calculate an estimated total utilization.

***The Importation price is the unit cost of the drug in each respective country, converted to US Dollar, with a 45% markup for the supply chain.

****The Average Percent Savings was calculated using the difference between Colorado's 2020 total cost and each test country's total importation cost price divided by Colorado's 2020 total cost.

Appendix VI. Prescription Drug Pipeline Report

This report provides an overview of (a) the impact specialty and orphan drugs have on drug expenditures, (b) insights into drugs that are currently in the development pipeline, and (c) disease states and related innovative therapies, which will likely represent drug therapies of the future.

FDA Approval Process

The drug pipeline refers to the set of pharmaceutical drugs that are in the process of being developed, researched, and approved for market adoption at any given time. Understanding this process yields vital insights into predicting future pharmaceutical trends. After a manufacturer develops a drug and obtains approval to test the drug in humans, a three-phase process is used to assess whether drugs are safe and effective for use in humans.[195]

- A Phase 1 clinical trial is generally tested on a small population (typically, 20 to 100 people) and is used to establish drug safety and appropriate doses in healthy humans.
- A Phase 2 clinical trial can involve several hundred people and further look at drug safety and efficacy in humans with the disease/condition.
- A Phase 3 clinical trial involves hundreds to thousands of participants who are tested to help determine population side effects and overall effectiveness in achieving a desired outcome. Sometimes the medication is tested against a placebo (no active medication) or standard of care and sometimes it is tested against a drug already approved to treat the disease or condition.
- Normally, once the Phase 3 trial is complete, a drug is reviewed by the FDA for approval.

Monitoring the drugs that are in Phase 2 or 3 trials, and estimating their approval dates, allows stakeholders to prepare for the impact of a new drug hitting the market. Currently, many of the drugs in the drug pipeline target the COVID-19 virus, hemophilia (A and B), Duchenne muscular dystrophy, spinal muscular atrophy, cystic fibrosis, sickle cell disease, nonalcoholic steatohepatitis (NASH), atopic dermatitis or specific cancers (for example, acute lymphocytic leukemia, multiple myeloma, or breast cancer).

Orphan and Specialty Drugs: Impact on Expenditures

The Orphan Drug Act was created in 1983 to "provide incentives for the development of potentially promising orphan drugs that may not otherwise be developed and approved."[196] These incentives include tax incentives for clinical testing, avoidance of the required prescription drug user fee with the drug application, and seven (7) years of market exclusivity.[197] The Act has successfully improved research in the area of rare disease, but it may also have paved the way for higher cost therapy and new income streams. In 2019, the FDA approved 48 new drugs. Twenty-one of those were for rare or orphan diseases which are diseases affecting 200,000 or fewer Americans.[198] According to a 2019 study by America's Health Insurance Plans, a trade association of health insurance companies, the average annual cost (based on list price) of an orphan drug is $186,758.[199]

195 Office of the Commissioner. (2018, January 4). *Step 3: Clinical Research.* FDA. https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

196 Food and Drug Administration (2019). Orphan drug regulations: Regulatory history. FDA. https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/orphan-drug-regulations-regulatory-history

197 Electronic Code of Federal Regulations (eCFR), §316 (2013). https://www.ecfr.gov/

198 Center for Drug Evaluation and Research. (2020). *New drug therapy approvals 2019.* Food and Drug Administration. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019

199 America's Health Insurance Plans. (2019). *The Rise of Orphan Drugs* [Issue Brief]. AHIP. https://www.ahip.org/wp-content/uploads/IB_OrphanDrugs-1004.pdf

In addition, the growth of specialty drugs has led to an increase in pharmacy drug expenditures. Specialty drugs are high cost oral or injectable medications used to treat complex chronic conditions. These drugs are often biologics which require special handling and administration through injection or infusions. To illuminate the effect that these innovative therapies have on health plan expenditures, an analysis of 2019 claims data from Colorado Medicaid revealed that 48% of total pharmacy expenditures were for specialty drugs, while only representing 1.42% of utilization. Due to the lack of competition or access to alternative therapies, payers and patients are forced to utilize the highly expensive orphan or specialty drug.

Drug Therapy Development

Drug therapies can be developed in various ways, such as gene therapies, chimeric antigen receptor T-cell (CAR T-cell) therapies, clustered regularly interspaced short palindromic repeats gene editing technologies (CRISPR), or exon skipping therapies. All these development processes are described below.

