



CONTRACTOR PROJECT REPORT

International Prescription Drug Price Comparisons: Estimates Using 2022 Data

Assistant Secretary for Planning and Evaluation (ASPE)
U.S. Department of Health & Human Services

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This research was funded by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation under Contract Number HHSP233201500038I and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.

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ASPE Executive Summary

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) contracted with RAND Health Care to analyze IQVIA MIDAS data on U.S. prescription drug prices in comparison to drug prices in other Organisation for Economic Co-operation and Development (OECD) countries. Key takeaways are summarized below.

- In 2022, U.S. prices across **all drugs** (brands and generics) were nearly three times as high as prices in 33 OECD comparison countries. For every dollar paid in other countries for drugs, consumers in the U.S. pay \$2.78. The gap is widening over time as U.S. drug prices grow faster than drug prices in other countries and the mix of drugs changes.
- U.S. prices for **brand drugs** were 422 percent of prices in the comparison countries, or at least 322 percent if we adjust for estimated rebates in the U.S., but not for estimated rebates in other countries (for which data are generally unavailable).
- In contrast, U.S. prices for **unbranded generics** were lower than prices in comparison countries. For every dollar the other countries on average pay for these drugs, in the U.S., consumers pay 67 cents. Unbranded generics made up 90 percent of U.S. prescription volume, compared with 41 percent of volume in the other countries.

This study updates a prior ASPE study based on data for 2018:

Andrew W. Mulcahy, Christopher Whaley, Mahlet G. Tebeka, Daniel Schwam, Nathaniel Edenfield, and Alejandro U. Becerra-Ornelas, "International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies," July 1, 2022, <https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons>.

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Research Report

ANDREW W. MULCAHY, DANIEL SCHWAM, SUSAN L. LOVEJOY

International Prescription Drug Price Comparisons

Estimates Using 2022 Data

For more information on this publication, visit www.rand.org/t/RR788-3.

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About This Report

This report compares prices for prescription drugs in the United States with those in other high-income countries using a price index approach. The analysis uses 2022 data and updates a previous report using 2018 data: Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation, RR-2956-ASPEC, 2021b.

The current report, like the prior version, compares prices for different categories of drug products, including brand-name originator drugs, unbranded generic drugs, biologics, and nonbiologic drugs. This report adds new analyses on biosimilar price comparisons and on changes in price comparison findings over time.

This research was funded by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation under Contract No. HHSP23320095649WC-TO38, and the update was funded under Contract No. HHSP233201500038I and carried out within the Payment, Cost, and Coverage Program in RAND Health Care.

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Ornelas were coauthors on the earlier report. We thank Christine Eibner and Erin Taylor of RAND and Patricia Danzon of the University of Pennsylvania for their suggestions and comments as peer reviewers of the initial report (Mulcahy et al., 2021b), and we thank Annetta Zhou, Christine Buttorff, and Erin Taylor of RAND for their review of new material in this report.

Summary

Understanding the extent to which prescription drug prices are higher in the United States than in other countries—after accounting for differences in the volume and mix of drugs—is useful when developing and targeting policies to address both growth in drug spending and the financial impact of prescription drugs on consumers.

A prior RAND analysis compared 2018 manufacturer gross drug prices in the United States with those in 32 Organisation for Economic Co-operation and Development (OECD) countries using a price index approach.¹ The earlier analysis reported results for all drugs combined, for specific categories of drugs, and under different methodological approaches. This report updates the main results from this earlier report using more recent data through 2022.² It also includes new analyses focusing on price comparisons for biosimilars and changes in price comparison results over time.

In brief, when analyzing data for all prescription drugs available in the United States and comparison countries, we found that U.S. manufacturer gross prices for drugs in 2022 were 278 percent of prices in the 33 OECD comparison countries combined. Put another way, prices in other countries were 36 percent—or a little more than one-third—of those in the United States.

These results stem from the combination of starkly different price comparison findings for brand-name versus generic drugs: U.S. prices for brand-name originator drugs were 422 percent of prices in comparison countries, while U.S. unbranded generics, which we found account for 90 percent of U.S. prescription volume, were on average cheaper at 67 percent of prices in comparison countries, where on average only 41 percent of prescription volume is for unbranded generics. U.S. prices for brand-name drugs remained 308 percent of prices in other countries even after adjustments to account for rebates paid by drug companies to U.S. payers and their pharmacy benefit managers.

These high-level findings from the current report are consistent with results from the prior analysis using 2018 data.³ Overall, the gap between U.S. and other countries' prices widened slightly between the two analyses because of faster growth in U.S. prices, a change in U.S. drug

¹ Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation, RR-2956-ASPEC, 2021b.

² The prior analysis compared U.S. prices with those in 32 OECD countries. Colombia joined the OECD in April 2020, after the prior analysis was completed. Our main results in this updated report include Colombia. Costa Rica became an OECD member in May 2021 but is not included in this updated analysis because IQVIA's MIDAS data do not include Costa Rica as a separate market.

³ Mulcahy et al., 2021b.

mix, a change in the overlap of drugs sold in both the United States and other countries, or a combination of factors.

Study Approach

We used 2022 IQVIA MIDAS data to calculate price indexes comparing prescription drug prices in the United States with those in 33 OECD comparison countries.⁴ For our main results, we used presentation-level data (that is, data with separate records for each combination of active ingredient, formulation, and dosage strength) for all prescription drugs in the IQVIA MIDAS dataset.⁵ We then compared prices between the United States and individual OECD comparison countries bilaterally, using as many presentations overlapping between the United States and the other markets.⁶ Separately, we compared U.S. prices with those in all other countries in our data aggregated together as a summary measure. We used U.S. volume weights (that is, the share of total volume accounted for by each presentation) to calculate price indexes because of our interest in price differences from a U.S. policy perspective.

IQVIA MIDAS sales and volume estimates are projected from IQVIA's audits of standardized list prices and manufacturer, wholesaler, and other invoices; they do not reflect net prices realized by the manufacturers. These data are designed to support country-level trend and pattern analyses, but they remain estimates. The MIDAS data used in this analysis were obtained under license from IQVIA. Our MIDAS extract was prepared on May 19, 2023. The main body of the report presents results in bar charts comparing U.S. prices with those in G7 (to focus the comparison on larger OECD economies), excluding the United States—plus Mexico due to its geographic proximity to the United States and its close economic connections with the United States under the United States–Mexico–Canada Agreement) (results for other countries are available in Appendix B). We separately report a comparison of U.S. prices with prices in the 33 comparison countries combined. Price indexes greater than 100 indicate that U.S. prices are higher than those in the comparison country; indexes less than 100 indicate that U.S. prices are lower than those in the comparison country.

⁴ MIDAS is a registered trademark of IQVIA. This report does not reproduce any IQVIA MIDAS data directly.

⁵ To avoid outlier presentations from exerting undue influence on our overall results, we excluded a small number of observations with (1) very low volume or sales or a given country and presentation, or (2) extreme ratios of U.S. prices to other-country prices.

⁶ The share of volume and sales contributing to each analysis varied widely but was generally considerably less than 100 percent. For example, for the United States–Canada comparison, 72 and 63 percent of Canadian and U.S. volume and 84 and 71 percent of Canadian and U.S. sales, respectively, contributed to our analysis. Among the Group of Seven (G7) countries, Japan had the smallest overlap with the United States, with only 17 and 30 percent of Japanese and U.S. volume and 48 and 46 percent of Japanese and U.S. sales, respectively, contributing to our analyses. The overlap in drugs sold in the United States and Japan was much higher at the active ingredient level (rather than the presentation level) at nearly 60 percent of volume and 80 percent of sales. This finding motivated robustness checks (as described in the main body of the report) wherein we calculated prices at the active ingredient rather than the presentation level.

Gross Price Comparison Results

In 2022, U.S. prices across all drugs were 278 percent of prices in the 33 OECD comparison countries.⁷ Prices in the United States were higher than those in each individual comparison country (see Figure S.1 for comparisons of U.S. prices with those in the G7 countries and Mexico). For example, U.S. prices were 229 percent of prices in Canada (or, alternatively, Canadian prices were 44 percent of U.S. prices). Across all 33 comparison countries, U.S. prices ranged from 172 percent of prices in Mexico to 1,028 percent of prices in Turkey (see Appendix B for comparisons with individual countries).

The gap between U.S. prices and prices in other countries was larger for brand-name originator drugs. U.S. prices were 422 percent of prices of non-U.S. countries for these drugs. However, prices for unbranded generic drugs were generally lower in the United States than in other countries. U.S. prices were 67 percent of prices of non-U.S. countries for unbranded generics. We found that U.S. prices were higher than most comparison countries when combining data for all non-originator drugs, including unbranded generics and brand-name non-originator drugs.⁸

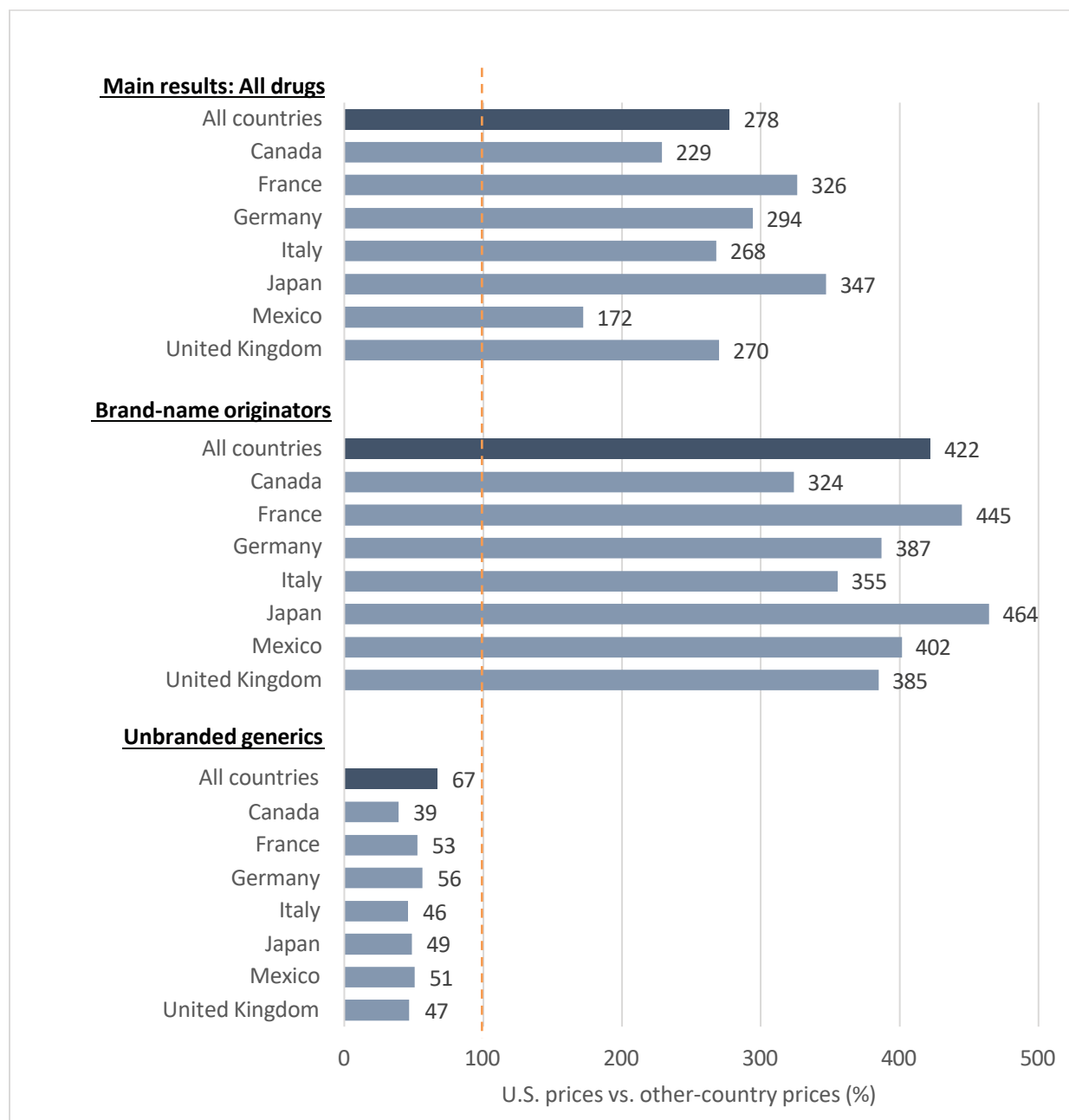
France and Japan generally have the lowest prices among the comparison countries for all drugs and for brand-name originator, biologics, and nonbiologic drugs separately. Canada, Germany, and the United Kingdom tend to have higher prices across each subset of drugs.

Our main findings—that U.S. gross prices are higher than those in comparison countries for all drugs and for brand-name originator drugs but lower for unbranded generic drugs—held through several additional sensitivity analyses related to how price indexes were calculated.

⁷ The number of drug presentations included in each bilateral analysis varied given the overlap between U.S. and comparison country data. The analysis comparing U.S. prices with prices in all comparison countries combined used data from 4,690 presentations and 1,646 active ingredients.

⁸ Prices in the United States were exactly 100 percent of prices in all other countries combined when unbranded generics and brand-name non-originator drugs were combined. While drugs labeled in IQVIA MIDAS as “unbranded non-originator” drugs are primarily unbranded generics, drugs designated as brand-name non-originators are more diverse and include (1) multisource branded generics (generic drugs marketed under a brand name, which is common in some countries outside the United States but very rare in the United States) and (2) brand-name drugs approved in the United States via the 505(b)(2) regulatory approval pathway (such as EpiPen). Drugs in the second category are often non-originator drugs, but they might be priced and marketed as brand-name originator drugs.

Figure S.1. U.S. Manufacturer Gross Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, "MIDAS," webpage, undated (run date May 19, 2023).

NOTE: *All countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Biologics were excluded from unbranded generics. Only some presentations sold in each country contribute to bilateral comparisons. *Brand-name originators* and *Unbranded generics* reflect IQVIA's assignment of drug products in individual countries.

