Reducing Prescription Drug Costs in Colorado

Cost Drivers and Strategies to Address Them





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Definitions

For the purposes of this report, the terms utilized herein have the following definitions.

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).

Brand Name Drug

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

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.

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.

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.

Prescription Drug Product

A drug product that requires a prescriber's order.

Label

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

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.

Manufacturer

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

Wholesale Distributor

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

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.

Insurance Carrier

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

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.

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 to encourage utilization of a product.

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 insurer.

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).

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 Medicaidcovered drugs to the Centers for Medicare & Medicaid Services (CMS) guarterly as a requirement of the Medicaid drug rebate program.

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.

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.

Third Party Administrator

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

Executive Summary

Introduction and Purpose

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 changes to the industry.^{1,2} Branded and specialty drug costs are growing significantly faster than inflation rates, industry profits are disproportionately high compared to others in health care, and 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 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. Left uninterrupted, prescription drug cost trends will continue upward on an unsustainable trajectory.

The Polis administration is committed to saving people money on health care and that includes working on solutions to drive down the out of control costs 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 other public plans supported through taxpayer dollars, such as Medicaid. To accomplish this, the report provides an overview of various drivers of rising prescription drug costs, as well as potential state and federal strategies for controlling those costs. The Department of Health Care Policy & Financing (the Department) welcomes feedback on the report, requests for additional research on areas of keen interest, and how future iterations of the report can enhance Colorado's ability to lower prescription drug costs.

The pharmaceutical industry as a whole plays an essential role in our health care system. Pharmaceutical companies develop and distribute some of the greatest innovations in health care. The result of prescription drug innovation and best practices is improved health and millions of lives saved.

Clearly, the positive impact of pharmaceutical advances is not in dispute; the innovations from the industry, as well as researchers employed by universities, charities, and federal and state agencies are incredibly valuable. The purpose of this report, however, is to identify opportunities to better control prescription drug costs; it is that quest which will propel the balance of this report.

Cost Drivers

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,
- Anticompetitive practices and
- Marketing and lobbying investment.

the State of Colorado, as well as the federal government, to help address them.



This report includes a deeper dive into each of these three drivers, and outlines opportunities for

¹ "Health Sector Economic Indicators: Insights from Monthly National Price Indices Through June 2017," Altarum Institute, (2017), https://altarum.

² "Prescription Drug Spending in the U.S. Health Care System: An Actuarial Perspective," American Academy of Actuaries, (2018), https://www.

³ "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science, (2018), https://www.

org/sites/default/files/uploaded-related-files/CSHS-Price-Brief Aug 2017.pdf. actuary.org/content/prescription-drug-spending-us-health-care-system. iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.

Below are the cost drivers discussed in this report. The icons included throughout the report associate the topic with to these 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;
- Inadequate price controls;
- Prohibition for public programs like Medicare to negotiate drug prices directly;
- Rebates and other manufacturer compensation that may be retained by middlemen organizations like PBMs or insurance carriers, and therefore do not result in cost savings to employers or consumers;
- Hospital drug pricing mark-up as well as variation in pricing between dispensing settings.

Anticompetitive Practices

- Patent laws and market exclusivity that delay access to generic drugs at lower costs;
- Anticompetitive practices among pharmaceutical companies, such as price-fixing or coupons 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 payer decision-making; manufacturer investment and focus on specialty drugs;
- Costs related to marketing, including direct-to-consumer and direct-to-physician marketing, which both increase pricing and result in the increased utilization of higher cost drugs; and
- Pharmaceutical industry lobbying, which results in legislation and policy that benefits the industry, to the detriment of consumers, employers or public payer 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: demanding price transparency, passing along rebate savings, getting physicians access to cost effective information and

preparing state laws so they can parallel federal laws expanding countries approved for importation.

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. While changing federal policy is not always "quick", there are some opportunities to prioritize efforts where there is already momentum such as: expanding importation from countries beyond Canada, tying U.S. prices to international prices, and expediting the approval of generic drugs. Taken together, these changes would have a meaningful impact on the cost people pay for drugs, and lead to better health outcomes as more people gain access to the medications they need.

Solutions for Saving Colorado Money on Prescription Drugs

On behalf of Coloradans and their employers, Colorado has an opportunity to address the rising cost of prescription drug costs. This report reviews attainable policies that other states have successfully enacted for our consideration, 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. This report further reviews some of the immediate and "quick win" opportunities Colorado may wish to explore, including new policy and best practices related to:

- waivers for drug importation;
- Investing in physician tools, like the prescriber tool, that fuel more cost effective prescribing practices;
- Requiring rebates to be passed through to employers and patients; and
- throughs that serve to offset the cost of the prescription drug benefit.

Other intermediate solutions for policy-makers and state leaders to consider that may have a longer implementation timeline include:

- prescribing best practices;
- Public-private partnerships that support hospitals or public entities in direct price negotiations, purchasing, or manufacturing of drugs to meet local needs; and

• Prescription drug price transparency, such as disclosures related to price increases, payments to middlemen like insurance carriers and pharmacy benefit managers (PBMs) and price composition transparency (i.e., R&D, distribution, profits, promotional marketing, etc.);

• Aligning state importation policy with potential expansion of federal regulations and/or

 Empowering and educating employers to negotiate contracts that maximize the prescription drug pricing discounts, improve utilization management controls and maximize rebate pass-

• Creating a board to review drug affordability issues and a board to provide guidance on

 Alternative and innovative reimbursement methodologies and value-based purchasing from manufacturers that focus on achievement of intended outcomes and quality of life.

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 trend increases 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 beyond Canada with strong safety standards;
- Indexing U.S. prices to international prices;
- Expediting FDA reviews and approvals for generic drugs entering the market;
- Reforming patent and exclusivity laws and regulations that prevent competition and delay access to generic drugs;
- Revisiting Food and Drug Administration regulations to increase accountability; and
- · Limiting direct to consumer advertising.

This report was produced by the Department of Health Care Policy & Financing. The Department also gathered input from a variety of stakeholders, including carriers, providers, union trusts (which include employers) and consumer advocates.

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

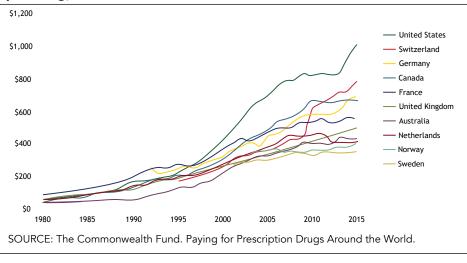
Industry Trends and **Background Information**

U.S. Costs versus Other Countries

"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.⁴ The 17-country price survey concluded that U.S. drug prices are "1.8 times that of the average international ex-manufacturer price in the first guarter of 2018." (Ex-manufacturer price is the price received by the manufacturer as opposed to the distributor.) The United States pays three times more than the UK for the top 20 selling drugs.⁵

A 2017 study from The Commonwealth Fund reported a similar result.⁶ Prescription drug spending per capita in the U.S. ranges from 30 percent to 190 percent 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 other nations, as noted in the below chart.

Figure 1. National Trends in Per Capita Pharmaceutical Spending, 1980-2015



U.S. Drug Trend **Projections**

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 percent from 2019 to 2027, from \$360.3 billion to \$576.7 billion.⁷ This unsustainable growth is evidenced by the fact that 14

⁴ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures," (2018), https://aspe.hhs.gov/system/files/ pdf/259996/

⁵ Ben Hirschler, "How the U.S. Pays 3 Times More for Drugs," The Scientific American, October 13, 2015, https://www.scientificamerican.com/

⁶ Dana Sarnak, David Squires, and Shawn Bishop, "Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?," The Commonwealth Fund, October 5, 2017, https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-

⁷ Centers for Medicare and Medicaid Services, Office of the Actuary, "2018-2027 Projections of National Health Expenditures," (2018), https://

ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf. article/how-the-u-s-pays-3-times-more-for-drugs/

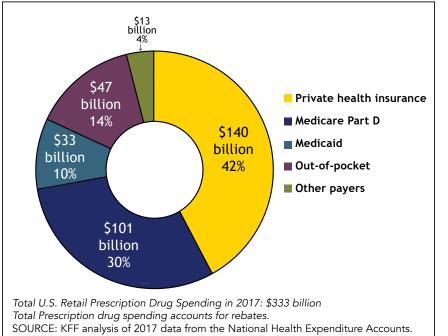
around-world-why-us-outlier?redirect_source=/publications/issue-briefs/2017/oct/prescription-drug-costs-us-outlier. www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2018-2027-projections-national-health-expenditures.

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 percent.⁸

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 percent of retail prescription drug spending in the U.S. in 2017.9 Medicare Part D spending, though less costly in the early years than initially expected, has doubled over the past decade, and is projected to increase faster than any other category of health spending over that year.¹⁰ On a national basis. Medicaid has also seen prescription drug spending rise precipitously with the introduction of new specialty drugs. For example, in the same year when the Hepatitis C drug Sovaldi was first introduced in 2013 at the price of \$84,000 per course of treatment, Medicaid prescription drug spending increased by nearly 25 percent.¹¹

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

Figure 2. U.S. Retail Prescription Drug Spending by Payer



Prescription Drug Utilization

More than half of all Americans routinely use prescription drugs, and 15 percent of the population regularly takes five or more drugs.¹² 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.¹³ According to

⁸U.S. Congress, House, Committee on Oversight and Government Reform, Democratic Staff Report, : "Skyrocketing Drug Prices: Year One of the Trump Administration" report prepared for Rep. Elijah E. Cummings, (2018), https://oversight.house.gov/sites/democrats.oversight.house.gov/ files/Skyrocketing%20Drug%20Prices-Year%20One%20of%20the%20Trump%20Administration.pdf.