Gene Therapy

To address diseases related to a single gene, a working copy of a missing or dysfunctional gene is created and placed into a vector, such as a virus (in most cases, an adeno-associated virus, which does not cause known disease or harm). The vector then transports the gene to the target cells within the patient's body, where the gene is incorporated into the cell nucleus and creates the desired change.[200] This methodology is highly specialized and frequently used in rare diseases.

One example of a therapy developed with this method is valoctocogene roxaparvovec. This therapy is intended to treat severe hemophilia A and will enable patients to produce their own coagulation Factor VIII to achieve adequate clotting levels.[201] If approved, this will be a breakthrough therapy for hemophilia patients. The FDA issued a complete response letter (meaning the FDA did not approve the application with the submitted information) in August 2020, requesting the drug manufacturer to provide more follow-up data to assess how well the therapy maintains its effect over time.[202] This additional information should provide more safety and efficacy data to help the FDA make a determination on whether or not the drug is approved. Once this data is supplied, health care providers and payers will have more robust evidence to guide clinical decision making, such as when the drug should be used, which patients are anticipated to receive the best effects, and how long the treatment is expected to last. In addition, after a drug of this nature is approved and available in the U.S. market, a muh larger number of patients with different concomitant health conditions can receive it. In some cases, new clinical information may be learned during the approval process, which, in severe cases of safety concerns, can lead to removal of the drug from the market.

> Projected Price: Gene therapies are very expensive. Valoctocogene roxaparvovec has a projected one-time price of $2 to $3 million per patient.[203]

200 *How does gene replacement therapy work*? (n.d.). Explore Gene Therapy. Retrieved November 6, 2020, from https://www.exploregenetherapy.com/how-gene-replacement-therapy-works

201 Roctavian (formerly Valrox/BMN 270). (2020, August 25). Hemophilia News Today. https://hemophilianewstoday.com/bmn-270/

202 Carvalho, J. (2020, August 19). FDA delays decision on roctavian, hemophilia a gene therapy candidate, for a year or more. *Hemophilia News Today.* https://hemophilianewstoday.com/2020/08/19/fda-delays-decision-roctavian-hemophilia-a-gene-therapy

203 Ahle, S. (2020, March 1). Biomarin sets high price tag for hemophilia gene therapy candidate. *ASH Clinical News*. https://www.ashclinicalnews.org/online-exclusives/biomarin-sets-2-3-million-price-tag-hemophilia-gene-therapy-candidate/

Chimeric Antigen Receptor T-cell (CAR T-cell) Therapy

CAR T-cell therapy is a unique treatment because the therapy is manufactured using the patient's own immune system cells. The drug manufacturing process begins by extracting blood from the patient (leukapheresis) and sending T-cells from the patient's blood to a specialized lab where they are modified so they can better recognize and attack cancer cells. The modified cells are then packaged and sent to the original patient, where they are administered through an IV infusion.[204]

In currently approved CAR-T therapies, severe side effects frequently occur. These side effects include cytokine release syndrome, which may require patient hospitalization and treatment with immune-suppressing medications to counter the patient's increased immune response triggered by the CAR T-cell therapy. Currently, three CAR T-cell therapies are FDA-approved to treat certain blood cancers. Research for use in other conditions such as solid organ tumors, opportunistic fungal infections or viral infections is ongoing.[205] CAR T-cell therapy is currently reserved for use after other treatments have failed, which limits its use to a smaller population. However, these therapies may be improved to one day be used earlier as the standard of care, such as in replacement of a stem cell transplant or chemotherapy treatment for cancer.

> Projected Price: These therapies are intended to be once-per-lifetime treatments and CAR-T therapies already on the market are priced at $373,000 - $475,000 per patient.[206,207]

CRISPR

Another innovation in the drug pipeline is the use of clustered regularly interspaced short palindromic repeats gene editing technologies, or CRISPR. This complex mechanism uses a naturally occurring system by which bacteria prevent viral infections by identifying and targeting genetic sequences for destruction. Many individual contributors and researchers have aided in the discovery of CRISPR technology, but the 2020 Nobel Prize in Chemistry was given to Jennifer Doudna and Emmanuelle Charpentier for their discovery of this gene editing technique.[208] The technology has many potential applications in medicine, but also has brought ethical concerns and controversy with its use in embryos carried to term birth. The most advanced clinical studies for drug treatments using this technology are for blood diseases such as sickle cell anemia and thalassemia, but CRISPR treatments have potential for a wide range of diseases and patient populations including cystic fibrosis, hereditary blindness, and cancer.[209,210]