Addressing U.S. Gross-to-Net Discounts

One important limitation of our analysis is that we use manufacturer prices for the purposes of comparison, because net prices (that is, the prices realized by manufacturers after negotiated and other discounts are applied) are not released by the pharmaceutical companies. The magnitude of the difference between manufacturer gross and net prices is difficult to quantify across all drugs. Net prices reflect confidential rebates negotiated between manufacturers and plan sponsors (often through their pharmacy benefit managers) that vary depending on market conditions and negotiating leverage. Net prices also reflect Medicaid best price and rebate program provisions, discounts from the 340B prescription drug discount program that may or may not be applied as drugs are sold by manufacturers, and discounts from other sources. In cases in which net prices can be reliably estimated, the magnitude of gross-to-net reductions varies substantially across therapeutic classes.⁹

To assess how our results might change if net price information were available, we conducted a final set of sensitivity analyses in which we adjusted U.S. prices downward based on published estimates of the relative differences between manufacturer gross and net prices. The resulting U.S. prices remained substantially higher than prices in other countries—but with a smaller difference than in our main results. When adjusting prices for U.S. brand-name drugs dispensed through the retail channel downward by 37.2 percent,¹⁰ U.S. prices for brand-name drugs were 308 percent of prices in other countries (versus 422 percent in our main results).

Because of a lack of available estimates, we did not adjust prices in other countries downward to reflect increasingly common discounts on manufacturer prices.¹¹ U.S. prices would appear relatively higher—that is, more in line with our main results—if we were able to also adjust for rebates and other discounts applied to manufacturer prices in other countries.

Building on prior findings, this update provides further evidence that gross manufacturer drug prices are higher in the United States than in comparison countries. Although we apply a single, market-wide adjustment to approximate rebates and other discounts applied to U.S. brand-name prices, we recognize gross-to-net margins vary substantially across drugs and therapeutic classes and that our estimates of U.S. net prices therefore incorporate substantial measurement error. We also recognize that resulting price indexes will understate differences between prices in the United States and other countries because they adjust only U.S. prices

⁹ Andrew W. Mulcahy, Daniel Schwam, Preethi Rao, Stephanie Rennane, and Kanaka Shetty, “Estimated Savings from International Reference Pricing for Prescription Drugs,” *JAMA*, Vol. 326, No. 17, 2021a.

¹⁰ We calculated the 37.2 percent as one minus the 2022 ratio of net to invoice prices measured across protected brand drugs from IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*, May 2, 2023b.

¹¹ Ulf Persson and Bengt Jönsson, “The End of the International Reference Pricing System?” *Applied Health Economics and Health Policy*, Vol. 14, No. 1, 2016.

downward even though rebates and similar discounts are increasingly common in other countries.

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Chapter 1. Introduction and Background

U.S. health plans and patients paid an estimated \$603 billion for prescription drugs in 2022.¹² Even after adjusting for general inflation, U.S. retail prescription drug spending increased by 91 percent from 2000 to 2020,¹³ and spending is expected to further increase by 5 percent year-on-year through 2030.¹⁴ These spending levels and trends reflect net spending on drugs—that is, spending after adjusting for rebates and other discounts paid to health plans and their pharmacy benefit managers (PBMs). Without considering these important reductions, gross spending by health plans and patients is growing even more rapidly, driven in part by increasing list prices for drugs.¹⁵

Previous research demonstrates that spending on prescription drugs is higher in the United States than in other countries on a per capita basis but accounts for a similar share of total health care spending.¹⁶ Utilization rates, the mix of dispensed drugs, and prices all contribute to higher U.S. spending on drugs.¹⁷ The relationships among utilization rates, mix, and price are complex. However, when holding utilization rates and the mix of drugs constant, higher prices translate directly to higher spending on drugs—which, in turn, contributes to higher health insurance premiums and higher out-of-pocket spending by patients on health care more broadly.

The robust policy discussion surrounding U.S. prescription drug prices focuses on whether prices in the United States are too high or appropriate relative to the benefits that they offer to patients. Broad, systematic comparisons of U.S. drug prices to those in other high-income countries are useful for informing this discussion. International drug price comparisons also have the potential to serve as a more direct input in future U.S. drug price policy. For example, recent but now abandoned policy proposals and initiatives include international reference pricing for certain Medicare Part B drugs and using international prices for drugs as a ceiling for negotiated

¹² IQVIA Institute for Human Data Science, *The Use of Medicines in the U.S. 2023: Usage and Spending Trends and Outlook to 2027*, May 2, 2023b.

¹³ U.S. Centers for Medicare & Medicaid Services (CMS), “National Health Expenditure Data,” webpage, undated-b.

¹⁴ John A. Poisal, Andrea M. Sisko, Gigi A. Cuckler, Sheila D. Smith, Sean P. Keehan, Jacqueline A. Fiore, Andrew J. Madison, and Kathryn E. Rennie, “National Health Expenditure Projections, 2021–30: Growth to Moderate as COVID-19 Impacts Wane,” *Health Affairs*, Vol. 41, No. 4, 2022.

¹⁵ Bosworth, Arielle, Steven Sheingold, Kenneth Finegold, Nancy De Lew, and Benjamin D. Sommers, “Price Increases for Prescription Drugs, 2016–2022,” Office of the Assistant Secretary for Planning and Evaluation, 2022.

¹⁶ Dana O. Sarnak, David Squires, and Shawn Bishop, “Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?” Commonwealth Fund, October 5, 2017.

¹⁷ Comparisons of prescription drug spending involve volume and mix in addition to price. Some studies attempt to decompose differences in spending along these dimensions. See, for example, Sarnak, Squires, and Bishop, 2017.

U.S. prices.¹⁸ Other current and future policy proposals may rely on prices in other countries as a benchmark for determining fair U.S. drug prices.¹⁹

Report Updates

A prior RAND Corporation report systematically compared U.S. with other countries' drug prices using 2018 data.²⁰ Like the earlier report, this update presents descriptive comparisons of drug prices between the United States and other high-income Organisation for Economic Co-operation and Development (OECD) countries using price indexes as a basis for comparison. Our updated analyses use data from 2022. Although the main analyses in the report focus on gross prices received by manufacturers, we estimate price comparisons with adjustments to reflect important gross-to-net discounts for brand-name drugs in the United States.

In addition to results from a similar array of subgroup analyses and robustness checks that were included in the earlier report, this update presents the following findings from new analyses, including price comparisons for subsets of drugs with the potential to lower drug prices and spending in the United States: biosimilars and their reference biologics (which are previously approved biologics that biosimilar applicants reference to support their biosimilar application). This update also introduces an analysis of trends in price comparison results from 2017 to 2022.

Measuring Prescription Drug Prices

There are many measurable prices in prescription drug markets, with some easier than others to measure and analyze across all drug products. Figure 1.1 is a stylized comparison of the relationships between the magnitudes of key prescription drug prices for retail-dispensed, brand-name drugs. The relevant prices are in two broad categories: manufacturer prices and prices paid by health plans and their PBMs.

The largest of the three key manufacturer prices is a manufacturer-determined catalog or *list* price called wholesale acquisition cost (WAC). Despite its name, WAC is not the actual transactional price between drug companies and purchasers of drugs, such as distributors and large health care delivery systems. The actual transactional price is the *gross* or *invoice* price reflecting the amount paid, including on-invoice discounts, to the manufacturer by distributors or other buyers.

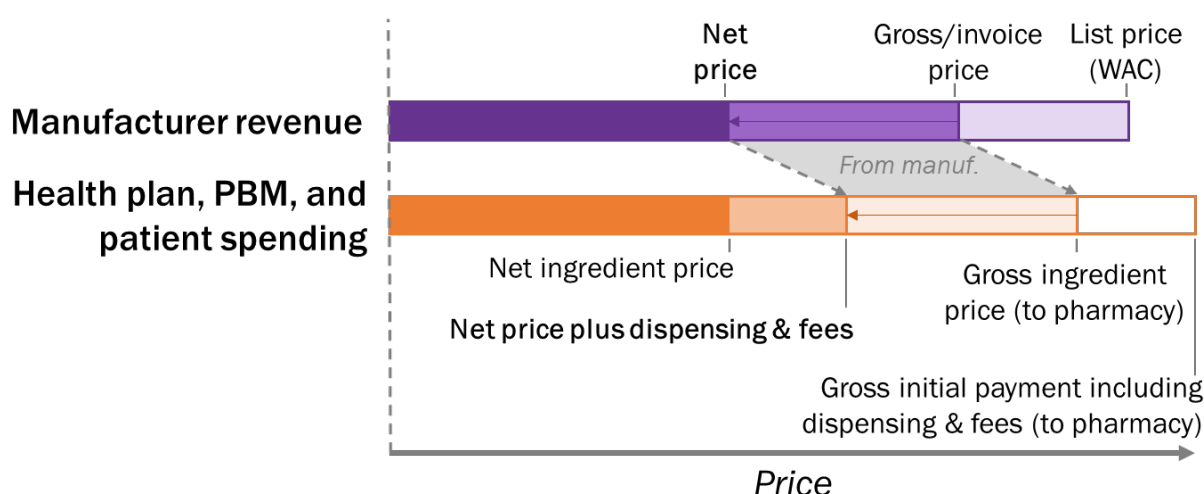
¹⁸ CMS, "Most Favored Nation Model," webpage, undated-a; H.R. 3, Elijah E. Cummings Lower Drug Costs Now Act, April 22, 2021.

¹⁹ One current proposal would cap U.S. prices at the median price across five high-income OECD countries. See S. 909, Prescription Drug Price Relief Act of 2021, March 23, 2021.

²⁰ Andrew W. Mulcahy, Christopher M. Whaley, Mahlet Gizaw, Daniel Schwam, Nathaniel Edenfield, and Alejandro Uriel Becerra-Ornelas, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*, RAND Corporation, RR-2956-ASPEC, 2021b.

Manufacturer *net* prices reflect the set of complex business arrangements that have evolved over time among plan sponsors, PBMs, and drug companies. U.S. health insurers often work with a PBM to develop prescription drug formularies and benefit designs and to negotiate rebates with drug manufacturers. PBMs negotiate lower prices from manufacturers by offering larger shares of volume—driven by such tools as tiered formularies and exclusive contracts—with preferred drugs tied to lower cost-sharing for patients and fewer authorization steps for prescribing. PBMs realize these lower negotiated prices by collecting rebates from drug manufacturers. Manufacturers’ net prices account for these off-invoice rebates paid after the fact.

Figure 1.1. General Drug Price Relationships for Brand-Name Drugs and Commercial PBMs or Payers



Among prices paid by health plans, patients, and their PBMs, the initial outlay to pharmacies—reflecting the price of the drug product with markups through the supply chain, dispensing fees, and potentially other amounts—is the largest. These prices appear in prescription drug claims data and are often used in analyses of drug spending.

The net price ultimately paid by the health plans and PBMs differs from the initial gross payment to pharmacies on several dimensions. First, the net price reflects rebates paid by manufacturers. These rebates determine the net manufacturer price described above and the amount paid by the health plan or PBM for the drug product itself. However, the final net price paid by health plans and PBMs is greater than the manufacturer’s net revenue because of dispensing fees and other amounts paid by the health plan or PBM. Both of these net prices paid by health plans or PBMs are generally not known by policymakers and researchers because rebates from manufacturers are considered trade secrets.

Furthermore, the relationships between net prices to health plans and to PBMs are difficult to disentangle. Although PBMs are able to negotiate lower prices, the extent to which they pass the lower prices on to health plans is not well understood. All or a portion of the rebates might be

passed on to consumers through lower premiums—a process that is also opaque. Even if negotiated rebates are completely passed on to health plans, fee-based amounts paid to PBMs must also be considered. If a large portion of the rebates and other discounts is passed on to payers, then PBMs could offer value by reducing prescription drug spending, even if they retain a share of the discounts. One 2017 study suggests that PBMs retain 7 percent of U.S. spending on prescription drugs from the plan sponsor and patient perspective.²¹

Net prices—both to manufacturers and to health plans and PBMs—are likely the most relevant prices to ongoing policy discussions in the United States. Estimates of the magnitude of gross-to-net discounts hinge on two factors: (1) whether the focus is on the net price to manufacturers, PBMs, or health plans (2) and how exactly the discount is measured. One 2018 study estimated rebates of 23 percent from the plan sponsor perspective.²² Another recent study suggests that U.S. manufacturer net prices—including rebates and other discounts—are 37 percent below invoice prices and 52 percent below WAC.²³ However, the same study finds net prices to payers are 41 percent higher than manufacturer net prices, reflecting markups and margins throughout the supply chain, including the margin retained by PBMs.²⁴

In other countries, the functions performed by PBMs in the United States are typically performed by government or quasi-governmental entities, often in conjunction with direct and indirect price controls on drugs. Discounts that would not be reflected in manufacturer sales and prices are increasingly important in other countries.²⁵ For example, German sickness funds (similar to U.S. insurers) receive statutory rebates that are not reflected in manufacturer sales. In the United Kingdom, off-invoice discounts paid to the National Health Service and formulary-based rebates are not reflected in manufacturer sales.

Although drug prices after rebates and all discounts are particularly relevant to U.S. policymakers and payers, data on prices measured in this way have historically not been available to researchers. Researchers increasingly use estimates of net prices from third-party vendors and from U.S. Securities and Exchange Commission filings from publicly traded drug companies to approximate U.S. manufacturer net prices.

Our analysis uses IQVIA MIDAS licensed data, which offer data on volume and spending at manufacturer list or invoice prices (depending on the country) for nearly all OECD countries and

²¹ Neeraj Sood, Tiffany Shih, Karen Van Nuys, and Dana Goldman, “Flow of Money Through the Pharmaceutical Distribution System,” Leonard D. Schaeffer Center for Health Policy & Economics, June 6, 2017.

²² Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, Altarum Institute, April 2018.

²³ IQVIA Institute for Human Data Science, *The Global Use of Medicines 2023: Outlook to 2027*, January 18, 2023a, p. 65.

²⁴ The IQVIA report estimates 2022 net manufacturer revenue of \$429 billion versus 2022 payer net payments of \$603 billion, or 41 percent higher. IQVIA Institute for Human Data Science, 2023a, pp. 27, 29.

²⁵ Ulf Persson and Bengt Jönsson, “The End of the International Reference Pricing System?” *Applied Health Economics and Health Policy*, Vol. 14, No. 1, 2016.

drugs.²⁶ For single-source brand-name drugs, these prices are likely between manufacturer net prices and WAC. In Chapter 2, we present results from some price comparisons, applying aggregate U.S. gross-to-net adjustment factors to approximate how U.S. net prices would compare with those in other countries. However, the resulting price comparisons understate differences between prices in the United States and other countries because they adjust only U.S. prices downward, even though rebates and similar discounts are increasingly common in other countries. We return to these gross-versus-net-price issues as a limitation of our price index approach in Chapter 4.