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

¹⁰ Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, The Boards of Trustees, "2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," April 22, 2019, https://www.cms. gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.

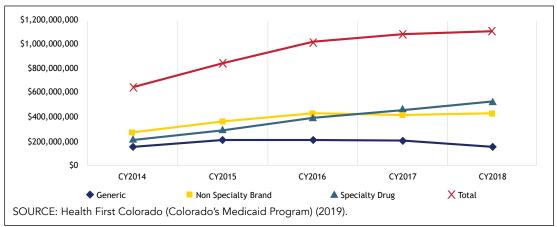
¹¹ Medicaid and CHIP Payment and Access Commission, "High-Cost HCV Drugs in Medicaid: Final Report, "March 2017, https://www.macpac. gov/ publication/high-cost-hcv-drugs-in-medicaid..

² ED Kantor, CD Rehm, JS Haas, AT Chan, EL Giovannucci, "Trends in prescription drug use among adults in the United States from 1999-2012," JAMA, (2015) 314(17):1818-1830.

¹³ "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science.

estimates from the Colorado State Demography Office, Colorado's population ages 65 and older reached 805,950 in 2018, an increase of 293,100 or 57.2 percent from 2008. The share of the population over age 65 in Colorado is now just over 14 percent. According to the U.S. Census Bureau, Colorado has had the third-fastest aging population over 65 behind Alaska and Nevada.

Drug Expenditures, by Calendar Year and Drug Type



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

In a 2019 report, the Kaiser Family Foundation found that nearly 8 in 10 Americans believe prescription drugs costs are unreasonable. It further found that 1 in 4 Americans who are taking medications are struggling to afford them.¹⁴ The high cost of prescription drugs also has a direct impact on patient compliance with their medications; in fact, more than 11 percent of Americans did not

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 percent higher than the average Social Security retirement benefit (\$16,848). The annual drug cost was also more than three-quarters of the median income for Medicare beneficiaries (\$26,200) and almost one-third of the median U.S. household income (\$60,336).

Figure 3. Colorado Medicaid Total Pharmacy and Physician-Administered

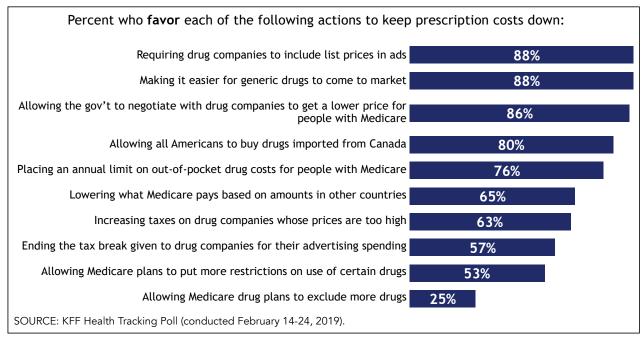
SOURCE: AARP. Prescription Drug Prices Increase by Double the Rate of Inflation. https://www.aarp.org/ politics-society/advocacy/info-2019/prescription-drug-price-report.html

¹⁴ Ashley Kirzinger, Lunna Lopes, Bryan Wu, Mollyann Brodie, "KFF Health Tracking Poll – February 2019: Prescription Drugs. Kaiser Family Foundation." March 1, 2019, https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/.

take their medicine as prescribed in order to save money.¹⁵ Similarly, 10.8 percent of Coloradans did not fill a prescription due to cost in 2019, with variations by geographic area; for example in Pueblo, it was 18.3 percent.¹⁶ Patients not taking their medication may experince 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.

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 4.

Figure 4. Majority Favor Most Actions To Keep Prescription Cost Down



Major Drivers of Prescription Drug Prices

Patent Protections

U.S. federal patent law, codified in Title 35 of the United States Code, gives manufacturers a property right 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.^{17,18} 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 to drive the price down. This is a significant contributor to rising prescription drug costs.^{19,20}

Further exacerbating this impact on prescription drug costs, drug manufacturers file new patents on existing drugs for new formulations.²¹ 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 percent of new patents filed to be for existing drugs, not new drugs.²²

Adding new patents is especially common among blockbuster drugs: among the 100 best-selling drugs, more than 70 percent had their patent protection extended at least once and almost half had their patent protection extended more than once.²³ This limits competition for an extended 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 assures that prices will remain high, without competition - which incentivizes pharmaceutical manufacturers to file new patents. All of these practices increase the prices of prescription drugs to health plans, employers and ultimately consumers.

¹⁷U.S. Code Title 35 – Patents

¹⁸ U.S. Code Title 21 – Food and Drugs, Chapter 9—Federal Food, Drug, And Cosmetic Act (§§ 301 – 399i) ¹⁹ Himanshu Gupta, Suresh Kumar, Saroj Roy, and R.S. Gaud, "Patent Protection Strategies," Journal of Pharmacy & Bioallied Sciences, (2019), 2(1), 2-7. doi:10.4103/0975-7406.62694 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/ ²⁰ "Applications for FDA Approval To Market A New Drug," Code of Federal Regulations, Title 2, §314.108(B)(2) ²¹ Arun Kumar and Arun Nanda, "Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries," Pharm Regul Aff, 6:185. 2018. doi:10.4172/2167-7689.1000185 ²² Robin Feldman, "May Your Drug Price Be Evergreen," Journal of Law and Biosciences 5.3 (2018): 590-647. ²³ Robin Feldman, "May Your Drug Price Be Evergreen."

¹⁵ National Center for Health Statistics, "Strategies used by adults aged 18–64 to reduce their prescription drug costs," by Robin Cohen, Peter Boersma, and Anjel Vahratian, NCHS Data Brief, no 333, (2019), https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf. ¹⁶ "2019 Colorado Health Access Survey: Progress in Peril," Colorado Health Institute, October 31, 2019, https://www.coloradohealthinstitute.org/ research/CHAS

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 will continue to increase in the U.S., sold with monopoly price protections until at least July 2023.24,25

Anticompetitive 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. Specifically, these drug makers have been able to 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 anticompetitive deals cost consumers and taxpayers \$3.5 billion in higher drug costs every year.²⁶ 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.²⁷

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, 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.²⁸

In May 2019, 44 states filed suit against 20 major pharmaceutical companies, including Teva, Pfizer, Novartis and Mylan.²⁹ The lawsuit alleges that the companies engaged in a scheme to allocate markets and fix prices of generic drugs, allowing them to raise prices. It alleges that the companies worked together to raise prices on as many medications as possible. The lawsuit also alleges the manufacturers raised prices on 112 generic drugs between July 2013 and January 2015 – some with increases of more than 1,000 percent. Some medications affected by this were for treatment of cancer, HIV, asthma, high cholesterol and depression. Colorado has joined this lawsuit.

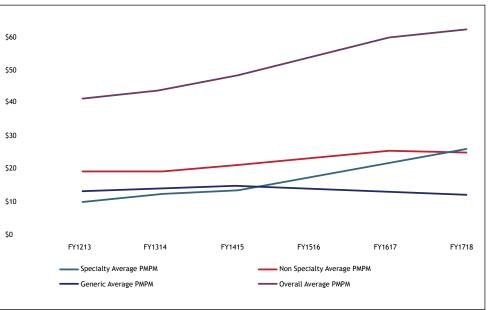


Specialty drugs are a dominant driver of drug expenditures; per capita spending on specialty drugs accounts for \$384 of the \$895 (43 percent) average spent on medicines per person every year.³⁰ Over six years (2012-2018), Health First Colorado's (Colorado's Medicaid program) prescription drug benefit costs, before credits from manufacturer rebates, rose 51 percent (75 percent is driven by specialty drugs), or an average of 8.5 percent a year. However, the trends were not evenly spread.

- per year)

This specialty drug trend drove three-guarters of the 51 percent cost trend. Medicaid generates about \$1 billon in prescription claim costs. (All statistics are before the application of manufacturer rebates.)

Figure 5. Rising Prescription Costs in Medicaid (before rebates)



³⁰ "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science.

• Generic drug spending slightly decreased (8 percent over 6 years, or 1.3 percent a year)

• Brand name drug spending increased slightly (30 percent over 6 years, or about 5 percent

• Specialty prescription drugs rose 171 percent or an average of 28.5 percent per year

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 that previously had none. Determining the price of such drugs is complex, considering cost of research and development, quality of life, and low volume of

²⁴ Danny Hakim, "Humira's Best-Selling Drug Formula: Start at a High Price Go Higher," The New York Times, January 6, 2018, https://www. nytimes.com/2018/01/06/business/humira-drug-prices.html.

²⁵ Cynthia Koons, "This Shield of Patents Protects the World's Best-Selling Drug.," Bloomberg Businessweek, September 7, 2017, https://www. bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

²⁶ Federal Trade Commission, "Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions," An FTC Staff Study, January 2010, https:// www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staffstudy/100112payfordelayrpt.pdf.

²⁷ Federal Trade Commission, "Pay for Delay Cases," 2019, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay. ²⁸ Virgil Dickson, "MACPAC Proposes Changes to Medicaid Drug Rebate Program," Modern Healthcare, June 19, 2018, https://www. modernhealthcare.com/article/20180619/NEWS/180619894/macpac-proposes-changes-to-medicaid-drug-rebate-program.