Projected Price: At this time, therapies utilizing CRISPR technology are expected to be priced in the range of $1,000,000-$2,000,000 per treatment.[211,212]

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204 https://www. Cancer. Gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy. (2011, February 2). [NciAppModulePage]. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/car-t-cell-therapy

205 Seif, M., Einsele, H., & Löffler, J. (2019). CAR T Cells Beyond Cancer: Hope for Immunomodulatory Therapy of Infectious Diseases. Frontiers in immunology, 10, 2711. https://doi.org/10.3389/fimmu.2019.02711

206 Andrews, M. (2018, July 17). Staggering prices slow insurers' coverage of CAR-T cancer therapy. *Kaiser Health News*. https://khn.org/news/staggering-prices-slow-insurers-coverage-of-car-t-cancer-therapy/

207 *Gilead's second act in cell therapy gets its first approval*. (n.d.). BioPharma Dive. Retrieved December 3, 2020, from https://www.biopharmadive.com/news/gileads-second-act-in-cell-therapy-gets-its-first-approval/582295/

208 Ledford, H., & Callaway, E. (2020). Pioneers of revolutionary CRISPR gene editing win chemistry Nobel. Nature, 586(7829), 346–347. https://doi.org/10.1038/d41586-020-02765-9

209 Terry, M. (2019, November 19). *CRISPR therapeutics and Vertex: Promising gene therapy data for sickle cell disease and beta thalassemia*. BioSpace. https://www.biospace.com/article/crispr-therapeutics-and-vertex-report-promising-results-in-crispr-trials

210 Gene Editing for Cystic Fibrosis. (n.d.). Cystic Fibrosis Foundation. Retrieved November 6, 2020, from https://www.cff.org/Research/Research-Into-the-Disease/Restore-CFTR-Function/Gene-Editing-for-Cystic-Fibrosis/

211 Terry, M. (2019, November 19). *CRISPR therapeutics and Vertex: Promising gene therapy data for sickle cell disease and beta thalassemia*. BioSpace. https://www.biospace.com/article/crispr-therapeutics-and-vertex-report-promising-results-in-crispr-trials

212 Cystic Fibrosis Foundation. (n.d.). Gene Editing for Cystic Fibrosis. Retrieved December 3, 2020, from https://www.cff.org//Research/Research-Into-the-Disease/Restore-CFTR-Function/Gene-Editing-for-Cystic-Fibrosis/

Exon skipping therapies

Another novel mechanism in drug treatment includes exon skipping drugs. There are three exon skipping therapies currently approved and they are intended to treat Duchenne muscular dystrophy (DMD), an inherited disease occurring primarily in young boys. In this disease, muscular atrophy and wasting hinders the ability to walk, stand, or effectively pump blood in the heart and ultimately can lead to death. Exon skipping drugs fix or repair the missing part of the gene so that it may function more normally and produce a protein called dystrophin. So far, in clinical trials, these medications have been shown to increase the amount of dystrophin in the patient.

The exon skipping therapies are examples of approvals based on surrogate markers or biomarkers as the measured outcome.[213] These terms are used to describe a physical change, for example a lab value or number, but do not directly indicate a clinical change or an effect that the person can feel or experience, such as being able to move, function more normally or feel better. While some surrogate outcomes have been subsequently proved to correlate with better clinical outcomes for a patient, other surrogate outcomes, such as the level of dystrophin, have not yet been proved to provide a health benefit. In such cases, further studies are required.

While dystrophin is known to play a role in DMD, the direct correlation to clinical improvement is not fully known; nevertheless, they are currently FDA approved, based on the surrogate outcome of increased dystrophin levels. The FDA required the drug manufacturers to include in the prescribing label that "Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials."[214,215,216] The FDA will determine further next steps (including if a label change is needed) based on this post approval submission of clinical trial data.

> Projected Price: Approved therapies on the market are priced in the range of $300,000-$748,000 per patient, per year.[217,218] Dosing for these therapies are based on a patient's weight and therefore, vary significantly in cost.