The Motivation for Price Indexes

Calculating the average price for drugs in one country by dividing total drug sales and volume yields a result that reflects both prices and the mix of drugs used. Prescription drug utilization can vary from country to country on many dimensions, such as the following:

- mix of *active ingredients* (specific molecules or combinations of molecules)
- mix of *presentations* (prices and quantities calculated narrowly for each combination of an active ingredient, formulation, and strength)
- mix of manufacturers for each active ingredient and presentation
- mix of brand-name originator, brand-name non-originator, unbranded generic, and over-the-counter drugs
- mix of drugs that reach patients through retail outlets, health care facilities, and other channels.

Without addressing differences in mix, a comparison of average prices in two countries may say as much about differences in the mix (or *market basket*) of drugs in those countries as it does about prices directly. For example, if the mix of drugs in the United States contains a greater number of expensive brand-name originator drugs than the mix in a comparison country, the resulting difference in average price could be the result of this difference in mix; a difference in price; or, most likely, both.

Price indexes are a tool used to compare differences in prices over time or across markets (such as countries). The rationale behind price indexes is that a comparison of prices is most meaningful when it focuses on prices alone without the risk of interference from differences in the mix of products. Price indexes accomplish this by holding a market basket of goods constant while allowing prices to vary across markets. The best-known price index—the Consumer Price Index (CPI)—is calculated by the U.S. Department of Labor’s Bureau of Labor Statistics and compares prices for a broad market basket of consumer goods over time. The approach that serves as the foundation for the CPI can be used to compare prices for market baskets of prescription drugs between countries.

²⁶ IQVIA MIDAS includes (subtracts) customary discounts that appear on invoices, so these prices will be below manufacturer gross, which we do not know directly.

The prior RAND report described the many methodological decisions needed to calculate and compare price indexes for prescription drugs—for example, whether to use a U.S., other-country, or blended market basket (or *volume weights*); the breadth of products included; and whether to adjust prices to account for differences in purchasing power parity.²⁷

Prior Research

In Mulcahy et al., 2021b, the authors found that 2018 U.S. prices across all drugs were 256 percent of prices in other OECD countries. U.S. prices for brand-name originator drugs were relatively higher at 344 percent of prices in other countries, while prices for unbranded generics were generally cheaper in the United States versus other countries. Findings from a broad set of subgroup analyses and robustness checks yielded results similar to those presented in this report. In general, as we discuss in Chapter 4, the gap between U.S. and other countries' prices is slightly larger in the results presented here compared with those in Mulcahy et al., 2021b.

Several prior studies used similar data and price index approaches to systematically compare U.S. and other countries' drug prices.²⁸ These studies consistently found higher U.S. prices for drugs, especially for brand-name drugs.²⁹ However, each of these studies used data that are now over a decade old.

A small number of more-recent studies directly compares U.S. to other countries' drug prices—for example, Mattingly et al., 2021, and Kang et al., 2021.³⁰ These studies cover a relatively small number of drugs (20 brand and 20 generic drugs in Mattingly et al., 2021, and 79 top drugs by spending in Kang et al., 2021) and use prices from a relatively small set of countries (ten OECD countries in Mattingly et al., 2021, and Canada, Japan, and the United Kingdom in

²⁷ Mulcahy et al., 2021b.

²⁸ The studies described in this section are each broad, systematic comparisons of U.S. to other-country drug prices. Other studies present price comparisons for much smaller sets of drugs (e.g., the top seven drugs by sales in the United States) and sometimes for individual drugs. Comparing prices for specific drugs or narrow sets of drugs might not yield results that are representative of broader price differences because each specific drug represents a small share of total utilization and spending. See Mulcahy et al., 2021b, for more information on these narrower studies.

²⁹ See Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Biopharmaceuticals: An International Comparison," *Health Affairs*, Vol. 25, No. 5, 2006; Patricia M. Danzon and Michael F. Furukawa, "International Prices and Availability of Pharmaceuticals in 2005," *Health Affairs*, Vol. 27, No. 1, 2008; Panos Kanavos and Sotiris Vondoros, "Determinants of Branded Prescription Medicine Prices in OECD Countries," *Health Economics, Policy and Law*, Vol. 6, No. 3, 2011; and Panos Kanavos, Alessandra Ferrario, Sotiris Vondoros, and Gerard F. Anderson, "Higher US Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs," *Health Affairs*, Vol. 32, No. 4, 2013. See also Mulcahy et al., 2021b, for a detailed comparison of the methods and results from these studies.

³⁰ T. Joseph Mattingly II, Dominique Seo, Adam M. Ostrovsky, David J. Vanness, and Rena M. Conti, "60 Years After Kefauver: Household Income Required to Buy Prescription Drugs in the United States and Abroad," *Research in Social Administrative Pharmacy*, Vol. 17, No. 8, 2021; So-Yeon Kang, Michael J. DiStefano, Mariana P. Socal, and Gerard F. Anderson, "Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries," *Health Affairs*, Vol. 38, No. 5, 2019.

Kang et al., 2021). These studies both find that U.S. prices are higher than those in other countries. One recent study compared U.S. to other-country prices for top brand-name drugs by spending at net prices after adjusting for rebates and other discounts offered by manufacturers in the United States.³¹ This study found that U.S. net prices remained roughly twice as high as manufacturer prices in other countries overall and across therapeutic classes.

Report Overview

Chapter 2 describes the methodological decisions and steps underlying our main analysis, separate analyses for several subsets of drugs, and robustness checks in which we varied methodological decisions. We present the findings from our analysis in Chapter 3. Chapter 4 concludes with a discussion on the usefulness, limitations, and future directions for price index–based systematic international comparisons of drug prices.

³¹ Mulcahy et al., 2021a.

Chapter 2. Price Index–Based Drug Price Comparisons Using 2022 Data

In this chapter, we describe the data and methods for our comparisons of drug prices between the United States and OECD countries, present results from our main approach, and compare results with those from various sensitivity analyses using different sets of drugs or approaches.

Data

We used 2022 IQVIA MIDAS data for the United States and the following 33 countries:³²

Australia	Estonia	Italy	New Zealand	Spain
Austria	Finland	Japan	Norway	Sweden
Belgium	France	Latvia	Poland	Switzerland
Canada	Germany	Lithuania	Portugal	Turkey
Chile	Greece	Luxembourg	Slovakia	United Kingdom
Colombia	Hungary	Mexico	Slovenia	
Czechia	Ireland	Netherlands	South Korea	

Our IQVIA MIDAS data extract listed sales for specific drugs in terms of quarterly 2022 *manufacturer amounts paid* in U.S. dollars, converted at quarterly exchange rates, and quarterly volume measured in *standard units*.³³ Each row in the IQVIA MIDAS extract is defined by a combination of country; manufacturer; sector (retail or hospital); active ingredient;³⁴ formulation

³² Sales and volume data for calendar year 2022 (run date May 19, 2023) from IQVIA, “MIDAS,” webpage, undated. Data were not available for three OECD countries: Denmark, Iceland, and Israel. Colombia joined the OECD in April 2020 and was not included in the prior analysis (Mulcahy et al., 2021b). Costa Rica became an OECD member in May 2021 but was not included in this updated analysis because IQVIA’s MIDAS data does not include Costa Rica as a separate market. While we refer to *Czechia* in this report rather than the *Czech Republic* as in the previous report; this change affects table labeling only.

³³ *Manufacturer amounts paid* refers to the sale price paid to manufacturers by wholesalers or distributors as reflected on invoices. These prices might reflect bulk and other discounts paid at this point in the distribution chain. These prices do not include retail markups or rebates paid from manufacturers to insurers. Note that IQVIA MIDAS data do include other prices, including estimated retail prices, although our extract did not include these prices. Instead, IQVIA provided a set of adjustment factors that can be applied to manufacturer prices as a way to convert them to retail prices. A *standard unit* is a tablet or capsule for oral solid drug formulations; 5 mL for oral liquid formulations; and a count of vials, syringes, autoinjectors, other counting unit for injected and infused formulations, and other prespecified counting units for each other formulation.

³⁴ The active ingredient of a drug is the molecule that has a biologic impact or effect. Most drugs have a single active ingredient (such as simvastatin). Some drugs have multiple active ingredients (such as ezetimibe and simvastatin). We defined the active ingredient for combination drugs with multiple active ingredients as the full list of active ingredients.

and route of administration; strength; over-the-counter indicators; and indicators for whether the drug was a brand-name originator drug, a brand-name non-originator drug, or an unbranded generic drug. Each record at this level lists volume and sales for the four quarters of 2022 in the data used for our main results; analyses looking at trends over time use quarterly data from 2017 to 2022.

IQVIA MIDAS sales and volume estimates are projected from IQVIA's audits of standardized list prices and manufacturer, wholesaler, and other invoices; they do not reflect net prices realized by the manufacturers. These data are designed to support country-level trend and pattern analyses, but they remain estimates. The MIDAS data used in this analysis were obtained under license from IQVIA. Our MIDAS extract was prepared on May 19, 2023.

We excluded data for specific products flagged in the IQVIA MIDAS data as "over-the-counter" in a given country.³⁵ Over-the-counter drugs were out of scope for our analyses and have markedly different prices across countries. We also excluded records that did not have positive volume or sales. We aggregated the remaining records that shared the same country and presentation (that is, the same active ingredient, formulation and route of administration, and dosage strength) into a single country-presentation-level record by summing sales and volume.³⁶ We aggregated by presentation rather than by active ingredient to address concerns that differences in the mix of presentations relating to active ingredients could be driving differences in price. We calculated U.S. and other countries' unit prices by dividing presentation-level sales by presentation-level volume.

As in the prior RAND report, we excluded 32 country-presentation records with incorrect sales and/or volume data.³⁷ We also excluded 49 blood factor active ingredients from our analysis because of inconsistencies across country and channel markets in how volume was measured for these drugs in IQVIA MIDAS.³⁸

Overview of Drug Markets Using IQVIA MIDAS Data

Table 2.1 compares 2022 prescription drug market size for all OECD countries with data available for analysis in an extract from the IQVIA MIDAS dataset (run date May 19, 2023). We

³⁵ For drugs sold over the counter in one country and by prescription in another, or sold both over the counter and by prescription in the same country, we excluded all over-the-counter products and included data from prescription products.

³⁶ As an example, one of the resulting rows of data from this step is U.S. sales and volume in 2018 for atorvastatin 10 mg film-coated tablets. There was a separate row for this same presentation in each country and separate rows for different presentations (such as 20 mg film-coated tablets) in each country.

³⁷ We excluded pertuzumab presentations in Italy, acridinium bromide presentations in Canada, ranibizumab presentations in Germany, and gadobenic acid presentations in Hungary. These specific drugs were confirmed by IQVIA to have volume measured inconsistently across countries. Although the underlying issues may have been resolved at the time of our analysis, we excluded these records out of an abundance of caution.

³⁸ Blood factors accounted for 0.1 percent of volume and 0.6 percent of sales across all countries.

calculated total sales of \$988.9 billion and total volume of 1,099.1 billion standard units across OECD countries in our data. The United States accounted for 62.4 percent of sales but only 23.8 percent of volume. The ratio of sales-to-volume weight is much higher in the United States than in any other country; without addressing issues around the mix of drugs, this is an initial sign that U.S. prices are much higher than those in other countries. Japan, by comparison, accounted for 6.6 percent of sales and 20.0 percent of volume.³⁹

There are also important differences in the mix of drugs among countries, such as the relative contributions of brand and generic drugs to sales and volume totals. Table 2.2 presents the share of drug sales and volume from brand-name originator drugs, brand-name non-originator drugs, and unbranded drugs for each country. Brand-name originator drugs are those marketed by the original developer of the drug (that is, the originator manufacturer). Brand-name non-originator drugs are uncommon in the United States and are typically competing “branded generic” versions of off-patent drugs marketed under brand names.⁴⁰ Most generic drugs in the United States are unbranded generics. Unbranded generics accounted for greater shares of U.S. volume in 2022 than in the earlier analysis using 2018 data (90 percent in 2022 versus 84 percent in 2018).⁴¹

³⁹ The OECD countries in the analysis include eight of the ten countries globally with the most spending on prescription drugs in 2018 (the exceptions are China and Brazil). IQVIA Institute for Human Data Science, *The Global Use of Medicine in 2019 and Outlook to 2023*, January 29, 2019.

⁴⁰ IQVIA categorizes some brand-name drugs approved in the United States via the 505(b)(2) regulatory approval pathway, such as EpiPen, as brand-name non-originators. Biosimilars are categorized in IQVIA MIDAS as brand-name originator, brand-name non-originator, or unbranded depending on the product and country. Authorized generics, which are usually generic drugs manufactured and marketed under a license from the originator company, are usually listed in the unbranded generic category rather than the brand-name non-originator category.

⁴¹ Mulcahy et al., 2021b.

Table 2.1. Prescription Drug Market Shares by Sales and Volume, 2022

Country	Sales (billions, U.S. \$)	Volume (billions, standard units)	Share of Sales (%)	Share of Volume (%)
All countries	988.9	1,099.1	100.0	100.0
United States	617.2	261.6	62.4	23.8
All countries excluding the United States	371.7	837.6	37.6	76.2
Japan	64.9	219.8	6.6	20.0
Germany	46.5	63.9	4.7	5.8
France	37.5	51.1	3.8	4.6
Italy	33.0	44.3	3.3	4.0
United Kingdom	31.6	66.8	3.2	6.1
Spain	27.4	48.6	2.8	4.4
Canada	26.6	30.6	2.7	2.8
Korea	15.3	54.9	1.5	5.0
Australia	10.9	15.6	1.1	1.4
Belgium	7.3	8.8	0.7	0.8
Mexico	7.3	16.3	0.7	1.5
Poland	7.2	29.7	0.7	2.7
Turkey	6.7	73.0	0.7	6.6
Switzerland	6.5	5.8	0.7	0.5
Austria	5.7	6.5	0.6	0.6
Sweden	4.7	9.1	0.5	0.8
Portugal	4.3	11.1	0.4	1.0
Czechia	3.7	8.9	0.4	0.8
Netherlands	3.6	13.5	0.4	1.2
Norway	3.2	4.7	0.3	0.4
Greece	3.0	10.3	0.3	0.9
Finland	2.7	5.4	0.3	0.5
Ireland	2.6	4.5	0.3	0.4
Hungary	2.4	7.8	0.2	0.7
Slovakia	1.5	4.4	0.2	0.4
Chile	1.4	5.4	0.1	0.5
New Zealand	1.2	5.0	0.1	0.5
Colombia	0.9	6.1	0.1	0.6
Slovenia	0.8	1.6	0.1	0.1
Lithuania	0.7	1.8	0.1	0.2
Latvia	0.3	1.1	0.0	0.1
Estonia	0.3	0.8	0.0	0.1
Luxembourg	0.2	0.4	0.0	0.0

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: The numbers in each column might not sum to totals because of rounding.