²⁹ Heather Murphy, "Teva and Other Generic Drugmakers Inflated Prices Up to 1,000%, State Prosecutors Say," The New York Times, May 11, 2019, https://www.nytimes.com/2019/05/11/health/teva-price-fixing-lawsuit.html.

patient need. However, current pricing models are unsustainable for patients, for employers and for payer–public and private. As an illustration of the impact of specialty drugs on overall prescription drug spend, for Health First Colorado (Colorado's Medicaid program), 1.25 percent of the prescriptions written to treat covered members were so expensive that they consumed 40 percent of the program's total prescription drug spending in fiscal year 2017-18 (before the application of manufacturer rebates to offset a portion of that cost). This impact of high cost drugs before rebates is in line with commercial or industry trends.³¹

The increasing availability and utilization of specialty drugs on overall prescription drug costs relates directly to increasing manufacturer investments and focus on specialty drugs. The graphic illustrate 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 in the years to come.³²

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 "Advancing Health Through Innovation 2017 New Drug Therapy Approvals" U.S. Food and Drug Administration, January 2018. Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma has commented on the high cost of specialty drugs. Speaking of her concerns about drugs that cost upward of \$2 million per dosage, she said, "That kind of innovation doesn't mean anything if people can't afford the treatment."³³

People making serious health decisions do not always have the luxury of price shopping, often because there is only a single medication that can provide relief. Employers and carriers that provide coverage are challenged to maintain risk and cost controls.

Three factors are creating a perfect storm that is fueling rising prescription drug cost trends: the extended patent protection monopoly period, combined with a manufacturer focus on specialty drugs, and the lack of transparency into the pricing of specialty drugs. To further complicate matters, the market price of the emerging specialty drugs has little relationship with the cost to develop and manufacture the new specialty drug therapies.

A recent example of the disconnect between a drug's development cost and its price is Zolgensma, a gene therapy currently the most expensive pharmaceutical product in the world at \$2.1 million per patient treatment.^{34,35} It targets a rare genetic disorder, spinal muscular atrophy (SMA), that can result in death within the first two years of life. The most common form of the disorder afflicts about 215 newborn children per year in the U.S. Zolgensma is thought to replace the defective or missing gene in order to slow disease progression, potentially with a one-time infusion.³⁶ Despite the low volume, sales of the gene therapy are expected to surpass \$2 billion a year within three years.³⁷

Development of the drug started with a researcher who was a state university employee in a nonprofit hospital lab in Ohio. The researcher then started a company, AveXis to develop the drug and spent approximately \$250,000 on research and development between 2013 and 2017, according to their SEC filings. AveXis was subsequently purchased by Novartis in 2018, a Swiss pharmaceutical corporation, for \$8.7 billion.^{38,39} Novartis' announcement of the price of Zolgensma did not link it to the research, development or production costs.⁴⁰ Rather, the price was calculated based on its effectiveness and costs compared to existing treatments. Considering the total cost of research that was filed is less than 15 percent of the cost of a single course of treatment, the original research cost and the price of the drug are not meaningfully connected.

Hospital Pricing Mark-up 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 to acquire the drug at a particular price and then charge the health plan a higher list-price.

A growing body of research examining the site of care where injectable and infused drugs are administered indicates that commercial payers reimburse hospital clinics at a higher rate than physician offices.⁴¹ Analysis done by the Partnership for Health Analytic Research shows that

³¹ "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," IQVIA Institute for Human Data Science.

³² Richard Frank and Paul Ginsburg, "Pharmaceutical Industry Profits and Research and Development," Health Affairs, November 13, 2017, https:// www. healthaffairs.org/do/10.1377/hblog20171113.880918/full/.

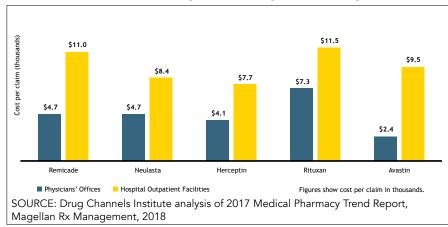
³³ "No matter How Successful They Are, Drugs with Million-Dollar Price Tags Are Unsustainable, CMS Chief Says", Kaiser Health News, October 18, 2019, https://khn.org/morning-breakout/no-matter-how-successful-they-are-drugs-with-million-dollar-price-tags-are-unsustainable-cms-chiefsays/.

³⁴ Christopher Rowland, "The FDA Approves A Gene Therapy That Is the Most Expensive Drug in the World," The Washington Post, May 24, 2019, https://www.washingtonpost.com/business/economy/the-fda-approves-a-gene-therapy-that-is-the-most-expensive-drug-in-theworld/2019/05/24/57c66500-7e4a-11e9-8ede-f4abf521ef17 story. 35 Rob Stein, "At \$2.1 Million, New Gene Therapy Is The Most Expensive Drug Ever," NPR, May 24, 2019 https://www.npr.org/sections/healthshots/2019/05/24/725404168/at-2-125-million-new-gene-therapy-is-the-most-expensive-drug-ever. "AveXis Receives FDA Approval for Zolgensma," Novartis, May 24, 2019, https://www.novartis.com/news/media-releases/avexis-receives-fdaapproval-zolgensma-first-and-only-gene-therapy-pediatric-patients-spinal-muscular-atrophy-sma. ³⁷ "\$2.1M Novartis Gene Therapy to Become World's Most Expensive Drug," The Guardian, May 24, 2019, https://www.theguardian.com/ science/2019/may/25/21m-novartis-gene-therapy-to-become-worlds-most-expensive-drug. ³⁸ Alberto Delclaux, "Novartis Bets \$8.7 Billion on Gene Therapy Company," The Wall Street Journal, April 9, 2018, https://www.wsj.com/articles/ novartis-to-buy-gene-therapy-company-avexis-for-8-7-billion-1523251511. ³⁹ "About Us", Telocyte, https://telocyte.com/about-us/our-people/470. ⁴⁰ "AveXis Announces Innovative Zolgensma Gene Therapy Access Programs for US Payers and Families," Novartis, May 24, 2019, https://www. novartis. com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families. ⁴¹ Aaron Winn, Nancy Keating, Justin Trogdon, et al., "Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014," JAMA Oncol., (2018), 4(4):580. doi:10.1001/jamaoncol.2017.5544.

physician offices and hospital clinics treat similar numbers of patients, but hospitals receive a larger share of gross profits.⁴² Accordingly, health plans often work with 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.

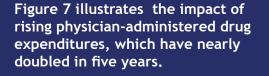
An example of the cost difference by site of care is the average cost per unit of Remicade, which is used to treat rheumatoid arthritis, among other illnesses. In a physician's office, it is \$90, yet it is \$227 in the hospital outpatient setting.⁴³ Figure 6 shows other drug examples of the difference in cost to the health plan by setting.

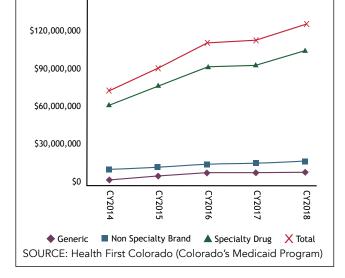
Figure 6. Claims Costs For Outpatient Specialty Drugs Are As Much As 3.9 Times Higher In Hospital Settings



\$150,000,000

Figure 7. Physician-Administered Drug **Expenditures by Service Date Calendar Year**





⁴²Jesse Ortendahl and Katalin Bognar, "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.pdf

⁴³ Adam Fein, "Still Possible: Hospitals Overcharge Health Plans for Specialty Drugs," Drug Channels, August 8, 2018, https://www.drugchannels. net/2018/08/ still-possible-hospitals-overcharge.html.

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. Though 92 percent of Americans believe that policy should be overturned,⁴⁴ numerous proposals to do so have been defeated. A bipartisan group of former governors and senators, citing research from the Congressional Budget Office, concluded that allowing the federal government to negotiate drug prices would save an average of \$11 billion a year.45



In the commercial market, a rebate is the return of part of the purchase price by the seller to the buyer.⁴⁶ For commercial health plan carriers, the rebates are paid by the manufacturers to the PBMs and carriers to encourage the use of a particular drug. The unfavorable impact of rebates and other manufacturer compensation to PBMs/carriers on prescription drug prices may include the following consequences:

- price to accommodate the payment of rebates to middlemen like PBMs and insurance carriers.
- prescription drug benefit to employers and consumers.
- and consumers.

• The lack of transparency into the pricing of a drug enables manufacturers to increase a drug's

• 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

• PBMs and carriers may not share all manufacturer rebates and other such compensation paid to them with employers and other clients. This increases PBM and health plan profits and reduces the funds available to offset the overall cost of prescription drugs to employers

• 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.⁴⁷

⁴⁴ Juliette Cubanski, Tricia Neuman, "Searching for Savings in Medicare Drug Price Negotiations," Kaiser Family Foundation, April 26, 2018 45 "Fact Sheet: How much money could Medicare save by negotiating prescription drug prices?," Committee for a Responsible Federal Budget, April 11, 2016, https://www.crfb.org/press-releases/fact-sheet-how-much-money-could-medicare-save-negotiating-prescription-drug-prices. ⁴⁶ Gabriela Dieguez, Maggie Alston, and Samantha Tomicki, "A Primer on Prescription Drug Rebates: Insights Into Why Rebates Are a Target for Reducing Prices,", Milliman, May 21, 2018, http://www.milliman.com/insight/2018/A-primer-on-prescription-drug-rebates-Insights-into-whyrebates-are-a-target-for-reducing-prices/.