Solutions to Address High Cost Specialty and Orphan Drugs

The aforementioned drug therapies offer patients novel treatment options that may lead to increased health outcomes, including a higher quality of life and a longer life. However, as this report illuminated, the unfortunate downside to these novel treatments is their exceptionally high price. Patients, employers and health plans need federal and state regulations to inhibit drug manufacturers from setting drug prices as high as the market will bear. Below are possible solutions:

- **FDA Approval Process:** Incorporate a cost ceiling into the FDA drug approval process.

213 Katz R. (2004). Biomarkers and surrogate markers: an FDA perspective. *NeuroRx: the journal of the American Society for Experimental NeuroTherapeutics,* 1(2), 189–195. https://doi.org/10.1602/neurorx.1.2.189
214 National Institutes of Health. (2020, July 8). EXONDYS 51- eteplirsen injection. *DailyMed*. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=33bff678-7829-479e-9110-b8e33a0bc0aa
215 National Institutes of Health. (2020, August 27). VYONDYS 53- golodirsen injection. *DailyMed*. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=35c227d1-5b24-44b0-b5d3-f0f6b1c46bd5
216 National Institutes of Health. (2020, August 12). VILTEPSO- viltolarsen injection, solution. *DailyMed*. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1ffff9a8-6d6a-4dcb-8493-1b6cc3a5d123
217 Figueiredo, M. (2019, December 20). Vyondys 53 Available to Duchenne Patients in the U.S. *Muscular Dystrophy News Today.* https://musculardystrophynews.com/2019/12/20/vyondys-53-available-duchenne-patients-in-the-us/
218 Fidler, B. (2020). *FDA gives speedy approval to another Duchenne drug* [Brief]. Biopharma Dive. https://www.biopharmadive.com/news/viltolarsen-duchenne-fda-approval-ns-pharma/583410/

Several countries currently factor a drug's price into their drug approval process, which serves as an effective pricing containment measure. In the U.S., however, drug pricing is not considered a part of the FDA approval process, nor can a maximum cost be used for consideration of coverage for certain payers, like state Medicaid programs. Therefore, framework and implementation of a drug pricing ceiling or limit is needed.

- **Orphan Drug Status:** Re-examine the criteria to obtain orphan drug status. Over 40% of new drug approvals are for drugs that treat rare disease, and financial and exclusivity incentives are allowing Orphan Drugs to become blockbusters. The FDA should consider restricting the conditions determining which drugs receive the financial incentives for development. Reasonable restriction of the current criteria could help maintain needed development in rare diseases. Incentives could also be paid back, or measures could be added to ensure public programs receive significant discounts as a trade-off for financial incentives.
- **Drug Affordability Board:** Establish a Drug Affordability Board in Colorado which can set upper payment limits on high cost prescriptions. The board could use specific criteria to identify which drugs are the best candidates for an affordability review and then impose an upper payment limit if the board determines that the drug has led or will lead to an affordability challenge for Coloradans, employers or benefit programs financed by taxpayer dollars, such as the Colorado state employee benefit program.
- **Drug Price Transparency:** Create transparency policy in Colorado to require health insurers, prescription drug manufacturers and pharmacy benefit management firms to report information about the cost of prescription drugs. Transparency insights might include initial pricing build-up of drugs new to market; year over year price increases over a specific percent; pricing averages by market (small employer, large employer, etc.), or rebates and other compensation paid by drug manufacturers to insurance carriers and their PBMs. This information would provide further insights to setting upper payment limits and developing new methodologies for better controlling the prices paid for new, specialty drugs.
- **Value-Based Contracts:** Value-Based Contracts are negotiated between manufactures and payers such as Medicaid or commercial insurance carriers. They reward or penalize manufacturers for not achieving their clinical promises, further motivating manufacturers to achieve desired outcomes in exchange for their high prices. Such arrangements also discourage the use of high cost drugs for off label treatments where the clinical outcomes are less proven.

Appendix VII. Zolgensma®: Public Investments and Private Profits, Corrected

NOTE: The previous report incorrectly underreported the amount of research and development funding related to the drug, Zolgensma. The below report corrects previous statements published in the 2019 report.