Table 2.2. Within-Country Shares of Brand-Name Originator, Brand-Name Non-Originator, and Unbranded Generic Drugs, by Percentage

Country	Share of Sales: Brand-Name Originator	Share of Sales: Brand-Name Non-Originator	Share of Sales: Unbranded Generic	Share of Volume: Brand-Name Originator	Share of Volume: Brand-Name Non-Originator	Share of Volume: Unbranded Generic
All countries	82	8	10	23	24	53
United States	87	5	8	7	2	90
All countries excluding the United States	74	13	13	29	31	41
Australia	83	8	8	34	31	35
Austria	78	11	12	43	29	28
Belgium	84	7	9	48	15	38
Canada	77	5	19	19	11	69
Chile	31	60	9	10	41	49
Colombia	20	49	31	7	42	51
Czechia	73	19	8	31	50	18
Estonia	74	17	9	42	35	23
Finland	76	14	10	31	37	33
France	76	8	16	27	18	55
Germany	77	9	14	19	16	65
Greece	68	28	4	49	46	6
Hungary	74	17	9	38	43	20
Ireland	81	9	10	40	32	28
Italy	78	11	11	44	29	27
Japan	75	10	15	29	20	51
Korea	52	43	5	26	67	7
Latvia	65	25	11	28	42	29
Lithuania	75	17	8	40	35	25
Luxembourg	89	7	3	66	21	13
Mexico	41	50	9	15	43	42
Netherlands	61	10	29	17	11	72
New Zealand	77	15	8	23	52	26
Norway	74	12	15	37	22	41
Poland	62	32	5	24	67	9
Portugal	72	14	14	35	26	39
Slovakia	68	24	8	28	54	18
Slovenia	80	16	4	45	51	4
Spain	79	8	13	40	18	42
Sweden	76	12	12	21	27	52
Switzerland	77	8	15	39	29	33
Turkey	49	50	1	30	69	1
United Kingdom	75	8	17	22	14	64

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: The numbers in each row might not sum to totals because of rounding.

In the United States, brand-name originator drugs account for 87 percent of sales but only 7 percent of volume. Brand-name originator drugs account for a larger share of volume in

countries other than the United States (29 percent) but a smaller share of sales (74 percent). The United States has the highest share of volume for unbranded generic drugs (90 percent), and these drugs account for 8 percent of sales compared with 41 percent of volume and 13 percent of sales in the OECD comparison countries. Brand-name non-originator drugs account for larger shares of both volume (31 percent) and sales (13 percent) in the other OECD countries than in the United States, where they are only 2 percent of volume and 5 percent of sales.

Main Price Index Method

Because of our interest in price differences from a U.S. policy perspective, we used U.S. volume weights (that is, the share of total U.S. volume accounted for by each presentation) to calculate price indexes. For each bilateral comparison, we calculated a U.S. volume-weighted price equal to the sum of the products of the U.S. volume weights and U.S. prices. Similarly, we calculated an other-country volume-weighted price equal to the sum of the products of the U.S. volume weights and other countries' prices.

We used all available IQVIA MIDAS data after applying the exclusions described above (for example, for blood products) and after further excluding country presentation records with fewer than 1,000 standard units in volume or less than \$1,000 in sales in both the United States and the individual comparison country.⁴² See Appendix A for more information on these exclusions.

Our reported price indexes are the ratio of the U.S. volume-weighted price to the other countries' volume-weighted price scaled by 100. We did not adjust price indexes by per capita gross domestic product or purchasing power parity or for other differences across markets. To compare U.S. prices with those in other countries broadly, we calculated a separate "all non-U.S. countries" price index using prices calculated by aggregating sales and volume across all non-U.S. countries in our data. The price indexes were calculated as described earlier.

Additional Analyses

Subgroup and Sensitivity Analyses

Replicating our main approach using subgroups of presentations by type, we conducted the following additional analyses:

- We compared prices separately for all brand-name originator drugs and for unbranded generic drugs.⁴³ The latter analysis focuses on drugs typically thought of as generic drugs in the United States. Prior studies found that the United States had relatively low prices

⁴² We excluded presentations with fewer than 1,000 standard units in volume or less than \$1,000 in sales because these records tended to have outlier prices.

⁴³ We excluded a small number of presentations categorized as "unbranded biologics" in MIDAS when we calculated unbranded generic price indices. These presentations tended to be older biologics and not biosimilars (which are usually marketed under a brand name).

for generics and relatively high prices for brand-name originator drugs.⁴⁴ We also compared prices for brand-name non-originator and unbranded generic drugs combined (that is, combining unbranded generics and brand-name non-originator drugs).

- We compared prices for nonbiologic drugs and biologics and, among biologics, for reference biologics and biosimilars separately because manufacturer prices might be different across countries for these categories of drugs.

We also changed the following individual steps in our main method as a series of sensitivity analyses:

- We aggregated sales and volume to the active ingredient level rather than the presentation level to test whether the mix of drugs within each active ingredient is driving price differences.
- We calculated price indexes using volume weights from comparison countries rather than from the United States. Relatedly, we calculated price indexes using a blended, geometric mean of U.S. and other countries' volume weights (known as a Fisher index).
- We used retail instead of manufacturer prices to test whether higher wholesale and retail markups in other countries narrow price differences between them and the United States.
- We applied more restrictive (excluding more records) and less restrictive (excluding fewer records) price ratio exclusion criteria.

Finally, we explored how our price comparison results changed over time from 2017 through 2022. We did this in two ways: first, allowing the market basket of drugs used to compare prices to vary year to year and, second, holding the market basket constant at 2018 levels for a set of drugs sold consistently in the United States and each comparison country. Other than the addition of historical data, we used the same methods for the price comparison as in the main analysis.

Addressing U.S. Gross-to-Net Discounts

We used four approaches to adjust U.S. manufacturer gross prices to reflect rebates and other discounts leading to lower manufacturer net prices. The first approach reduced U.S. prices for *all drugs* (that is, across brand-name originator, brand-name generic, and unbranded generic drugs) by 37.7 percent—a factor calculated from IQVIA Institute, which reports ratios of manufacturer gross to net prices across all drugs⁴⁵—then compared prices across all drugs. For each of the second through fourth approaches, we reduced U.S. retail-dispensed brand-name prices by 37.2 percent—a similar factor calculated from the same source but specifically for brand-name

⁴⁴ Danzon and Furukawa, 2008.

⁴⁵ IQVIA Institute for Human Data Science, 2023b. This IQVIA report noted invoice and manufacturer net prices as a share of WAC prices separately for all drugs and for protected brand drugs that we considered a close analog to brand-name originators. We used these estimates to calculate proportional reductions from invoice prices to net prices (as one minus the ratio of net to invoice prices). The resulting reductions to U.S. ex-manufacturer prices were 37.7 percent for all drugs and 37.2 percent for retail-dispensed brand-name originator drugs.

originator drugs.⁴⁶ The second through fourth approaches differ in the scope of drugs included in the subsequent price comparison, which were

- across **all drugs**
- across **all brand-name originator drugs**
- across **all retail brand-name originator drugs**.

Gross-to-Net Discounts Outside the United States

Although rebates and other discounts that are not reflected in manufacturer and retail sales and prices are increasingly common in other countries, our sensitivity analysis focused on adjusting U.S. prices only, recognizing that the resulting prices will understate the gap between U.S. prices and other countries' prices.

Presenting Results

Bar charts illustrate the ratio of the U.S. price index to the comparison country (or all comparison countries combined) price index (that is, other countries' prices equal 100; a result of 250 means U.S. prices are 2.5 times those in other countries). Most bar charts present results for six OECD countries with relatively large economies—Canada, France, Germany, Italy, Japan, and the United Kingdom (the Group of Seven [G7] countries, excluding the United States)—and for Mexico because of its geographic proximity to the United States and its close economic connections with the United States under the United States–Mexico–Canada Agreement. We also present results for the 33 OECD comparison countries combined. Results for all analyses, including price indexes for other countries and from sensitivity analyses not presented as figures, are in Appendix B.

⁴⁶ IQVIA MIDAS distinguishes between retail and hospital distribution channels for most countries, with additional distribution channels for the United States. We did not adjust U.S. prices for drugs dispensed through the U.S. hospital or clinic channels because discounts for these purchases, which often involve group purchasing organizations, are less likely to involve off-invoice rebates and other discounts (see Andrew W. Mulcahy and Vishnupriya Karedy, *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships*, RAND Corporation, RR-A328-1, 2021).

Chapter 3. Results

Our main results present 2022 price differentials for pairwise comparisons of the United States with a set of other countries (or 33 OECD comparison countries combined) using presentation-level prices, U.S. volume weights, and all presentations that are sold in both the United States and the comparison market.

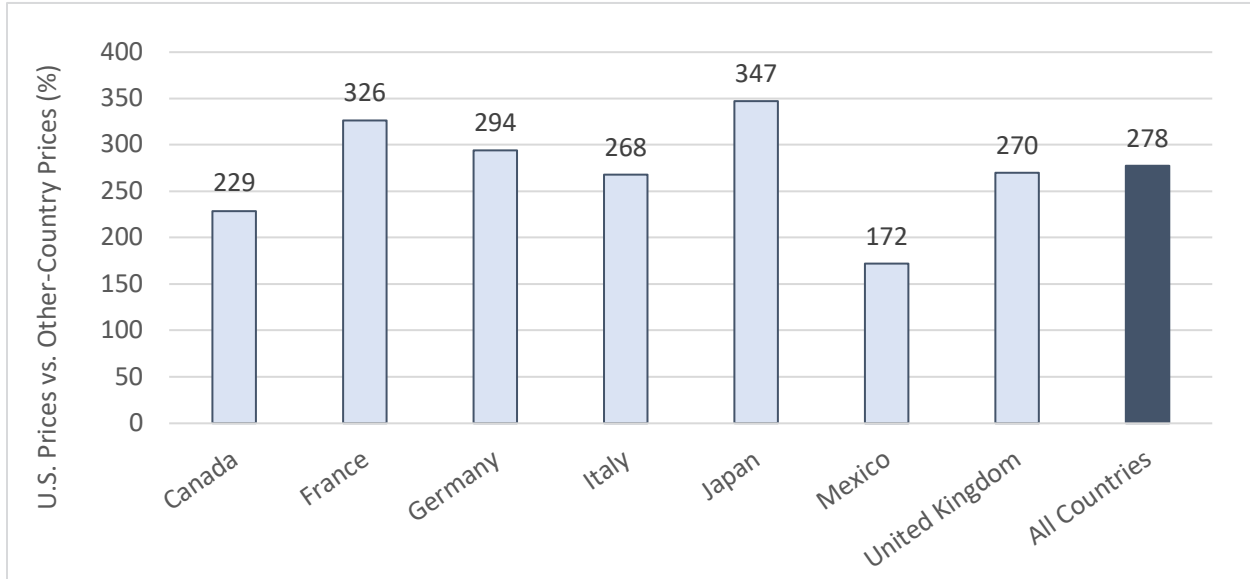
Prices in the United States were higher than prices in each of the 33 comparison countries individually and all comparison countries combined (see Figure 3.1 for comparisons of U.S. prices with those in Mexico and the G7 countries; see Appendix B for comparisons with other individual OECD countries). Each result illustrated in Figure 3.1 shows U.S. prices relative to those in a comparison country fixed at 100 percent. For example, the 229 percent result for Canada means that U.S. prices were 229 percent of those in Canada. The same result can be alternatively framed as U.S. prices being 2.29 times those in Canada, or as Canadian prices being 44 percent (100 percent over 229 percent) of U.S. prices.

U.S. prices were 278 percent of prices in the 33 OECD comparison countries combined. Among comparisons with individual G7 countries, U.S. prices ranged from 229 percent of prices in Canada to 347 percent of prices in France.

Across all 33 individual comparison countries, U.S. prices ranged from 172 percent of prices in Mexico to 1,028 percent of prices in Turkey. Both Mexico and Canada had prices relatively closer to those in the United States compared with those in other countries. This may be partially explained by geographic proximity, more shared generic formulations between the United States and these countries compared with the United States and other countries, and cross-border flow of prescription drugs.

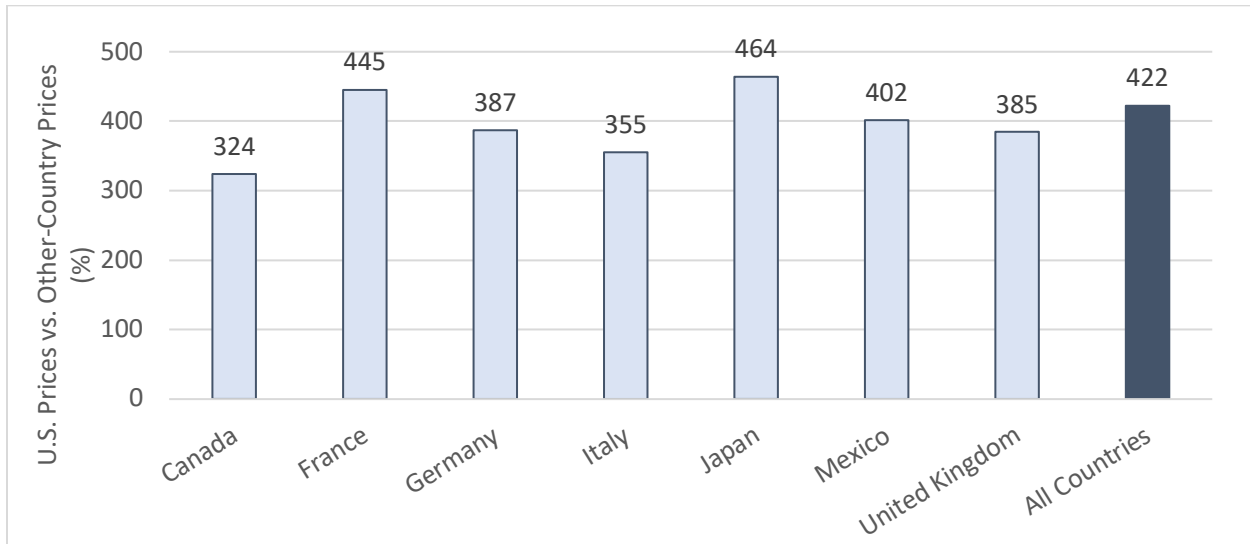
Figure 3.2 illustrates price comparisons for brand-name originator drugs. U.S. manufacturer gross prices were 422 percent of prices in other countries. As in Figure 3.1, Canada had prices that were closest to those in the United States among the countries for which Figure 3.2 shows results individually. In the opposite direction, France and Japan had the relatively lowest prices for brand-name originator drugs.