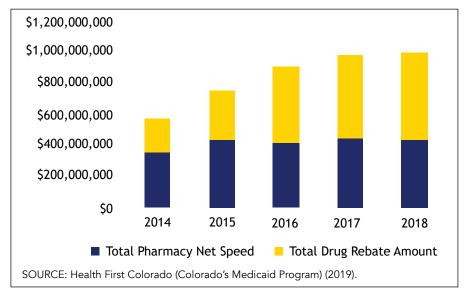
⁴⁷U.S. Congress, Senate, Finance Committee, transcript of testimony by John Prince, CEO OptumRx, April 9, 2019, https://www.finance.senate. gov/imo/media/doc/John%20Prince%20OptumRx%20Testimony%20Senate%20Finance%20Committee_04.09.19.pdf.

Figure 8 indicates a 146 percent increase in prescription drug rebates as a percent of overall costs over the same 5-year period for a large national group benefit plan with members in Colorado [(9.93 percent minus 24.39 percent)/9.93 percent]. In this case, this large self-funded group has contracted with one of the nation's largest PBMs to receive 100 percent of rebates. These rebates represent a 163 percent 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.

Year	Total Drug Rebate Amount	Rebate Precentage 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%

Figure 8. Rebate Through The Years For A Large National Fund

Figure 9. Total Colorado Medicaid Pharmacy Expenditure, Including Rebate Offset



If employers are not receiving 100 percent of 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 middlemen PBMs and insurance carriers.

In a speech to the Bipartisan Policy Center in February 2019, Health and Human Services

Secretary 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.⁴⁸

Without transparency into rebates and other related compensation between 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 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 passthrough to employers and consumers is likely having an even more adverse

48 "Rebates and Coupons Run Rampant in Diabetes," Managed Care, June 7, 2016, https://www.managedcaremag.com/archives/2016/5/rebatesand-coupons-run-rampant-diabetes.

impact on rising prescription drug costs to both the small employer and individual markets, where bargaining power is extremely limited.

While Medicaid rebates are different, the increase in the actual rebates to Health First Colorado (Colorado's Medicaid program) as a percent of total prescription drug expenditures as noted in Figure 9 reinforces the directional increase in the value of rebates. In Medicaid, 100 percent of rebates flow to the state and federal government, enabling Health First Colorado (Colorado's Medicaid program) to reduce its prescription drug benefit cost – driving savings that benefit the state budget and taxpayers.

The Impact of Rebates on Insulin Prices

Insulin is an excellent example of how rebates may be increasing prices. Sticker price expenditures on insulins increased by \$4.8 billion from 2014 to 2015, but IMS Health said manufacturers gave back more than that in rebates and discounts to PBMs to position themselves in the market.⁴⁹ That could imply that insulin prices were simply increased by manufacturers to accommodate the payment of rebates intended to incentivize the formulary status or use of one drug over another.

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/PBMs may be benefiting from higher list prices as well as the increased spread between what the carrier/PBM pays for the drug and the retail price it charges 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 percent of the prescription drug market: Express Scripts owned by Cigna, CVS Caremark which owns Aetna, and Optum Rx owned by United Health Group.⁵⁰ Insurance carriers and PBMs have acquired each other for mutual financial gain.

- contracted PBM at the time)
- in 2012.

• OptumRx (United Health Group) acquired Catamaran in 2015⁵¹ (which was Cigna's

• Cigna acquired Express Scripts in 2018⁵² after Express Scripts had already acquired Medco

⁴⁹ Alex Azar, "Remarks to the Bipartisan Policy Center," U.S. Department of Health and Human Services, February 1, 2019, https://www.hhs.gov/

⁵⁰ Matthew Herper, "Cigna's \$54 Billion Purchase of Express Scripts Could Upend the Prescription Drug Market", Forbes, March 8, 2018, https://www.forbes.com/sites/matthewherper/2018/03/08/cignas-54-billion-purchase-of-express-scripts-could-upend-the-prescription-drug-

⁵¹ "OptumRx, Catamaran Complete Combination," OptumRx, July 23, 2015, https://www.optum.com/about/news/optumrx-catamaran-complete-

⁵² "Cigna Completes Combination with Express Scripts, Establishing a Blueprint to Transform the Health Care System," Cigna, December 20, 2018, https://www.cigna.com/newsroom/news-releases/2018/cigna-completes-combination-with-express-scripts-establishing-a-blueprint-to-

about/leadership/secretary/speeches/2019-speeches/remarks-to-the-bipartisan-policy-center.html market/#23820a323063.

combination.html.

transform-the-health-care-system?rel=0.

- CVS acquired Aetna in 2018, after it acquired Caremark Rx, a PBM, in 2007⁵³
- Anthem terminated its relationship with Express Scripts and created its own PBM holding company in 2019.⁵⁴

The alignment of PBMs and insurance carriers is correlated with significant increases in PBM profits as noted in Figure 10.

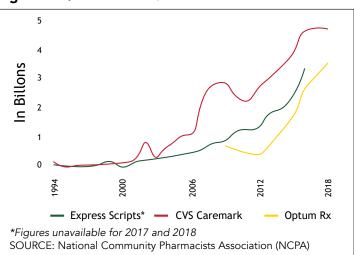


Figure 10. Annual PBM Profits

A

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 a year. At the same time, drug companies paid more than \$11 billion in fines for off-label or deceptive marketing.⁵⁵

In 2013, nine of the top 10 largest pharmaceutical companies spent more on marketing than on the research and development of new drugs.⁵⁶ Drug companies spend about \$40 billion a year more on marketing and administrative expenses than on research and development of new drugs, as noted 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.⁵⁷

Figure 11. Total Revenue And Spending By Category, Top 10 Pharmaceutical Firms, 2014.

Company	Total Revenue (\$bn)	R&D Spend (\$bn)	Sales and Marketing Spend (\$bn)	Profit (\$bn)	Profit Margin (%)
Johnson & Johnson (US)	71.3	8.2	17.5	13.8	19
Novartis (Swiss)	58.8	9.9	14.6	9.2	16
Pfizer (US)	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 (US)	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 (US)	23.1	5.5	5.7	4.7	20
AbbVie (US)	18.8	2.9	4.3	4.1	22

SOURCE: BBC, bbc.com/news/business-28212223

Direct-to-consumer marketing is the costly promotion of prescription products directly to potential patients.⁵⁸ This advertising began in the U.S. in the early 1980s. The FDA regulates the advertisements in accordance with federal laws and regulations, which includes 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 overtly reduced the number of letters being

under the First Amendment.⁶¹

⁵³ "CVS Health Completes Acquisition of Aetna, Marking the Start of Transforming the Consumer Health Experience," CVS, November 28, 2018, https://cvshealth.com/newsroom/press-releases/cvs-health-completes-acquisition-of-aetna-marking-the-start-of-transforming-the-consumer-healthexperience.

⁵⁴ "Anthem Reports Fourth Quarter and Full Year 2018 Results Reflecting Strong Core Performance," Anthem, January 30, 2019, https:// ir.antheminc.com/news-releases/news-release-details/anthem-reports-fourth-quarter-and-full-year-2018-results?field_nir_news_date_ value%5Bmin%5D=2019

⁵⁵ Lisa Schwartz and Steven Woloshin, "Medical Marketing in the United States, 1997-2016," JAMA, (2019), 321(1):80-96. doi:10.1001/ jama.2018.19320.

 ⁵⁶ Ana Swanson, "Big Pharmaceutical Companies Are Spending Far More on Marketing Than Research," The Washington Post, February 11, 2015, https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/.
 ⁵⁷ "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.

⁵⁸C. Lee Ventola, "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?," Pharmacy and Therapeutics, October 2011, https:// www.ncbi.nlm.nih.gov/pmc/articles/ PMC3278148/.

 ⁵⁹ "FDA Could Set Record Low for Drug Marketing Warning Letters – Again," BioPharmaDive, October 3, 2018, https://www.biopharmadive.com/ news/ fda-marketing-drug-warning-letters-record-low-trend/538688/.
 ⁶⁰ C. Lee Ventola, "Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?"
 ⁶¹ Congressional Research Service, "Drug Price Disclosures and the First Amendment" by Valerie Brannon, July 9, 2019, https://fas.org/sgp/crs/ misc/LSB10298.pdf.

Vivitrol's Approach to Marketing in the Criminal Justice System

Alkermes makes Vivitrol, which is a monthly injection to block opioid receptors in the brain. There are multiple FDA approved options to treat opioid addiction; Vivitrol is just one option. Alkermes has chosen to market their product directly to the criminal justice system: drug courts, judges, corrections officials, local law enforcement and incarcerated individuals. Following this marketing, some drug courts are showing a preference for Vivitrol even without extensive evidence that it is more effective than other options that are less expensive.