At $2.1 million per dose for commercial plans, Zolgensma (used to treat spinal muscular atrophy or SMA) is the most expensive drug in the world.[219] However, like many new, expensive drugs, Zolgensma was developed with the help of millions of dollars of subsidies from taxpayers, charities, and non-profit research institutions. These critical public investments led to large private windfalls when Swiss pharmaceutical giant Novartis bought the drug developer's company, AveXis for $8.7 billion in May 2018.[220]

The founder and chief scientific officer of AveXis, Dr. Brian K. Kaspar, began research on key technologies for Zolgensma while working at the Center for Gene Therapy at Nationwide Children's Hospital, a non-profit hospital in Columbus, Ohio and as an associate professor in the Department of Pediatrics and Department of Neuroscience at The Ohio State University College of Medicine.[221] His initial research was essential and not funded by AveXis.

A science watchdog group, Knowledge Ecology International, noted that federal taxpayers have contributed tens of millions of dollars to research that supported the development of Zolgensma. Specifically, KEI found that the National Institutes of Health database listed Kaspar as receiving $6.3 million of grants for 17 projects related to spinal muscular atrophy.[222] AveXis also received millions in key financial support from the nonprofit French Muscular Dystrophy Association and, reportedly, by charities organized by parents of children with the rare disease, such as Sophia's Cure and Miracle for Madison. Sophia's Cure reported raising $2.3 million for Kaspar's research lab.[223,224]

In exchange for license rights, AveXis initially granted Nationwide Children's Hospital ownership of 331,053 shares of AveXis, which increased to a 3% stake in 2015.[225] As for Kaspar himself, he was granted 2,334,391 shares of restricted common stock.[226] IRS rules allow AveXis to count stock grants to company executives as a research and development expense: "As a result of the vesting in full of (Kaspar's) unvested shares in January 2016, we recorded $10.4 million in research and development expense for the year ended December 31, 2016."[227]

Including these stock grants accounted for as research and development, AveXis's annual 10K filing with the U.S. Securities and Exchange Commission and other annual reports shows the

219 Stein, R. (2019, May 24). At $2.1 million, new gene therapy is the most expensive drug ever [NPR]. *Shots*. https://www.npr.org/sections/health-shots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever

220 Novartis successfully completes acquisition of AveXis, Inc. (2018, May 15). *Novartis Press Release.* https://www.novartis.com/news/media-releases/novartis-successfully-completes-acquisition-avexis-inc

221 Kaspar, Brian. PhD. (2020) The Ohio State University College of Arts and Sciences. Neuroscience Undergraduate Degree. https://neurosciencemajor.osu.edu/people/kasper.8

222 Charity and NIH funding related to Zolgensma. (2019, June 14). *Knowledge Ecology International*. https://www.keionline.org/charity-nih-funding-related-to-zolgensma

223 See, e.g., Gaynor, V. (2012, August 26). Because research matters…. *Sophia's Cure Foundation*. https://www.sophiascure.org/blog/because-research-matters

224 Charity and NIH funding related to Zolgensma. (2019, June 14). *Knowledge Ecology International.* https://www.keionline.org/charity-nih-funding-related-to-zolgensma

225 Page 19: *Annual report AveXis, Inc.* (Securities and Exchange Commission file number 001-37693). (2017). US Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1652923/000155837018001313/avxs-20171231x10k.htm

226 Page 104: *Annual report AveXis, Inc.* (Securities and Exchange Commission file number 001-37693). (2017). US Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1652923/000155837018001313/avxs-20171231x10k.htm

227 Ibid

company spent approximately $450 million on research and development from 2013-2018.[228,229]

In 2018, Novartis announced and completed a buyout of AveXis for $8.7 billion, or $218 per share.[230] At that price, the 331,053 shares granted to Nationwide Children's Hospital and the 2,334,391 shares granted to Dr. Brian Kaspar were worth hundreds of millions of dollars to those parties.

228 Page 95: *Annual report AveXis, Inc.* (Securities and Exchange Commission file number 001-37693). (2017). US Securities and Exchange Commission. https://www.sec.gov/Archives/edgar/data/1652923/000155837018001313/avxs-20171231x10k.htm

229 AveXis reports first quarter 2018 financial and operating results. (2018, May 3). *AveXis Press Release.* https://www.avexis.com/news-releases/news-release-details/avexis-reports-first-quarter-2018-financial-and-operating.html

230 *Novartis enters agreement to acquire AveXis Inc. for USD 8.7 bn to transform care in SMA and expand position as a gene therapy and Neuroscience leader.* (2018). [Press Release]. Novartis. https://www.novartis.com/news/media-releases/novartis-enters-agreement-acquire-avexis-inc-usd-87-bn-transform-care-sma-and-expand-position-gene-therapy-and-neuroscience-leader

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