Figure 3.1. U.S. Prescription Drug Prices as a Percentage of Prices in Selected Other Countries, All Drugs, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

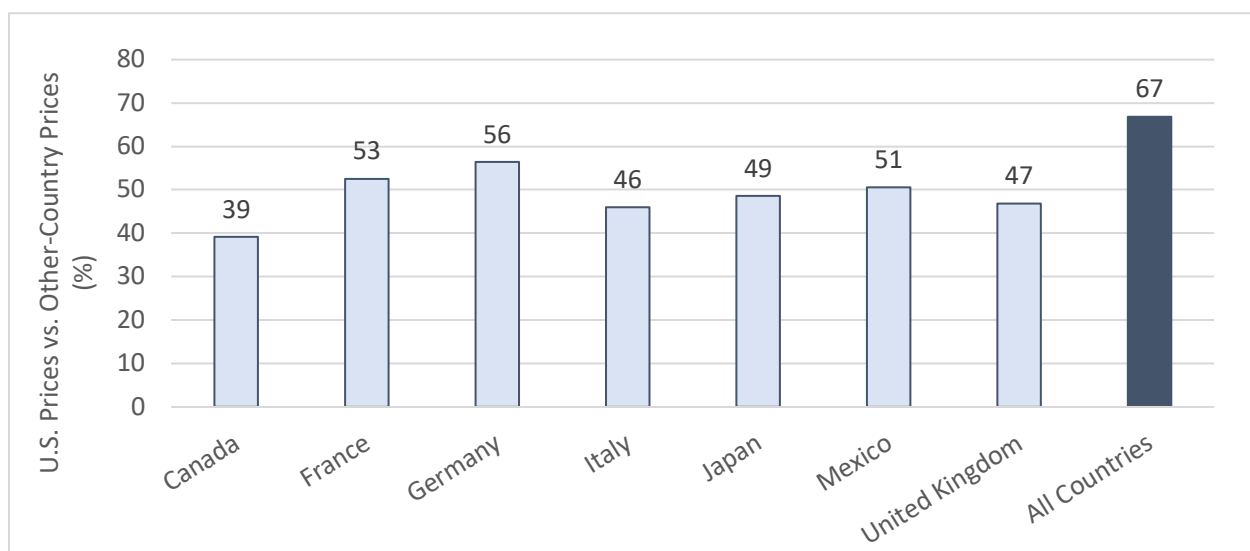
Figure 3.2. U.S. Brand-Name Originator Drug Prices as a Percentage of Other Countries' Prices, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Figure 3.3 illustrates compared prices for unbranded generic drugs. Overall, U.S. unbranded generic drug prices were 67 percent of prices in other countries, and most individual comparison countries have higher prices for unbranded generics than the United States does.⁴⁷ Unbranded generic prices in the United States were 39 percent of those in Canada and 56 percent of those in Germany. Combining brand-name non-originator drugs and unbranded generic drugs does substantively affect results, with many countries showing lower prices than the United States and U.S. prices on average exactly 100 percent of prices in other countries combined (see Table B.1). This reversal could be the result of some drugs categorized by IQVIA as brand-name non-originator drugs having high U.S. prices.

Figure 3.3. U.S. Unbranded Generic Drug Prices as a Percentage of Other Countries' Prices, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Biologics are excluded. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

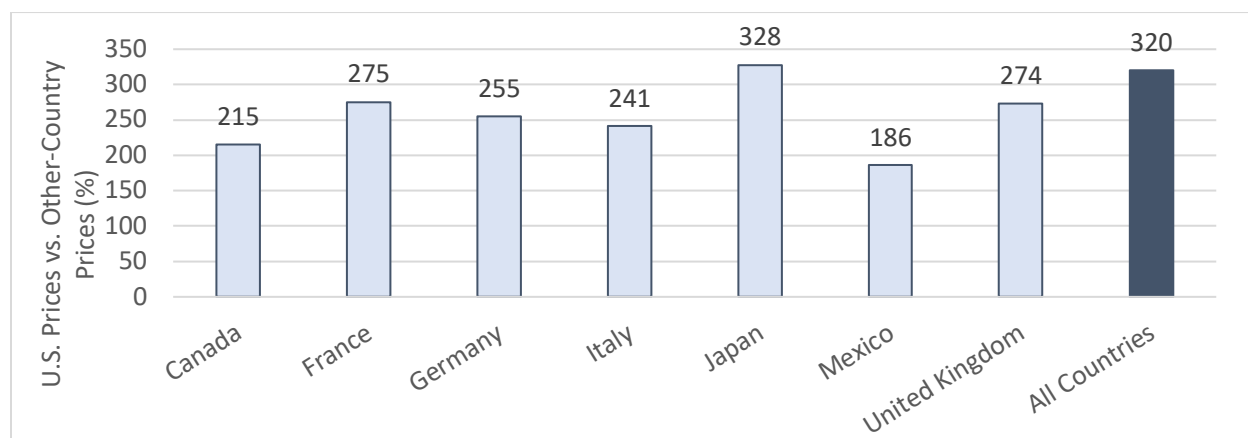
Results at the Active Ingredient Level

A presentation (that is, active ingredient, dosage form, and strength)-level market basket and price comparison uses only data for which there is a specific match between products sold in the United States and a comparison country. Figure 3.4 presents results from the robustness test comparing prices calculated at the broader active ingredient level instead of at the presentation level. The differences between U.S. and other countries' prices are typically larger at the active ingredient level than at the presentation level. U.S. prices were 320 percent of prices in other countries combined when price indexes were calculated using active ingredient-level data; they

⁴⁷ These results do not change substantively when unbranded biologics are included with other unbranded generic drugs.

were 278 percent of other countries' prices when using presentation-level data. This suggests the United States uses a more expensive mix of specific presentations and products within an active ingredient.

Figure 3.4. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, Active Ingredient Level, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some active ingredients sold in each country contribute to bilateral comparisons.

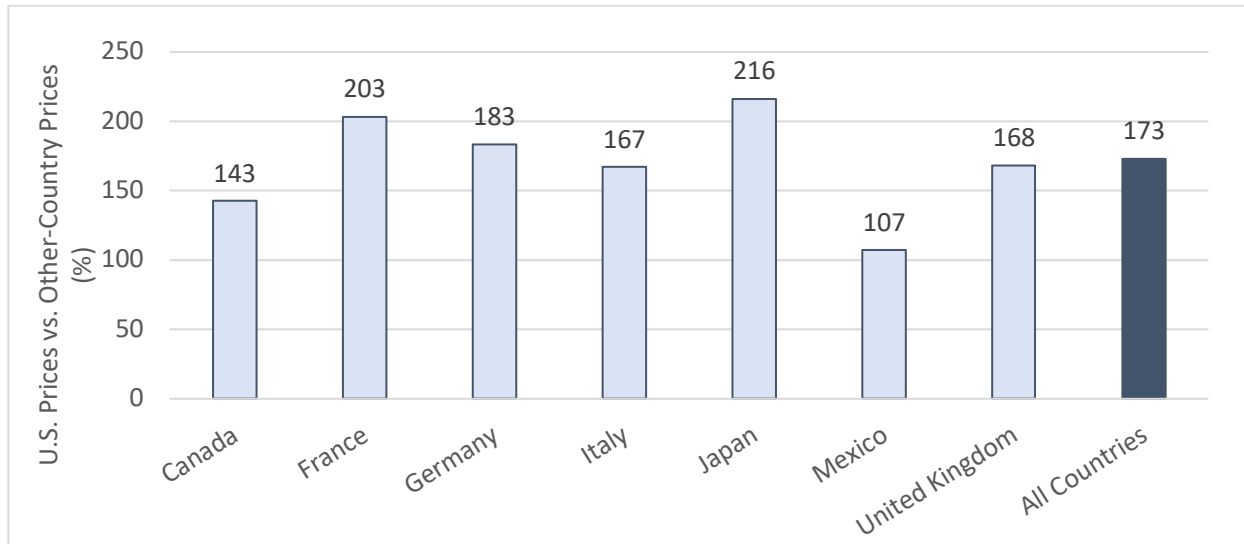
Results with Net Price Adjustments

We reduced U.S. prices based on estimates of the relative difference between U.S. manufacturer gross and net prices because of rebates and other discounts.⁴⁸ We used two alternative approaches to apply U.S. manufacturer net price adjustments. First, a constant 37.7 percent reduction across all U.S. prices yielded U.S. prices that were 173 percent of prices in other countries (Figure 3.5). Second, a 37.2 percent reduction to retail-dispensed, brand-name U.S. drug prices yielded U.S. prices that were

- 213 percent of prices in other countries when comparing across all drugs
- 308 percent of prices in other countries when comparing prices just for brand-name originator drugs
- 381 percent of prices in other countries when comparing prices for only retail-dispensed, brand-name drugs (Figure 3.6).

⁴⁸ IQVIA Institute for Human Data Science, 2023b. This IQVIA report noted invoice and manufacturer net prices as a share of WAC prices separately for all drugs and for protected brand drugs that we considered a close analog to brand-name originators. We used these estimates to calculate proportional reductions from invoice prices to net prices (as one minus the ratio of net to invoice prices). The resulting reductions to U.S. ex-manufacturer prices were 37.7 percent for all drugs and 37.2 percent for retail-dispensed brand-name originator drugs.

Figure 3.5. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, U.S. Net Price Adjustment Applied to All Drugs, 2022



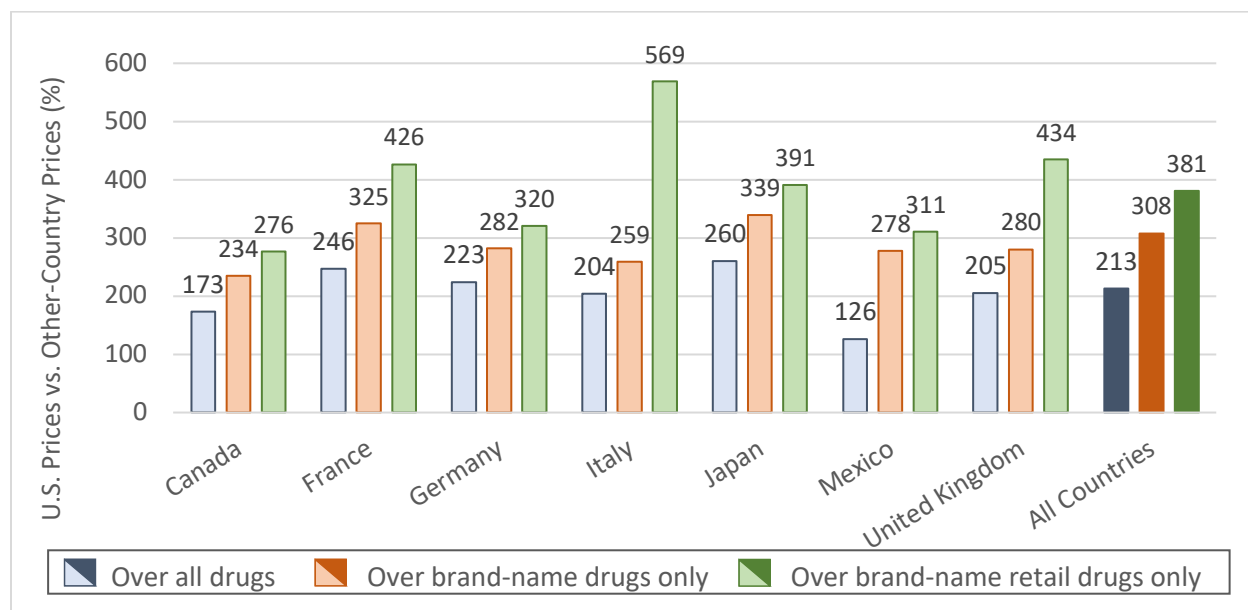
SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: For the purposes of this comparison, we reduced U.S. prices for all drugs by 37.7 percent. We calculated the 37.7 percent reduction using data presented in IQVIA Institute for Human Data Science, 2023b. *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

The relative magnitudes of these results line up with our findings without the U.S. net price adjustment: Without adjustment, U.S. prices were 278 percent of prices in other countries across all drugs and 422 percent of prices in other countries for brand-name originator drugs. As we noted, the results from these sensitivity analyses understate differences between prices in the United States and other countries because we have not applied similar adjustments to prices in other countries to reflect rebates and other discounts on manufacturer prices, such as statutory rebates to German sickness funds or “patient access scheme” payments from manufacturers to the National Health Service in the United Kingdom.⁴⁹

⁴⁹ Persson and Jönsson, 2016.