In Colorado, Alkermes has marketed to 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.⁶² Individuals leaving the corrections system may qualify for Medicaid coverage, in which case the State of Colorado pays for subsequent doses. Concurrent with these practices, Health First Colorado (Colorado's Medicaid program) has seen a significant increase in costs for Vivitrol from \$373.624 in 2014 to more than \$7.9 million in 2018.63 This medication is significantly more costly and harder to initiate than an equally effective medication for opioid addiction, buprenorphine.⁶⁴



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 direct to consumer marketing while over \$20 billion was spent on marketing to medical professionals.⁶⁵ 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

⁶³ Analysis of calendar year claims data conducted by the Department of Health Care Policy & Financing, May 2019.

⁶⁴ Joshua Lee MD et al, "Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioid relapse prevention (X:BOT): a multicentre, open-label, randomised controlled trial," vol. 391, iss. 10118, p309-318, January 27, 2018.

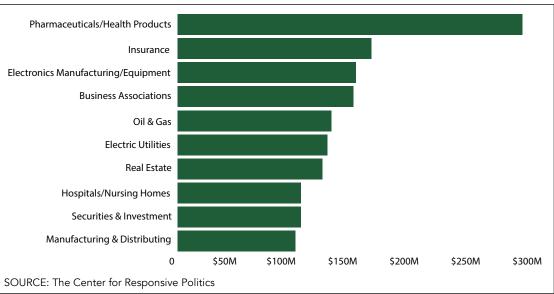
⁶⁵ Lisa M. Schwartz, Steven Woloshin, "Medical Marketing in the United States, 1997-2016," JAMA, (2019), 321 (1): 80-96. doi:10.1001/jama.2018.19320

with a 1.67 percentage point decrease in the market share of detailed drugs."⁶⁶ Two publicly accessible websites now make pharmaceutical payments to prescribers more transparent: ProPublica and a CMS website created under the Sunshine Act.⁶⁷



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 commerce, at more than \$280 million a year just in federal lobbying efforts, as illustrated below.⁶⁸

Figure 12. Top 10 Industries by Lobbying Spending, 2018



Rising Prescription Drug Manufacturer Profits ā

The profit margins among pharmaceutical manufacturers is higher than that of carmakers, oil and gas, or media. In 2014, the world's largest drug manufacturer, US-based Pfizer, made a 42% margin.⁶⁹ When total revenues for the top ten pharmaceutical companies range from \$24 to \$81 billion in 2018, these high margins are making an impact on overall health spending.⁷⁰ 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.

⁶⁶ L Larkin, D Ang, J Steinhart, et al., "Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing,"

⁶⁷ ProPublica and CMS tools for payment disclosure, https://projects.propublica.org/docdollars/, https://www.cms.gov/openpayments/ ⁶⁸ Karl Evers-Hillstrom, "Lobbying Spending Reaches \$3.4 billion in 2018, Highest in 8 Years," The Center for Responsive Politics, January 25, 2019, https://www.opensecrets.org/news/2019/01/lobbying-spending-reaches-3-4-billion-in-18/. 69 "Chart of the Day November 12, 2018: Big Pharm's Big Profits," The Fiscal Times, November 12, 2018, https://www.thefiscaltimes.com/2018/11/12/Chart-Day-Big-Pharmas- Profits.

⁷⁰ George Underwood, "The top pharma companies by revenue 2018," August 30, 2019, https://pharmaphorum.com/views-and-analysis/the-top-

⁶² Chris Vanderveen, Zack Newman, Anna Hewson, and Mike Grady, "An Opioid Addiction Treatment That Costs up to \$1,300 a Shot is Costing Colorado Taxpayers Millions," 9 News, May 8, 2019, https://www.9news. com/article/news/investigations/medical-cost/an-opioid-addictiontreatment-that-costs-up-to-1300-a-shot-is-costing-colorado-taxpayers-millions/73-43a5166c-a222-41d2-bb89-2b0a8a1e1fb9.

JAMA, (2017), 317(17):1785-1795, doi:10.1001/jama.2017.4039. ⁶⁹ Richard Anderson, "Pharmaceutical industry gets high on fat profits," BBC News 6 November 2014 https://www.bbc.com/news/ business-28212223

pharma-companies-by-revenue-2018/

Learning from Other States

Over the last two years, many states have acted to further regulate the prescription drug market. A short summary of this legislation is provided below. For the full list of state prescription drug legislation, please visit the National Academy for State Health Policy (NASHP) website.⁷¹

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. The bills primarily focused on transparency in drug costs increases. Maryland also passed a bill that created a board to regulate prices.



Maine enacted LD 1162, which requires manufacturers to report when the Wholesale Acquisition Cost (WAC) of a brand name drug increases by more than 20 percent over the past year.



Oregon, HB 2658, requires manufacturers to give advance notice of price increases for brand name drugs with an increase of 10 percent or more over the last year.

Texas, HB 2536, requires disclosure within 30 days of a 15 percent or more price increase over 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.



Washington, HB 1224, and **Colorado**, HB19-1131, also 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.

Maryland passed HB 768 in 2019 to create a Prescription Drug Affordability Board, 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. The Prescription Drug Affordability Board will look at prescription drugs with costs that greatly impact Marylanders, including medications that impact the budgets of state, county, and local government programs and facilities. 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.



In Utah, over 100 healthcare entities have come together to create their own drug manufacturing company locally. The goal is to combat the arbitrary pricing and prevent local shortages of essential drugs.⁷²

⁷¹ "State Legislative Action to Lower Pharmaceutical Costs," National Association of State Health Policy, https://nashp.org/rx-legislative-tracker-2019/.

⁷² Katie McKellar, "New Utah drug company to fight nation's 'crazy' drug prices, shortages," Deseret News, September 6, 2018, https://www. deseret.com/2018/9/6/20652851/ new-utah-drug-company-to-fight-nation-s-crazy-drug-prices-shortages. In 2018, 178 bills related to prescription drugs were introduced nationwide and 46 passed. Many of the bills passed related to regulating pharmacy benefit managers. Maine, New Hampshire, Oregon and Vermont passed bills related to price transparency. The legislation focused on mandating disclosures to government accountability agencies.



New Hampshire, HB 1418, requires 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.



Oregon, similarly, passed HB 4005, 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.



Finally, Vermont passed S 92. The bill requires 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.

Solutions for Colorado

The following section reviews opportunities that can be implemented through new state policies in Colorado, based on cost drivers and lessons learned from other states.

Ę Improve Prescription Drug Price Transparency

One state opportunity is to tackle the industry's obscure pricing practices first by building a foundation of insights through pricing transparency. Specifically, transparency in Colorado could include:

- Disclosure of prescription drug price increases for generics, brand name, specialty drugs and the like, 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;
- Payments in any form made by manufacturers to insurance carriers/PBMs (rebates, market share allowances, discounts, etc.), perhaps in the aggregate, recognizing confidentiality considerations;
- Identifying when price increases for existing drugs match a price increase for a competitor's drug (aka shadow pricing);
- Identifying manufacturers promoting drugs for use outside of their indicated purpose as approved by the FDA (aka off-label marketing);
- Comparing costs of new treatments to other current treatments;
- Reviewing pending patents as they relate to "evergreening" and "pay-to-delay" of generic drugs.

Transparency policy could also drive 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
- physician detailing payments
- rebate payments to third parties like insurance carriers and PBMs
- research and development costs as well as the offsets from federal grants, and grants from charitable organizations
- acquisition cost of technology
- cost to distribute
- · costs of ongoing safety and effectiveness research
- allocation of manufacturer overhead (administration)
- profit charge

Amend SB 19-005 to Allow State Importation Policy to Potentially Parallel Federal Changes

In 2019, Colorado passed the Import Prescription Drugs From Canada bill, Senate Bill 19-005. This bill followed the current federal legislation which only permits importation of prescription drugs from Canada.⁷³ If Congress considers such changes, Colorado would benefit from state laws that parallel importation expansion at the federal level. Amending SB 19-005 to allow the Colorado Department of Health Care Policy & Financing, which is charged with implementing importation legislation, to pursue importation from other countries in parallel to federal policy changes or waivers would avoid unnecessary delays in maximizing the impact of evolving federal importation policy.



Prescriber Tool in Development

The Department of Health Care Policy & Financing is coordinating the 2020 implementation of a tool that aims to be accessible to all prescribers in the state. The tool is intended to deliver the following benefits: improve prescription drug cost control, reduce opioid addiction risk, and improve patient health. Phase I of the tool's implementation would address all three benefits, while Phase II would further evolve the patient health improvement program benefit.

- maternity support, or social determinant of health supports and more.

The tool will be incorporated into the prescriber's Electronic Medical Record (EMR) to improve the providers' ease of use.

The Department created the original RFI 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 (consultant), and Department subject matter experts. As of the date of this report, the Department has received the proposals solicited through an invitation to negotiate and is negotiating with the bidders with the objective of a 2020 implementation, targeting both of the above Phase I features, if budgeted dollars are sufficient.

Phase I of the Prescriber Tool Implementation discloses to the treating physician or prescriber the cost to the patient (copay) and payer (employer, municipality, Medicaid, commercial health plans, etc.) of the various drug therapy alternatives available to treat the patient. This cost structure is specific to each patient (i.e. an Aetna patient's specific reimbursement rate and copay based on the patient's plan). This feature also alerts the prescriber when a patient might have a higher opioid addiction risk score before an opioid is prescribed, thereby reducing the risk of patient addiction and its consequences.

Phase II provides access to the health plans' health improvement programs through the tool so that a provider can prescribe or recommend a health improvement program to a patient, not just a pill. These programs might include tobacco cessation, diabetes management,

This tool has the potential to dramatically improve all prescribers' visibility into cost as part of the prescribing practice. Additionally, it would assist payers in rewarding providers with value-based payments for both improving patient health (outcomes) and better controlling costs and trends associated with prescription drugs. The Department is exploring including value-based rewards to hospitals as part of the Hospital Transformation Program for implementing the prescriber tool.

Lastly, this tool is intended to enable the production of report cards that assist in provider education around outlier behaviors including patient outcomes and utilization and prescribing patterns, as well as opportunities to reduce patient, employer, and Medicaid cost share.

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 reimbursements, plan designs, utilization review and prior authorization rules. From a competitive perspective, carriers and PBM plans 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 volunteered to help test the tool as have a number of Federally Qualified Health Centers. The Department may 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.

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Ensure Employers Benefit from All Manufacturer Rebates and Compensation to Their Insurance Carriers/PBMs

Medicaid is only paying about 44 percent of its gross prescription drug costs because it receives 100 percent of all manufacturer rebates, and uses all such funds to offset the costs of its prescription drug claims. The chart below shows both the impact on the net cost of prescription drugs to the state as well as the dramatic increase in rebates over the last five calendar years, as a percent. The increase from 39.01 percent to 56.1 percent represents a 44% increase in rebates paid by manufacturers to the Medicaid program.

Calendar Year	Total Pharmacy Expenditure Amount		Total Prescription Drug Rebate Amount	Rebate Percentage of Total Paid Amount
2014	\$573,305,555	\$349,676,759	\$223,628,796	39.01%
2015	\$752,880,375	\$432,094,344	\$320,786,031	42.61%
2016	\$906,762,480	\$418,836,790	\$487,925,690	53.81%
2017	\$981,469,207	\$445,706,439	\$535,762,768	54.59%
2018	\$993,671,586	\$436,269,588	\$557,401,998	56.10%

Figure 13. Colorado State Medicaid Expenditure

SOURCE: Health First Colorado (Colorado's Medicaid Program) (2019).

While Medicaid rebates are higher than rebates and other compensation paid to insurance carriers/PBMs for their commercial business, the point of the chart above is clear: employers, municipalities and union trusts that are not fully participating in rebate sharing are paying too much for their prescription drug benefit, and the unfavorable impact of that loss is getting worse.

In an article by Tami Luhby on May 7, 2018 titled "Just who gets those rebates?", Scott Gottlieb, 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 prices - 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.

Given that Colorado is a small employer state, and given the success of our individual market, policymakers can consider prescription drug policy that (a) provides transparency into rebates and all compensation between manufacturers, insurance carriers and their third party administrators (TPAs) as well as (b) legislation to require the pass through of manufacturer rebates and all compensation between manufacturers and insurance carriers/PBMs to employers, municipalities, union trust funds, and individual policyholders in the form of premium reductions.

Some have discussed policy that would pass along rebates to consumers. Policymakers should pause at this option; it can incent consumers for taking - and reward manufacturers for pushing - the higher cost 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. The preference could be to use manufacturer rebates and other compensation to offset the price of individual and group policies, as well as self-funded employer costs.



Related to the last paragraph above, some manufacturers provide "coupons" to consumers to offset their plan design copays, thereby encouraging them to try or continue to use their 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 copays. That is, a manufacturer coupon could fully offset the brand name copay 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 Prescription Drug Best Practices 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 Roadmap,⁷⁴ 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 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 the various relevant state agencies.

Upon inquiry, the Colorado Medical Society has agreed that Coloradans, employers, municipalities, 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 experts from a wealth of competent experts to frame prescribing best practices to the benefit of all Coloradans. 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 in development, or electronic health record (EHR) systems.



As prescription drug costs continue to soar, the state has an opportunity to follow Maryland's leadership by creating a Prescription Drug Affordability Board. This would be an independent body with the authority to evaluate expensive drugs and recommend appropriate methods for addressing these costs, including the potential to set upper limits on what Colorado government entities would pay for them. Similar to Maryland, this board could also explore the potential to set upper payment limits for health plans in Colorado. Different from Maryland, Colorado may wish to add provisions that require valued-based-contracting (covered in the following section), as well as exploring additional financial levers to hold manufacturers accountable for behaviors that impede affordability, access, and quality.

⁷⁴ Colorado Health Care Affordability Roadmap. https://www.colorado.gov/pacific/sites/default/files/Health%20Care%20Affordability%20 Roadmap%20Hospital%20Costs%20Focus.pdf.

The Prescription Drug Affordability Board could set upper payment limits on high cost prescription drugs in stages:

- of the state, county and local government programs and facilities.

The board could be comprised of members appointed by the Governor and General Assembly and include clinical experts, consumers, carriers and experts from the various agencies such as Health Care Policy & Financing, Public Health & Environment, Division of Insurance, Human Services, Department of Corrections, etc.

One option is to provide the board with appropriate access to agency prescription drug utilization and cost reporting, Center for Improving Value in Health Care (CIVHC) All Payer Claims Database reports, as well as access to HCPF staff and other agency staff who could maximize existing state repositories and analytics to support its analysis and upper payment limit recommendation 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 with increases over a specific percent, prescriptions that are driving economic hardships to consumers, employers, or state programs, and the like to determine appropriate upper payment limits, and cost control stratagies.

Legislation creating this board could be separate from other transparency bills, but the board would be most effective if it is preceded or accompanied by other legislative efforts that provide the board with insights into the increasing cost of various medications and the drivers of prescription drug pricing.

Public and Private Partnerships to Improve Access to Prescription Drugs

The state or a state-supported non-profit partner could support the manufacturing or negotiated direct purchase of certain high-cost, low-access or high-volume, high-cost drugs with the goal of driving down state and private pharmacy costs, increasing competition, and improving access to drug treatments. This could be managed or overseen by the previously outlined Prescription Drug Affordability Board. State and international agencies have created public policies that promote improved access to medications that are otherwise not available.

• The first stage could consider upper payment levels on medications that impact the budgets

• After monitoring the eventual outcomes in Maryland and Maine, which have established similar boards, the second stage could set upper payment limits for prescription drugs for the benefit of all purchasers throughout the state, with the exception of Medicare and Medicaid.

- In Utah, over 100 healthcare entities have come together to create their own drug manufacturing company locally. The goal is to combat the arbitrary pricing and prevent local shortages of essential drugs.⁷⁵ Colorado could mimic this evolving alternative.
- The World Health Organization (WHO) recently invested in testing and approving a new generic insulin to combat rising drug costs. The WHO previuosly used this approach to successfully increase global access to life saving drugs by driving down annual costs of HIV medications \$15,000 to \$75.76
- In Colorado, the state legislature through the Department of Public Health and Environment created a standing order (i.e. a blanket prescription for all residents) for the lifesaving overdose reversal drug, Naloxone, decreasing access barriers.⁷⁷ 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.⁷⁸



Monitor Innovative, Evolving Ways to Price Prescription Drugs

A nonprofit in Boston called the Institute for Clinical and Economic Review (ICER) is using 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 health a drug is restoring to patients who are sick.

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

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 may help payers leverage bigger discounts from drug makers, determine limitations to coverage for certain drugs, or indicate preferential coverage of alternative treatments with better estimated value.⁷⁹ QALY pricing methodology is also an opportunity that could be explored by a newly-created Affordability Board.



Children's Hospital and University Hospital are both in a unique position to negotiate prices on high cost specialty drugs, as well as value-based contracts with manufacturers. This is because these hospitals often serve as the regional providers for more costly specialty care drug therapies. Without these hospitals, the specialty drug manufacturers would be challenged to penetrate the Colorado market, giving these hospitals' leverage with the manufacturers.

There is an opportunity to partner with these systems to both assist them in this quest and to also ensure that the savings negotiated are passed along to the ultimate payers - employers, municipalities, Medicaid and the like. There may also be an opportunity to partner with other hospitals in time (i.e., HCA HealthONE, Centura Health or SCL Health), if they are also administering these high cost drugs.

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

Hospitals have a number of levers that impact the cost of drugs administered to patients. A hospital may contract with a specialty pharmacy 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 costs versus pricing as well as limiting hospital mark-up. Additionally, if an Affordability Board is created, the Board may consider setting an upper payment limit on the 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 policyholders rather than transforming these savings into profits.

Further, 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.⁸⁰ A best practice for insurance carriers 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 and insurance carriers are contracted (required) to do just that.

Utilize Hospital Leverage to Negotiate Specialty Drug Prices

⁸⁰ Aaron Winn, Nancy Keating, Justin Trogdon, et al., "Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014."

⁷⁵ Katie McKellar, "New Utah drug company to fight nation's 'crazy' drug prices, shortages."

⁷⁶ Donald McNeil, "To Drive Down Insulin Prices, W.H.O. Will Certify Generic Versions," New York Times, November 13, 2019, https://www. nytimes.com/2019/11/13/health/insulin-prices-generic-who.html

⁷⁷ Colorado Department of Public Health and Environment, "Naloxone Standing Orders," https://www.colorado.gov/pacific/cdphe/ naloxoneorders.

⁷⁸ Colorado General Assembly, "Harm Reduction Substance Use Disorders," https://leg.colorado.gov/bills/sb19-227

⁷⁹ Denise Roland, "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.



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

Value-based contracts (VBC) can be used by health plans and other payers to hold the manufacturer more accountable for their clinical promises, with financial price or rebate adjustments applied based on patient outcomes (i.e., retrospective price reduction for commercial health plans or an additional rebate paid under a Medicaid contract, etc.).