Figure 3.6. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, U.S. Net Price Adjustment Applied to Retail-Dispensed, Brand-Name Drugs, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: For the purposes of this comparison, we reduced U.S. prices for retail-dispensed, brand-name drugs by 37.2 percent. We calculated the 37.2 percent reduction using data presented in IQVIA Institute for Human Data Science, 2023b. *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

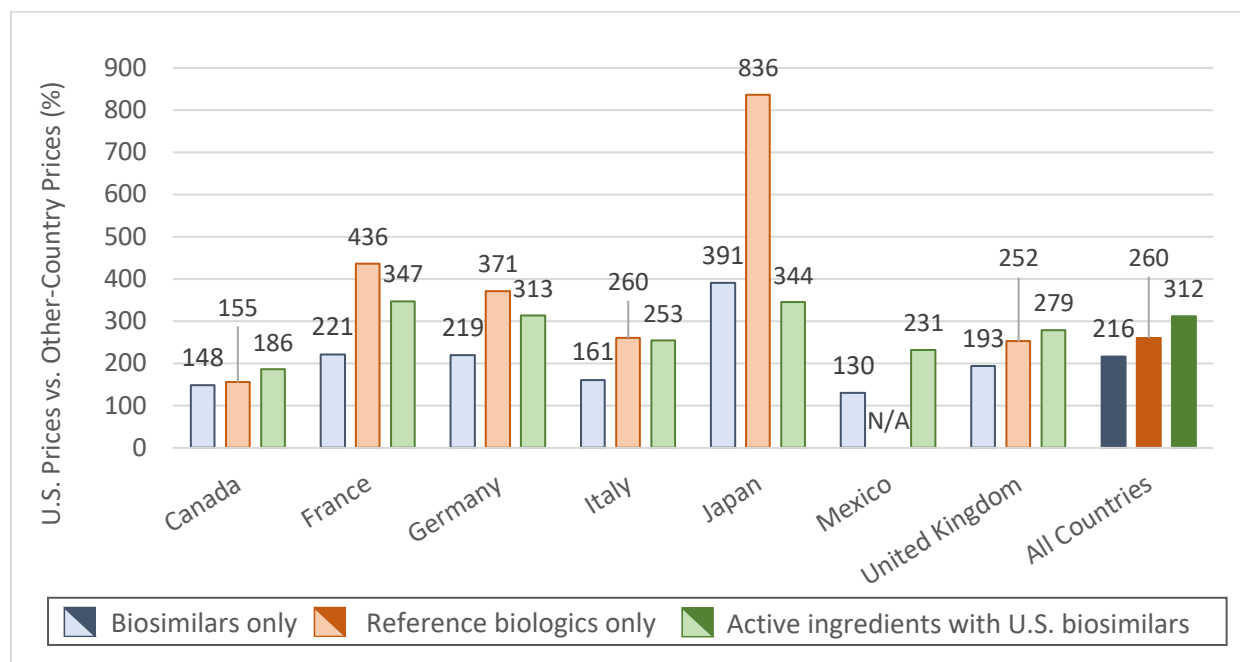
Results for Biosimilars and Reference Biologics

U.S. prices for biosimilar products were generally closer to those in other countries compared with all brand-name drugs and with reference biologics (Figure 3.7).⁵⁰ Across all countries, U.S. biosimilar and reference biologic prices were 216 and 260 percent, respectively, of prices in other countries. When comparing prices across all active ingredients facing biosimilar competition in the United States as of the end of 2022 (that is, pooling across biosimilars, reference biologics, and any other versions), U.S. prices were 312 percent of prices in comparison countries combined. Comparisons of U.S. prices for biosimilars and reference biologics to those in other individual countries varied, with U.S. prices still higher but relatively closer to those in in Canada and Mexico.⁵¹

⁵⁰ We found no overlap in the specific reference biologic products sold in the United States and Mexico.

⁵¹ Much higher U.S. reference biologic prices versus those in Japan are driven by a 16x price difference for teriparatide reference biologics. Although this is an outlier price, it may reflect the actual price for this drug in Japan, stemming from price regulation.

Figure 3.7. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, Biosimilar and Reference Biologic Categories, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons. We found no overlap in the specific reference biologic products sold in the United States and Mexico; N/A = not applicable.

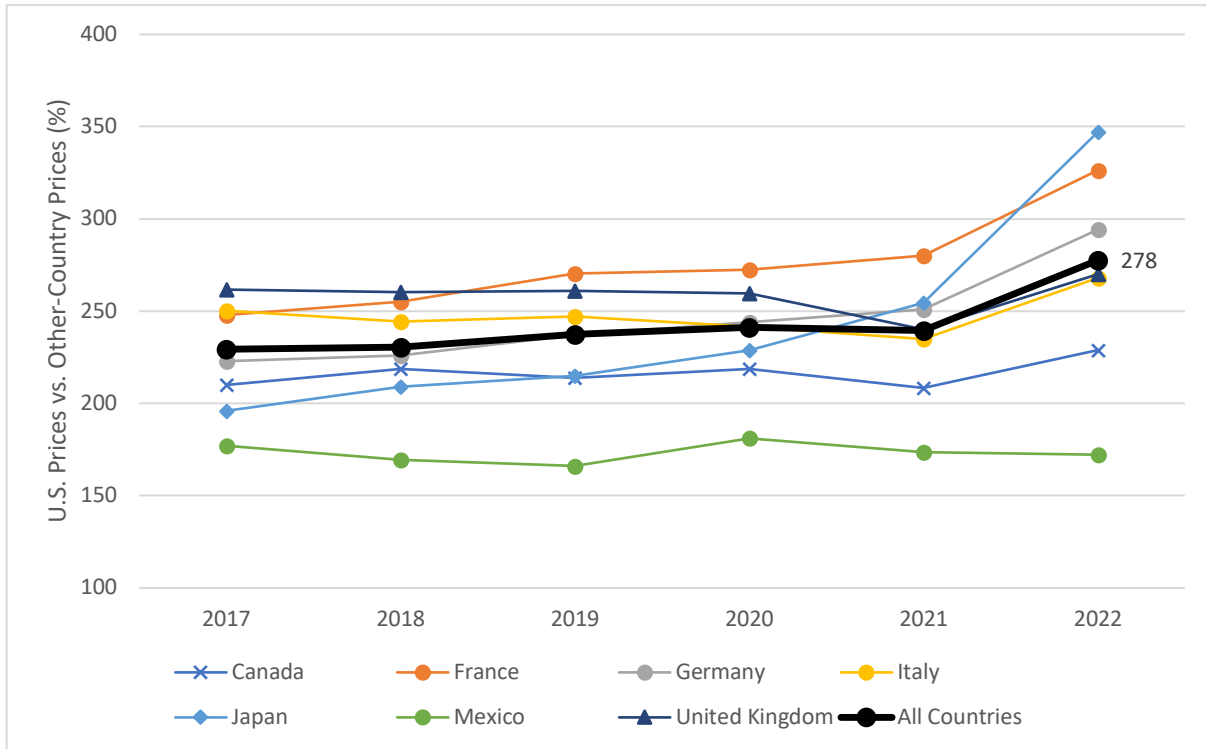
Trends in Results over Time

Figure 3.8 illustrates changes in the ratio of U.S. to other countries' prices from 2017 through 2022 for prices in comparison countries combined (thick black trend line) and for prices in individual G7 countries and Mexico. Although trends from 2017 through 2021 were relatively stable, U.S. prices were proportionally higher (or other countries' prices were proportionally lower, or both) in 2022. This may be due to the introduction of new brand-name drugs in the United States slightly before launching in some other countries, thereby changing the mix of drugs contributing to some bilateral comparisons (for example, with Japan and France where the 2021 to 2022 increases were greatest). Looking at 2021 prices, U.S. prices were 240 percent of prices in other countries, compared with 278 percent in 2022.

Changing the cohorts of matching drugs contributing to the price comparison for each comparison country and year effectively undoes the constant market basket integral to price index calculations. We also calculated changes in our price comparison results over time using a fixed market basket of drugs sold in the United States and other countries in each year from 2018 through 2022 (Figure 3.9). Trends, including the relative increase in U.S. prices from 2021 to 2022, looked relatively similar when restricting to this stable market basket. Given that Figure

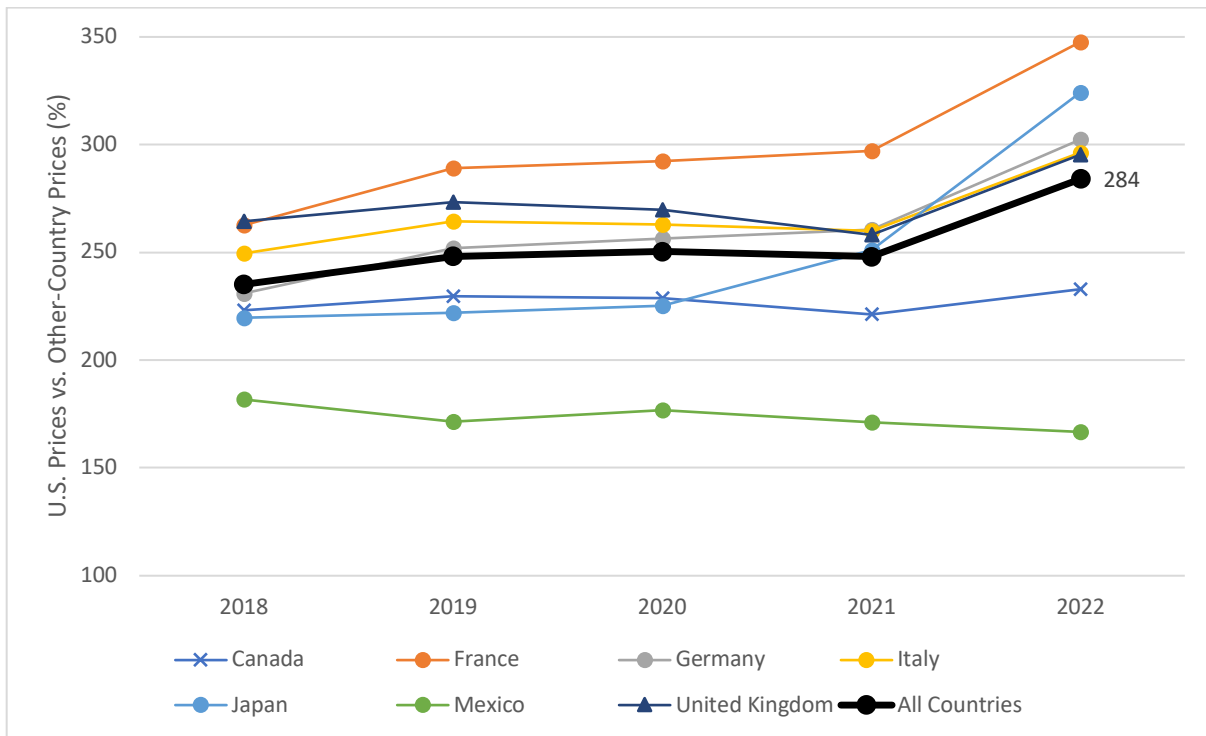
3.9 presents results using a time-invariant market basket of drugs, this increase appears to be at least partially driven by factors other than new drugs and warrants further investigation.

Figure 3.8. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, 2017–2022



SOURCE: Authors' analysis of 2017–2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
 NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100.
 Only some presentations sold in each country contribute to bilateral comparisons in each country year.

Figure 3.9. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, 2018–2022, Fixed Market Basket

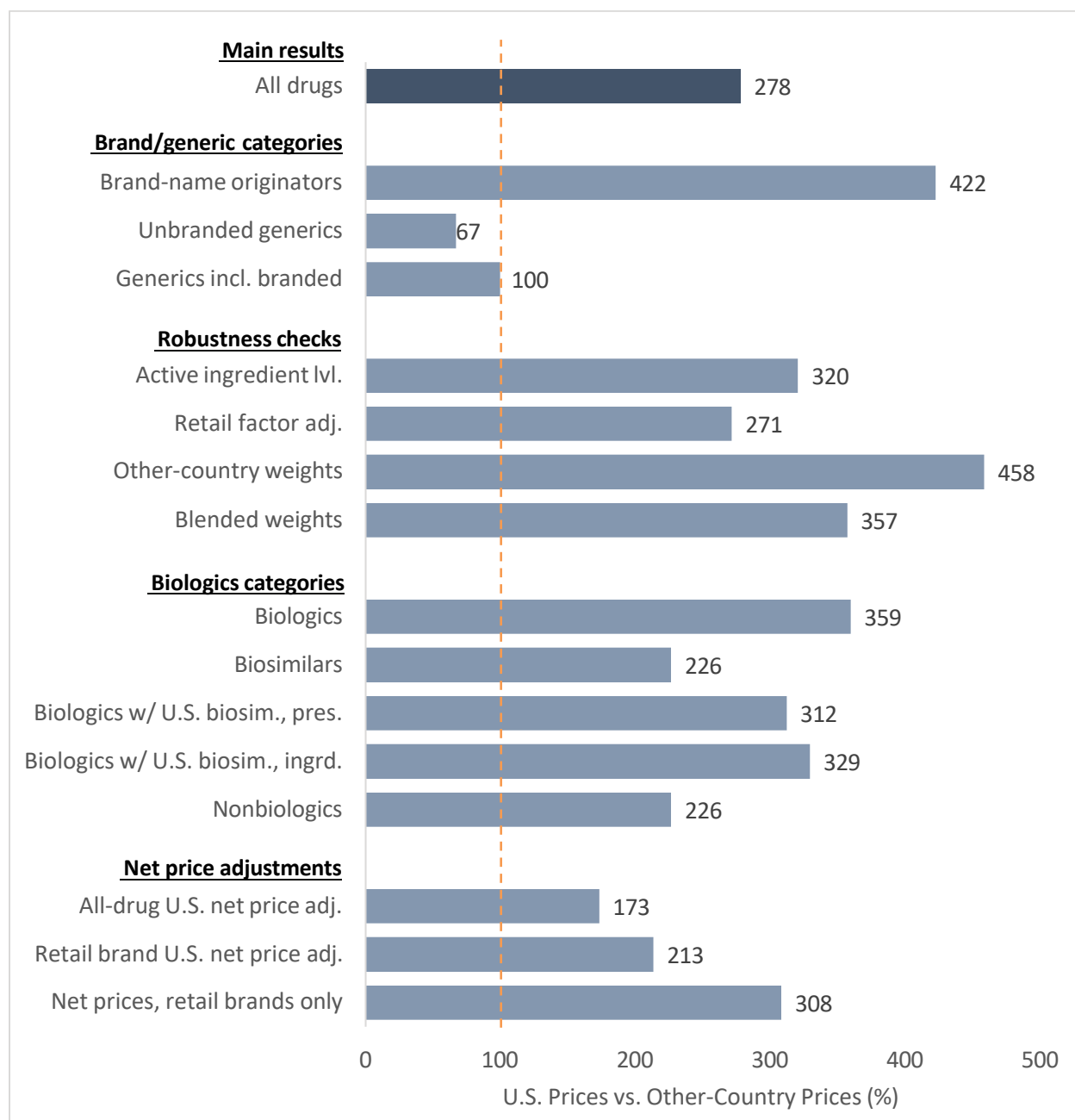


SOURCE: Authors' analysis of 2018–2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. The same set of presentations contributes to the analysis in each year (by design).

Summary of Results

Figure 3.10 shows ratios of U.S. to other countries' drug prices across a variety of subgroup analyses and robustness checks, including those described above and others that were included in Mulcahy et al. (2021b) but not separately presented above. See Appendix B for detailed findings from individual analyses not presented in the main body of the report.