Historically, VBCs are commonly employed with Multiple Sclerosis, Hepatitis-C specialty drug therapies and other high cost drugs where there is benefit to both sides - the health plan/ payer and the manufacturer. There is also an opportunity for the proposed Prescription Drug Affordability Board to consider the application of VBC in partnership with the upper payment limit configuration to further hold manufacturers accountable for their clinical promises.

VBCs are even more appropriate today since the FDA has recently changed its focus toward permitting manufacturers to release higher priced drugs to market with lesser clinical performance. 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.



The purpose of this section is to give employers suggestions of best practices in prescription drug cost control. Implementing the best practices in this section will enable employers to compare the prescription drug prices they pay, administrative fees and utilization review programs to industry best practices. 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. 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. Health insurance plans and pharmacy benefit management companies use a number of 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.⁸¹ 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 patients' 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:

⁸¹ "Drug Utilization Review," Academy of Managed Care Pharmacy, https://www.amcp.org/about/managed-care-pharmacy-101/conceptsmanaged-care-pharmacy/drug-utilization-review.

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 (PAs). 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 authorizations are both a safety and cost-saving measure. Some PBMs do not charge for PA's, 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.

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 that is necessary to achieve desired results. Step therapy is often performed as a type of prior authorization.⁸² 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. Recently, 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.⁸³

Employers should work with their brokers and consultants to ensure their hired vendors have active and appropriate programes 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.

• 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.

82"How does step therapy work?," Blue Cross Blue Shield of Michigan, https://www.bcbsm.com/index/health-insurance-help/faqs/plan-types/

⁸³ Office of Attorney General Maura Healey. (2019) "Colorado-Based Pharmacy Pay \$1M for Unauthorized Refill Program" Mass.gov. https://www.

pharmacy/what-is-step-therapy.html.

mass.gov/news/colorado-based-pharmacy-to-pay-1-million-for-operating-an-unauthorized-automatic-refill.



Preferred Drug Pricing for Employers

Employers have an opportunity to review their contracts with their carriers or PBM to ensure that they are receiving the lowest prices, highest rebates, and lowest administrative fees. The below chart can be used to help employers negotiate improved pricing with their contracted PBMs or carriers. 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). It is also impacted by their specialty and mail order drug utilization, the formulary and the utilization management programs in place. The below information has been provided by Mercer, a global consulting firm. It illustrates the dramatic difference in market pricing.

As noted in the rebate section, rebates are increasing each year. It is therefore important for employers and their representatives to negotiate the passthrough of all rebates. This rebate passthrough 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 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 accordingly. Employers are encouraged to push for preferred mail order drug pricing, recognizing this pricing variation. If an employee complains to their HR Department that their coinsurance burden is higher with the mail order drug vendor than at the retail or corner pharmacy, that insight may indicate that the mail order drug pricing is not as competitive as it could be, which is an invitation for further dialogue with the carrier. It is also critical for employers to negotiate guarantees on the generic utilization rate, also called the generic dispense rate (GDR), as well as brand name drug rebates, which can be quoted on rebatable prescriptions or all prescriptions. The Department is rolling out the Health Care Affordability Roadmap in communities 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.

Figure 14. 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

Figure 15. 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***

through the retail deliveral channel.

**Rebates assume an incentive plan design with at least \$15 differential between the preferred and non-preferred brand copayments 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



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

All claims for opioids are captured in the Prescription Drug Monitoring Program (PDMP). Authorizing Health First Colorado access to the PDMP would allow for better clinical management of members and their use of opioids. This, in turn, can help to 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 Medicaid, this policy change would align with nationwide best practices as other states allow Medicaid access to the PDMP. Health First Colorado's lack of access is 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 requested access to the PDMP. They are also working with the best intentions to improve member health and affordability, but are hindered without access to the PDMP.

NOTE: This report has intentionally not focused on opioid recommendations because of the concurrent Opioid Committee workstream. PDMP access is the only recommendation in the report relative to opioids.

*The overall specialty discount assumes an open specialty arrangement where members can obtain specialty drugs

Solutions to Lower Prescription Drug Costs for All Americans

Reducing the cost of prescription drugs has garnered bipartisan support and action at the federal level, which includes both administrative actions by the Department of Health and Human Services and the introduction of legislation in Congress.

The proposed federal changes focus on Medicare and include negotiating drug prices, modifying benefit design, capping increases at inflation rates, international reference pricing, modifying payments and rebates, providing Medicaid rebates for drugs prescribed to low-income beneficiaries (enrolled in both Medicare and Medicaid) and other changes. While there have been some regulatory actions in this space, attempts to compel increased transparency in drug pricing and advertising via the rulemaking process have thus far been unsuccessful. For example, in July 2019, the U.S. District Court for the District of Columbia held that HHS did not have the authority to obligate pharmaceutical companies to include the list prices of drugs in television ads.⁸⁴ However, additional options could be explored at the federal or state level to mitigate the prominence of direct-to-consumer marketing and its impact on utilization.

Both the U.S. House and Senate have presented legislation that addresses pricing transparency, patent law and rebates; however, to date, no bills have yet become law. The House of Representatives has introduced legislation that would allow Medicare to negotiate prices for certain drugs. The Senate has introduced bipartisan legislation that would cap what Medicare beneficiaries pay out of pocket for medicines and require drug makers to pay rebates to Medicare if they hike prices above the inflation rate. The Administration has recently signaled its support for the Senate bill.⁸⁵ The focus on controlling Medicare prescription drug spending is critical given that a recent Kaiser Family Foundation issue brief indicates that drug costs for the Medicare program account for 30 percent of total retail prescription drug spending in the United States.⁸⁶

Further detail on this legislation can be found in Appendix I.



In May 2019, SB19-005 was signed into law in Colorado. This state bill allows the Department of Health Care Policy & Financing to import drugs from Canadian suppliers. Similar to the state opportunity identified, if the federal government allowed states to import drugs from countries beyond Canada, Colorado would have more importation options to drive down the overall prices of prescription drugs. This could also reduce the Canadian concerns over the U.S. impact to their pescription drug market.

⁸⁶ Meredith Freed, Juliette Cubanski, and Tricia Neuman, "A Look at Recent Proposals to Control Drug Spending by Medicare and its Beneficiaries," Kaiser Family Foundation, August 2019, https://www.kff.org/medicare/issue-brief/a-look-at-recent-proposals-to-controldrug-spending-by-medicare-and-its-beneficiaries/?utm_ campaign=KFF-2019-Medicare&utm_source=hs_email&utm_medium=email&utm_ content=2&_hsenc=p2ANqtz--3KnP4yjGXP9ai7_AE1qQARd9brV-wTf5wRl93HEPEUjEwk_tzAHfC7cSRpesqxku6npWUCTAJjRutaHtP6LKxa2ajkQ&_ hsmi=2.



Both patents and exclusivity regulations were meant to reward innovation and give innovators a temporary monopoly to recoup their research and development costs.⁸⁷ Indeed, whenever discussion arises concerning reform of patents and exclusivity, manufacturers insist that reform will deter innovation. However, the system is not currently being used as designed. 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 intention, without competition, price transparency or price-setting controls.

The patent laws have been revisited from time to time, and the time of exclusivity has been modified. Perhaps it is time for federal policymakers to consider such legislation again to better align the period of patent protection to the recoupment of investment in today's market plus a reasonable return on investment on the creation of the new drug. Federal policymakers could also explore regulations or statute changes that allow for patents for true innovation, but curtail the use of the system to effectively continue the patent for an existing product by granting a patent for minimal changes. Some policymakers suggest it is time to implement a "one-anddone" approach that awards one patent for one drug.



If reforms to regulating prices or setting prices are considered, one methodology may be to require U.S. prices be aligned to prices in other countries. In October 2018, HHS announced its plans to explore an International Pricing Index Model for Medicare Part B Drugs. Part B covers a limited number of drugs under limited conditions when they are provided in a doctor's office, a clinic or an outpatient hospital rather than traditional prescription drugs covered by Part D.⁸⁸ This model ties the price of certain drugs under Medicare Part B to the average prices of other countries, such as Germany and Japan. Those countries are able to negotiate for lower drug prices in exchange for access to their healthcare systems. The U.S. could do the same.

This model faces opposition from the pharmaceutical industry, which claims it will stifle innovation and reduce access to the drugs. It 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.⁸⁹

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

⁸⁴ Bobby Allyn, "Federal Judge Blocks Trump Rule Requiring Pharma Companies to Disclose Drug Prices in TV Ads," National Public Radio, July 9, 2019, https://www.npr.org/2019/07/09/739770699/judge-blocks-trump-rule-requiring-pharma-companies-to-say-price-of-drugs-in-tv-a. 85 "White House Puts Heft Behind Bipartisan Compromise Drug Bill in Senate," Kaiser Health News, November 18, 2019, https://khn.org/morningbreakout/white-house-puts-heft-behind-bipartisan-compromise-drug-bill-in-senate/.

⁸⁷ Food and Drug Administration, "Frequently Asked Questions About Patents and Exclusivity.," https://www.fda.gov/drugs/developmentapproval-process-drugs/frequently-asked-questions-patents-and-exclusivity. ⁸⁸ Scope of Benefits; Definitions, 42 USC 1395k et seq, see also https://www.medicare.gov/coverage/prescription-drugs-outpatient and https:// www.medicareinteractive.org/wp-content/uploads/2015/08/B-vs-D-chart.pdf ⁸⁹ Shannon Firth, "Reactions Mixed to Part B Drug Pricing Plan," MedPage Today, October 26, 2019, https://www.medpagetoday.com/ publichealthpolicy/medicare/75967.



FDA-Based Clinical Performance Requirements

With prescription drugs coming to market more guickly with less evidence and fewer clinical studies, there are evolving concerns about the increased risk of adverse events post-launch. To compensate for this, the FDA may require post-market clinical trials. When the FDA requires post-market clinical trials, manufacturers could be held accountable to complete these postmarket clinical trials with consequences. Perhaps this could include having to pull the drug from the market or pay a fine that correlates to the product's revenue. The FDA has affirmed its commitment to post-market study requirements.⁹⁰

Given concern about safety issues raised by these statutory changes, there is an opportunity for Congress to re-examine this policy. There is also an opportunity to revisit drug launch pricing based on the lower costs to bring a drug to market given the new policy.



Further Limit Direct to Consumer Advertisement

Limiting or significantly regulating Direct to Consumer (DTC) advertising of pharmaceutical drugs at the federal level is needed to address these unnecessary costs and utilization of the most costly and profitable drugs. Billions are going into these ads, which drive patient demand for profitable brand-name drugs while increasing the volume of prescriptions written for the newest and most costly drugs.⁹¹ The Trump administration attempted to provide some pricing transparency by requiring drug-makers to put pricing information in their ads. This regulation was blocked by a federal judge in July 2019, who determined the regulation violated free speech.⁹² These ads fuel unnecessary costs that are passed onto the payers and consumers. Further exploration into federal policies that limit or mitigate the impact of these ads should be explored, recognizing this most recent federal decision.



Generics introduce competition; the sooner they can come to market, the faster 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.⁹³ From August to December 2018, the FDA approved the first five generic drugs through this new expedited approval pathway.⁹⁴

In 2019, the FDA commissioner at that time, Dr. Scott Gotllieb, 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.⁹⁵

⁹⁰ Food and Drug Administration, "FDA Affirms Commitment to Postmarket Study Requirements; Warns Company for Failure to Submit Final Postmarket Study Report," February 5, 2019, https://www.fda.gov/news-events/fda-brief/fda-brief-fda-affirms-commitment-postmarket-studyrequirements-warns-company-failure-submit-final.

⁹¹ Michael Wilkes, Robert Bell, and Richard Kravitz, "Direct-To-Consumer Prescription Drug Advertising: Trends, Impact, And Implications," Health Affairs, Vol 19 No. 2, March 2000, https:// www.healthaffairs.org/doi/full/10.1377/hlthaff.19.2.110.

⁹² Stephanie Armour, "Trump Rule Requiring Drug Prices in TV Ads Blocked," Wall Street Journal, July 8, 2019, https://www.wsj.com/articles/ trump-rule-requiring-drug-prices-in-tv-ads-blocked-11562634281.

⁹³ Food and Drug Administration, "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," June 18, 2019, https://www.fda.gov/news-events/press-announcements/ statement-new-effort-improve-transparency-and-predictability-generic-drug-applicants-help-increase. ⁹⁴ Food and Drug Administration, "Statement from FDA Commissioner Scott Gottlieb, MD on new policy to improve access and foster price competition for drugs that face inadequate generic competition," February 15, 2019, https://www.fda.gov/news-events/press-announcements/ statement-fda-commissioner-scott-gottlieb-md-new-policy-improve-access-and-foster-price-competition. ⁹⁵ Food and Drug Administration, "Statement from FDA Commissioner Scott Gottlieb, MD on new policy to improve access and foster price competition for drugs that face inadequate generic competition."

Conclusion

According to a national poll from the West Health Institute, a nonpartisan, nonprofit health care research organization,⁹⁶78 percent 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.⁹⁷ Given that prescription drugs are often the first line of offense and defense against illness, disease and injury, 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 into the cost to develop and manufacture drugs, or why costs fluctuate so wildly even among generic drugs. Drug costs are variable and inconsistent and are a significant driver of our affordability challenges. Business practices across manufacturers are driving prices up and are not aligned with free market competition that typically benefits consumers and purchasers.

This report has articulated a series of opportunities to address these cost drivers, including nearterm actions such as:

- Prescription drug price transparency, such as disclosures related to price increases, payments to middlemen like insurance carriers and pharmacy benefit managers (PBMs) and price composition transparency (i.e., R&D, distribution, profits, promotional marketing, etc.);
- Aligning state importation policy with potential expansion of federal regulations and/or waivers for drug importation;
- Investing in physician tools, like the Prescriber Tool, that fuel more cost effective prescribing practices;
- Requiring rebates to be passed through to employers and patients;
- Empowering and educating employers to negotiate contracts that maximize the prescription drug pricing discounts, improve utilization management controls and maximize rebate passthroughs that serve to offset the cost of the prescription drug benefit; and
- Creating boards that review potential benefits of upper payment limits on drug prices and provide other guidance to address prescription drug prices as well as prescribing best practices.

A sustained commitment to address cost drivers will require moving toward longer-term solutions over time including;

- Public-private partnerships that support hospitals or public entities in direct price negotiations, purchasing, or even manufacturing of drugs to meet local needs;
- Alternative and innovative reimbursement methodologies that focus on achievement of intended outcomes and quality of life;
- access to generic drugs;
- Limiting direct to consumer advertising.
- Indexing U.S. prices to international prices; and
- Expediting FDA reviews and approvals for generic drugs entering the market.

individuals and families, employers and tax-funded programs like Medicaid.

The innovation, research and development of life-saving drugs is extraordinary. Pharmaceuticals allow for extended lifespan for those who were once hopeless, prevention of life-threatening disease or disease progression and even cures for illnesses that were previously debilitating. By better addressing affordability, we can help to ensure that patients can afford access these breakthroughs in modern medicine and that employers and purchasers are able to provide comprehensive and equitable coverage to their communities.

The Department will be hosting events to invite stakeholders to actively participate in the dialogue that will help drive more effective prescription drug affordability policy and best practices to the benefit of employers, union benefit trusts, state programs like Medicaid, and all Coloradans. We invite your active engagement in these opportunities.

Colorado is a collaborative state, and it is our diversity of thought and collaboration that makes our policies stronger and more effective. We appreciate your engaged voice and perspective - it truly makes a difference.

⁹⁶ "High Prices, Broken Promises," West Health Institute and NORC at the University of Chicago, September 13, 2018 http://www.norc.org/ NewsEventsPublications/PressReleases/Pages/high-prices-broken-promises.aspx.

97 "KFF Health Tracking Poll (conducted February 14-24, 2019)," Kaiser Family Foundation, http://files.kff.org/attachment/Topline-KFF-Health-Tracking-Poll-February-2019.

• Reforming patent and exclusivity laws and regulations that prevent competition and delay

• Revisiting Food and Drug Administration regulations to increase accountability; and

These policies would help to mitigate the unsustainable cost increases that are affecting

Appendices

Appendix I. 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.⁹⁸

Senate Legislation

In the Senate, the bipartisan, S. 2543 Prescription Drug Pricing Reduction Act 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 between 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 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 the best deal possible.

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 percent 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 percent or ASP plus 6 percent 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 catastrophic portion of the benefit, which would require 20 percent 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. As well as, 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, improve provisions of Medicare parts A and B claims data to prescription drug plans, establish pharmacy quality metrics in Part D, star rating measures to encourage biosimilar uptake, and permanently authorize a successful pilot on retroactive Part D coverage for low-income beneficiaries, and create a Medicare and Medicaid prescription drug pricing dashboard.

⁹⁸ U.S. Congress, House, "Lower Drug Costs Now Act of 2019," HR 3, 116th Cong., introduced September 19, 2019, https://www.congress.gov/ bill/116th-congress/house-bill/3.

Notes:

Appendix II. Total Prescription Revenues in Billions

Figure 16. Largest 15 U.S. Pharmacies, by Total Prescription Revenues, 2018

Company	Stock Ticker	Estimated 2018 Prescription Revenues (billions)	Share of 2018 Prescription Revenues	Changes in Revenues vs. 2017	Primary Dispensing Format
CVS Health Corporation	CVS				
Retail Pharmacy		\$64.2	15.1%	+7.8%	Chain drugstore/LTC pharmacy
Pharmacy Services ¹		\$38.6	9.1%	-0.1%	Mail/Specialty pharmacy
Walgreens Boots Alliance ²	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 Corporation ⁶	RAD	\$11.1	2.6%	-29.4%	Chain drugstore
Humana Pharmacy Solutions	HUM	\$6.3	1.5%	+0.6%	Mail/Specialty pharmacy
Albertsons Companies ⁶	Private	\$5.0	1.2%	-0.3%	Supermarket with pharmacy
Diplomat Pharmacy ⁷	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	Private ⁸	\$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 booth companies

4. Includes Walmart and Sam's Club stores.

Includes retail pharmacies and Kroger Specialty Pharmacy (which Kroger reports separately in its financial reports).
 Includes estimated revenues from EvisionMail and EnvisionSpecialty, the mail and specialty pharmacies of EvisionRx. These were formerly known

are Orchard PharmaceuticalServieces.

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. SOURCE: The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefits Managers, Drug Channels Institute