Figure 3.10. Summary of Results: U.S. Prices as a Percentage of Other-Country Prices, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 4, 2023).

NOTE: *Other-Country Prices* refers to all 33 OECD comparison countries combined. Adj. = adjustment; biosim. = biosimilar; incl. = including; ingr. = ingredient; lvl. = level; pres. = presentation.

Chapter 4. Discussion

We found that 2022 manufacturer gross prescription drug prices in the United States were substantially higher than those in other countries. The magnitude of the difference between prices in the United States and other countries was substantial. For all drugs, U.S. prices were 278 percent of prices in other countries combined. U.S. prices for brand-name originator drugs were 422 percent of prices in other countries combined. Adjusting prices for U.S. brand-name originator drugs downward to reflect off-invoice rebates and other discounts closed the gap between U.S. and other countries' prices, but U.S. brand-drug prices remained over three times as high. Across all drugs, U.S. prices were higher than those in all 33 comparison countries individually, ranging from 172 percent of prices in Mexico to 1,028 percent of prices in Turkey.

Of the subsets of drugs that we examined, only unbranded generics had lower prices in the United States than in most comparison countries, with U.S. prices on average about one-third less than those in other countries. This finding suggests that robust price competition in U.S. unbranded generic markets continues to drive savings for consumers and health care payers relative to spending on these drugs in other countries. Although we found that generics account for 90 percent of U.S. prescription volume versus roughly 10 percent for brand-name originators, the much higher dollar amounts and price ratios for brand-name originator versus unbranded generics yield an overall price index ratio of 278 percent.

Our main findings—that U.S. prices are higher than those in comparison countries for all drugs and for brand-name originator drugs but generally lower for unbranded generic drugs—held through several additional sensitivity analyses, such as an analysis with and without outlier presentations in terms of price and analysis using different volume weights.

Comparisons with Prior Work

Our findings are broadly consistent with those described in Mulcahy et al. (2021b), which presents findings aligning with those from earlier studies.⁵² This updated report found U.S. manufacturer invoice prices were overall 278 percent of prices in other countries in 2022, which suggests a slightly wider gap in prices between U.S. and other countries' prices compared with the analogous 256 percent finding from the analysis of 2018 data in the earlier RAND report. However, we recommend caution when comparing results from the two reports. Relative to the 2018 data analyzed in the earlier report, the 2022 data used in the current analysis adds data from Colombia (which joined the OECD in April 2020) and includes additional presentations in

⁵² In addition to Mulcahy et al., 2021b, see Danzon and Furukawa, 2006; Danzon and Furukawa, 2008; Kanavos and Vondoros, 2011; and Kanavos et al., 2013.

bilateral comparisons due to increasingly standardized IQVIA MIDAS formulation and strength categories over time.

The current and prior findings from sensitivity analyses were also broadly consistent. One notable set of sensitivity analyses involve adjustments for lower manufacturer net versus manufacturer gross prices. In the absence of comprehensive information on manufacturer net prices, we used three approaches to make this adjustment, including one applying a fixed price reduction across all drugs and the other two applying a fixed price reduction to retail-dispensed brand-name drugs only. This approach differed slightly from Mulcahy et al. (2021b), in which a reduction was applied to all brand-name originator drugs, not just those dispensed via the retail channel. We made this change because drugs dispensed through other channels—for example, physician-administered drugs—appear to be less likely to have any rebates and other discounts.

We found that U.S. prices were closer to those in other countries—at 173 and 213 percent of international prices—when applying the overall and retail-dispensed, brand-name originator drug adjustments only, provided prices were then compared across all drugs. However, when adjusting retail-dispensed, brand-name originator prices downward and then comparing prices for only brand-name drugs, U.S. prices remained 308 percent of prices in other countries. The much higher relative U.S. prices when focusing just on retail-dispensed, brand-originator drugs emphasizes the importance of unbranded generic drugs in lowering overall U.S. drug spending and average prices. The differences in these results also highlight the importance of refining methodologies to estimate manufacturer net prices and the key decision of whether to apply an invoice-to-net reduction to drugs other than retail-dispensed, brand-originator drugs (which was not discussed in the earlier report).

The Role of Methodological Decisions

The magnitudes of estimated price differentials varied with our measurement approach. For our main results, we opted to use presentation-level data because these more-granular price and volume weights allow comparisons that reflect the mix of drugs in each market. The differences between U.S. prices and prices in other countries was slightly wider when we used active ingredient-level data instead. This suggests that, on average, the U.S. mix of drugs within an active ingredient tended toward higher-priced presentations. While active ingredient-level analyses can help address potential mismatches between the specific dosage forms and strengths of the selected drugs sold in the United States versus other countries, they introduce new concerns by effectively averaging prices across presentations (nested within an active ingredient) with potentially important differences in characteristics and prices.

Relatedly, our use of bilateral comparisons in which we had data for both the United States and a respective comparison country in some cases led to small shares of all presentations sold in the U.S. and comparison countries contributing to each comparison. This leads to concerns regarding the generalizability of our findings. However, as discussed earlier, the presentations

and active ingredients available for comparison tended to account for larger shares of volume and sales compared with presentations and active ingredients that did not contribute to our analysis.

Excluding U.S. and other countries' presentations for which the other country's price was very high or low compared with the U.S. price had generally modest implications on the magnitude of results. U.S. prices relative to other countries' prices without these outlier exclusion steps were almost always within 10 percent of those from our main results. We opted to implement these outlier exclusion steps because presentations with extreme differences between U.S. and other countries' prices have the potential to exert significant leverage over volume-weighted price calculations. Although our main concern was that inconsistencies in how sales or volumes are measured across markets could lead to outliers, there is the possibility that some of the excluded presentations with very high U.S. or other countries' prices could have reflected an actual price difference, and, in this case, their exclusion would bias our results. For example, high prices in non-U.S. countries could reflect high private-pay amounts outside a public health care system and price controls.

We chose to use data from all of 2022 to calculate price indexes. Other studies noted the relatively quicker approval and uptake of newer, typically more-expensive drugs and presentations in the United States compared with other countries.⁵³ Our bilateral comparisons omit new drugs and presentations released in the United States in 2022 but not yet in other countries. Access to innovative treatment likely has important benefits to patients. Our study does not address the trade-offs between higher prices and earlier access to new drugs.

We opted to use U.S. volume weights because of the U.S. policy focus of the analysis. This choice had important implications for our results. Using other countries' volume weights yielded U.S. prices that were 458 percent of prices in other countries (compared with 278 percent when using U.S. volume weights). Prescribing patterns outside the United States might be skewed toward drugs with favorable prices in individual countries as a result of price controls and/or volume purchasing. As a result, it is unsurprising that other countries' volume weights result in findings of relatively higher U.S. drug prices.

General Limitations

There are important limitations that apply to all of the prior studies that we describe in this report and to our own analysis. First, although the drug prices net of rebates and all discounts are particularly relevant to policymakers and other stakeholder groups, there is no comprehensive source of net prices paid for drugs—either to manufacturers or by payers—in the United States. We expect a significant difference between manufacturer prices and prices to payers net of rebates in the United States and in other countries (such as Germany and the United Kingdom)

⁵³ Danzon and Furukawa, 2008.

where similar rebates and discounts are increasingly common. We used manufacturer prices because they are the best available comparable data for all countries.

The price differentials between the United States and other countries presented here and in other studies could be biased upward if actual negotiated discounts are larger than the factor applied to brand-name originator drugs as an ad hoc adjustment. We applied an estimated adjustment to U.S. prices to approximate rebates and other discounts applied to manufacturer prices as one of our sensitivity analyses. However, U.S. gross-to-net reductions vary across therapeutic classes and with the extent of competition for specific drug products,⁵⁴ and we recognize that the resulting net prices will almost certainly differ from the actual U.S. net prices for individual products.

We also recognize that resulting price indexes might understate differences between prices in the United States and other countries because they adjust only U.S. prices downward even though rebates and similar discounts are increasingly common in other countries. U.S. prices would appear relatively higher—that is, more in line with our main results—if we were able to also adjust for rebates and other discounts applied to manufacturer prices in other countries.

Second, manufacturer prices (that is, the prices paid to manufacturers net of discounts at the time of purchase), such as those available from the IQVIA MIDAS data, are calculated in some countries by applying a set of assumed adjustment factors on observed local-level prices. In other words, IQVIA obtains a list price or average invoice price at the local level and then calculates manufacturer prices where necessary by applying a set of country-specific average margin factors. These average margin country-specific factors are generated and updated by local industry experts. The IQVIA MIDAS dataset is the standard for use in industry to compare manufacturer prices.

Finally, we use standard units as reported by IQVIA in the IQVIA MIDAS data as our unit of volume. Although standard units are designed to improve comparability in volume measurement between different drugs, there are remaining concerns, particularly when the number of units used in practice differs from country to country. As an example, lower-dosage presentations are more common in some other countries (for example, Japan) than in the United States, and volume could be higher. We address this, in part, by using presentation-level (rather than active ingredient–level) data. We did not have data available to further adjust the volumes reported in IQVIA MIDAS by a defined daily dose or other conversion factor to improve comparability.

Potential Further Analyses

Future analyses should address the core limitation of our work: the lack of systematic data on U.S. and other countries' net prices from either the manufacturer or payer perspectives. Although

⁵⁴ Mulcahy et al., 2021a; Immaculada Hernandez, Alvaro San-Juan-Rodriguez, Chester B. Good, and Walid F. Gelland, "Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018," *JAMA*, Vol. 323, No. 9, 2020.

there are promising avenues of research focusing on estimates of U.S. manufacturer net prices, other prices remain elusive. The Section 204 provisions introduced by the Consolidated Appropriations Act, 2021, will, for the first time, require plan sponsors to report net spending overall, for certain specific drugs, and by therapeutic class.⁵⁵ These data will be useful to the U.S. Department of Health and Human Services and other policymakers as an input into analyses on net prices to U.S. commercial payers, particularly when combined with other data available to the U.S. government, such as Medicare Part D rebates and Medicaid best price information.

Further research is also needed to measure net manufacturer prices in countries outside the United States. Off-invoice discounts through rebates, tendering, and other arrangements are increasingly common outside the United States. As a result, the magnitude of our price comparisons adjusting for lower U.S. net prices are likely too small because we did not have data available to apply similar adjustments to lower net prices in other countries. Although there are growing calls among OECD countries for transparency in drug prices, including net prices,⁵⁶ there have been few concrete steps toward net price publication or comparison among countries.

Several prior studies have noted that adjusting for differences in per capita income explains a portion of the difference in prescription drug prices across countries, particularly for drugs sold to middle- and low-income countries.⁵⁷ However, the differences in income are not large enough to explain the entire difference in prices between the United States and other OECD countries, and four OECD countries (Luxembourg, Ireland, Norway, and Switzerland) have both higher per capita gross domestic product and lower drug prices than the United States.⁵⁸ Other studies assess whether variations among countries in health care systems and regulatory characteristics explain variation in prices.⁵⁹ Because an improved understanding of the drivers of drug price differences among countries is an important input into U.S. policy discussions on drug prices, we recommend further study on this topic.

⁵⁵ Public Law 116-260, Consolidated Appropriations Act, 2021, December 27, 2020.

⁵⁶ Eliana Barrenho and Ruth Lopert, “Exploring the Consequences of Greater Price Transparency on the Dynamics of Pharmaceutical Markets,” Organisation for Economic Co-operation and Development, OECD Health Working Paper No. 146, September 8, 2022.

⁵⁷ Patricia Danzon, Andrew W. Mulcahy, and Adrian K. Towse, “Pharmaceutical Pricing in Emerging Markets: Effects of Income, Competition, and Procurement,” *Health Economics*, Vol. 24, No. 2, 2015.

⁵⁸ OECD, “Gross Domestic Product (GDP),” webpage, undated.

⁵⁹ For example, see Kanavos et al., 2013.

Appendix A. Price Index Methodology

We calculated bilateral price indexes for the United States versus each other country separately using all presentations that had more than 1,000 standard units in volume or \$1,000 in sales in both the United States and the individual comparison country.⁶⁰ We used low volume and low sales exclusion steps to prevent outlier presentations from exerting undue influence on our overall results. Less than 0.3 percent of sales and volume across all countries were excluded because of the low volume or sales exclusion criteria (see Table A.1).

Of the presentations remaining after these initial exclusions, only those presentations sold in both the United States and comparison countries contributed to bilateral comparisons (see Table A.2). In general, between one-third and two-thirds of presentations above sales and volume thresholds from comparison countries were also above sales and volume thresholds in the United States. Japan is an outlier; only 17 percent of its presentations by volume also sold in the United States. The United States had the largest number of presentations that could contribute to analyses, in part because the United States is the largest market, which increased the likelihood that each presentation was above sales and volume thresholds. Between 10 and 30 percent of presentations above volume and sales thresholds in the United States were also above volume and sales thresholds in other countries. As an example, 6,816 and 4,729 presentation-level records were above volume and sales thresholds for the United States and the United Kingdom, respectively. Of these, only 2,267 matched in both countries.⁶¹

Presentations that did not contribute to the calculation of a bilateral price index tended to have lower volume and smaller sales in terms of dollars than those that did. For example, the matched presentations between the United States and United Kingdom accounted for approximately 64 percent of total volume and 78 percent of total sales in both countries combined. Using active ingredient-level data rather than presentation-level data increased match rates considerably. For example, 53.3 percent of U.S. active ingredients and 63.4 percent of UK active ingredients meeting minimum volume and sales thresholds were used for bilateral comparison between the two countries, and these active ingredients accounted for 98.0 percent of volume and 99.7 percent of sales in both countries combined.

⁶⁰ We excluded presentations with fewer than 1,000 standard units in volume or less than \$1,000 in sales because these records tended to have outlier prices.

⁶¹ This represents 31 percent of U.S. presentations and 45 percent of UK presentations meeting volume and sales thresholds.

Table A.1. Initial Pool of Presentations and First Exclusion Step

Country	Total Presentations with Sales > \$0 and Volume > 0, No Other Exclusions (A)	Total Presentations with ≥ \$1,000 Sales and ≥ 1,000 Volume (B)	Share of Volume (B/A) (%)	Share of Sales (B/A) (%)
United States	7,427	6,816	>99.9	>99.9
All countries excluding the United States	31,630	26,990	>99.9	99.8
Australia	3,139	2,851	>99.9	99.3
Austria	3,800	3,284	>99.9	98.2
Belgium	3,433	2,907	>99.9	99.1
Canada	3,538	3,299	>99.9	99.3
Chile	2,802	2,176	>99.9	99.2
Colombia	3,436	2,751	>99.9	99.7
Czechia	3,075	2,689	>99.9	97.2
Estonia	1,776	1,361	>99.9	98.1
Finland	2,930	2,536	>99.9	97.5
France	4,093	3,686	>99.9	99.4
Germany	5,807	5,255	>99.9	99.0
Greece	2,675	2,235	>99.9	99.8
Hungary	2,658	2,366	>99.9	97.0
Ireland	3,224	2,710	99.6	98.0
Italy	4,987	4,475	>99.9	99.5
Japan	5,781	5,604	>99.9	>99.9
Korea	4,109	3,846	>99.9	99.4
Latvia	2,415	1,705	>99.9	95.5
Lithuania	2,472	1,843	>99.9	94.5
Luxembourg	2,071	1,542	99.7	94.2
Mexico	4,308	3,520	>99.9	99.5
Netherlands	3,398	2,986	>99.9	99.6
New Zealand	2,377	1,873	98.6	97.2
Norway	3,975	3,204	>99.9	97.3
Poland	3,778	3,229	>99.9	99.2
Portugal	4,336	3,568	>99.9	97.8
Slovakia	2,639	2,272	>99.9	96.5
Slovenia	2,202	1,793	>99.9	91.1
Spain	4,584	4,150	>99.9	99.4
Sweden	3,316	2,988	>99.9	98.2
Switzerland	3,639	3,237	>99.9	99.0
Turkey	3,279	3,041	>99.9	>99.9
United Kingdom	6,405	4,729	>99.9	99.3

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

Table A.2. Total Presentations Potentially Contributing to Bilateral Comparisons

Country	Total Presentations with ≥ \$1,000 Sales and ≥ 1,000 Volume (A)	Total Presentations Potentially Contributing to Bilateral Comparisons with the United States, Before Price Ratio Exclusion (B)	Share of Volume (B/A) (%)	Share of Sales (B/A) (%)
United States	6,816	N/A	N/A	N/A
All countries excluding the United States	26,990	4,467	45.6	70.8
Australia	2,851	1,683	70.9	75.1
Austria	3,284	1,676	54.7	78.1
Belgium	2,907	1,552	63.2	78.4
Canada	3,299	2,335	82.5	87.4
Chile	2,176	864	46.0	43.9
Colombia	2,751	889	48.7	41.8
Czechia	2,689	1,352	55.9	71.3
Estonia	1,361	754	56.0	71.7
Finland	2,536	1,453	62.7	78.0
France	3,686	1,825	57.7	76.9
Germany	5,255	2,277	65.2	79.1
Greece	2,235	1,126	56.1	67.4
Hungary	2,366	1,228	57.0	72.2
Ireland	2,710	1,541	60.3	82.6
Italy	4,475	1,894	54.9	73.5
Japan	5,604	1,295	17.4	54.2
Korea	3,846	1,553	37.2	59.6
Latvia	1,705	866	54.2	62.5
Lithuania	1,843	938	49.7	65.6
Luxembourg	1,542	864	62.1	75.3
Mexico	3,520	1,219	41.5	46.9
Netherlands	2,986	1,564	63.3	69.8
New Zealand	1,873	994	48.5	68.3
Norway	3,204	1,722	55.2	78.9
Poland	3,229	1,467	57.3	67.9
Portugal	3,568	1,666	54.6	72.6
Slovakia	2,272	1,171	51.6	67.4
Slovenia	1,793	1,046	55.7	75.5
Spain	4,150	1,973	58.1	79.3
Sweden	2,988	1,694	60.8	77.7
Switzerland	3,237	1,681	53.2	81.4
Turkey	3,041	1,337	38.3	65.9
United Kingdom	4,729	2,267	63.8	77.6

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: N/A = not applicable.

We also excluded any remaining presentations for which the ratio of prices between the United States and the comparison country was less than 0.01 or greater than 100. This step excluded a small number of presentations from each bilateral comparison and about 1 percent of sales and volume in most countries (see Table A.3). In exploratory analyses, we found that the most common scenario leading to outlier prices involved presentations with both (1) extremely low volume and relatively high sales in a non-U.S. country and (2) relatively high volume and very low prices in the United States. Some outliers could be the results of inconsistencies in the measurement of sales or volume across markets. It is also possible that the high prices in non-

U.S. countries reflect high private-pay amounts outside a public health care system and price controls. We cannot definitively distinguish between these cases. The differences in prices reported in the IQVIA MIDAS data might be more relevant to policymakers in the second case. We varied the price ratio exclusion thresholds in a set of sensitivity analyses that we describe in Appendix B.

These steps resulted in a different number of presentations being analyzed for each pairwise comparison between countries. Table A.4 compares the starting number of presentations in each country with the final number of presentations used for bilateral comparisons with the United States. Table A.4 also compares the share of starting U.S. and other countries' volume and sales that contributed to bilateral comparisons. Table A.5 replicates Table A.4 at the active ingredient level rather than the presentation level. Using active ingredient-level data rather than presentation-level data results in larger shares of sales and volume contributing to each comparison. These gains come at the cost of a less-precise overlap with the specific presentations sold. Table A.6 lists the distribution of volume and sales from presentations contributing to bilateral comparisons across brand-name originator, brand-name non-originator, and unbranded categories (similar to Table 2.2). In general, the presentations contributing to bilateral comparisons accounted for smaller shares of brand-name originator and brand-name non-originator sales and volume than all presentations sold in comparison countries did.

Table A.3. Presentations Contributing to Bilateral Comparisons After Price Ratio Exclusion

Country	Total Presentations Potentially Contributing to Bilateral Comparisons with the United States, Before Price Ratio Exclusion (A)	Total Presentations Contributing to Bilateral Comparisons, After Price Ratio Exclusion^a (B)	Share of Volume (B/A) (%)	Share of Sales (B/A) (%)
United States	6,816	N/A	N/A	N/A
All countries excluding the United States	4,467	4,222	98.5	98.1
Australia	1,683	1,640	99.2	99.6
Austria	1,676	1,637	99.6	99.3
Belgium	1,552	1,511	99.2	98.1
Canada	2,335	2,284	98.6	99.2
Chile	864	843	97.5	97.9
Colombia	889	855	94.2	97.2
Czechia	1,352	1,308	98.8	98.0
Estonia	754	737	98.4	99.3
Finland	1,453	1,418	98.6	97.0
France	1,825	1,770	98.7	97.2
Germany	2,277	2,198	99.4	98.2
Greece	1,126	1,094	99.1	98.9
Hungary	1,228	1,198	99.4	98.9
Ireland	1,541	1,510	97.8	99.1
Italy	1,894	1,820	99.2	99.1
Japan	1,295	1,257	97.1	96.8
Korea	1,553	1,500	98.5	98.5
Latvia	866	845	99.1	98.4
Lithuania	938	918	99.1	99.1
Luxembourg	864	849	98.2	96.8
Mexico	1,219	1,169	91.4	97.0
Netherlands	1,564	1,516	98.0	97.0
New Zealand	994	971	99.7	99.3
Norway	1,722	1,666	97.7	97.8
Poland	1,467	1,422	98.8	98.8
Portugal	1,666	1,606	97.4	98.7
Slovakia	1,171	1,134	98.9	98.3
Slovenia	1,046	1,025	99.3	98.2
Spain	1,973	1,907	98.1	98.4
Sweden	1,694	1,649	98.8	97.8
Switzerland	1,681	1,647	98.6	98.7
Turkey	1,337	1,293	98.8	98.5
United Kingdom	2,267	2,202	99.0	98.1

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: N/A = not applicable.

^a This excludes presentations with price ratio less than 1 percent of U.S. price or greater than 100x U.S. price.

Table A.4. Number of Presentations Used to Calculate Price Indexes

Country	Total Presentations in the MIDAS Extract	Total Presentations Contributing to Bilateral Comparisons	Other Countries' Shares Contributing to Bilateral Comparisons (%)		United States Shares Contributing to Bilateral Comparisons (%)	
			Volume	Sales	Volume	Sales
All countries	34,652	N/A	N/A	N/A	N/A	N/A
United States	7,427	N/A	N/A	N/A	N/A	N/A
All countries excluding the United States	31,630	4,690	45.6	70.8	88.3	90.2
Australia	3,139	1,787	70.9	75.1	52.0	61.1
Austria	3,800	1,906	54.7	78.0	55.1	72.6
Belgium	3,433	1,750	63.2	78.3	49.2	70.1
Canada	3,538	2,465	82.5	87.3	66.6	72.8
Chile	2,802	1,139	46.0	44.2	46.8	48.4
Colombia	3,436	1,130	48.7	41.8	47.5	40.2
Czechia	3,075	1,518	55.9	71.7	52.1	65.2
Estonia	1,776	941	56.0	72.0	42.4	40.9
Finland	2,930	1,640	62.7	78.1	51.4	71.4
France	4,093	1,957	57.7	76.5	50.1	67.0
Germany	5,807	2,424	65.2	78.9	61.9	75.6
Greece	2,675	1,313	56.1	67.4	48.9	43.7
Hungary	2,658	1,397	57.0	72.6	49.4	62.9
Ireland	3,224	1,765	60.2	82.4	55.7	68.1
Italy	4,987	2,025	54.9	73.4	51.4	71.9
Japan	5,781	1,334	17.4	54.1	33.0	55.8
Korea	4,109	1,642	37.2	59.7	53.0	61.6
Latvia	2,415	1,153	54.2	62.9	46.1	52.2
Lithuania	2,472	1,228	49.7	66.6	47.5	57.1
Luxembourg	2,071	1,097	62.1	75.3	47.1	50.2
Mexico	4,308	1,451	41.5	47.1	50.5	64.0
Netherlands	3,398	1,728	63.3	69.8	58.7	47.6
New Zealand	2,377	1,218	49.1	68.3	45.3	43.6
Norway	3,975	2,022	55.1	79.1	55.9	74.4
Poland	3,778	1,669	57.3	68.0	58.7	56.4
Portugal	4,336	1,893	54.6	72.8	54.4	69.9
Slovakia	2,639	1,367	51.6	68.1	50.9	60.1
Slovenia	2,202	1,259	55.7	76.3	46.4	64.7
Spain	4,584	2,088	58.1	79.0	55.3	72.4
Sweden	3,316	1,866	60.8	77.8	55.9	73.2
Switzerland	3,639	1,856	53.2	81.3	53.0	72.2
Turkey	3,279	1,413	38.3	65.9	51.4	58.1
United Kingdom	6,405	2,564	63.8	77.5	62.7	77.8

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: N/A = not applicable.

Table A.5. Number of Active Ingredients Used to Calculate Price Indexes

Country	Total Active Ingredients with Sales > \$0 and Volume > 0, No Other Exclusions (A)	Total Active Ingredients Contributing to Bilateral Comparisons, After Price Ratio Exclusion^a (B)	Share of Volume (B/A) (%)	Share of Sales (B/A) (%)
United States	2,180	2,029	N/A	N/A
All countries excluding the United States	31,630	1,646	75.2	88.2
Australia	1,151	912	91.4	95.2
Austria	1,526	976	78.1	90.8
Belgium	1,374	915	84.3	90.8
Canada	1,268	1,056	95.6	97.2
Chile	1,141	589	82.1	78.7
Colombia	1,322	591	80.4	74.0
Czechia	1,345	878	78.2	85.0
Estonia	831	520	80.3	86.6
Finland	1,200	841	88.1	91.8
France	1,540	1,024	83.9	91.8
Germany	1,845	1,157	84.0	90.7
Greece	1,104	709	82.9	87.0
Hungary	1,220	806	80.3	86.6
Ireland	1,225	868	90.9	95.0
Italy	1,804	1,118	83.3	91.2
Japan	2,127	1,056	59.5	79.0
Korea	1,706	990	60.7	76.8
Latvia	1,188	643	73.2	76.8
Lithuania	1,200	696	73.4	79.4
Luxembourg	890	552	85.8	88.7
Mexico	1,780	800	71.7	70.7
Netherlands	1,171	834	85.2	89.7
New Zealand	1,080	734	79.8	92.5
Norway	1,570	1,021	90.2	92.0
Poland	1,492	903	83.0	87.3
Portugal	1,756	1,036	79.4	87.6
Slovakia	1,222	787	71.7	80.1
Slovenia	1,044	706	84.2	85.2
Spain	1,703	1,091	84.1	91.8
Sweden	1,244	923	91.2	91.8
Switzerland	1,348	919	86.7	93.5
Turkey	1,383	851	67.7	84.1
United Kingdom	1,832	1,163	90.0	93.7

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: N/A = not applicable.

^a This excludes active ingredients below sales and volume thresholds and/or with ratios of less than 1 percent of U.S. price or greater than 100x U.S. price.

Table A.6. Within-Country Shares of Brand-Name Originator, Brand-Name Non-Originator, and Unbranded Generic Drugs, Presentations Contributing to Bilateral Comparisons, by Percentage

Country	Share of Sales: Brand-Name Originator	Share of Sales: Brand-Name Non-Originator	Share of Sales: Unbranded Generic	Share of Volume: Brand-Name Originator	Share of Volume: Brand-Name Non-Originator	Share of Volume: Unbranded Generic
United States	84	6	11	8	3	89
All countries excluding the United States	79	7	14	31	19	50
Australia	85	7	8	40	24	36
Austria	81	7	12	42	19	39
Belgium	85	5	10	49	10	41
Canada	78	4	18	20	11	68
Chile	45	41	13	10	21	68
Colombia	29	30	41	7	31	62
Czechia	81	10	9	37	34	29
Estonia	79	11	10	46	25	29
Finland	79	10	11	37	23	39
France	75	6	19	27	14	59
Germany	79	6	15	16	12	72
Greece	82	14	4	62	29	9
Hungary	81	9	10	39	31	30
Ireland	84	6	11	43	23	34
Italy	82	6	12	48	19	33
Japan	83	4	13	32	15	54
Korea	75	18	7	44	43	13
Latvia	75	11	14	33	24	43
Lithuania	81	9	10	41	25	33
Luxembourg	92	5	3	69	18	13
Mexico	62	22	16	19	23	57
Netherlands	65	8	27	14	6	79
New Zealand	80	11	8	26	33	41
Norway	78	10	12	37	16	47
Poland	75	18	7	31	53	16
Portugal	77	8	16	37	15	49
Slovakia	80	12	8	35	37	29
Slovenia	87	8	4	57	37	6
Spain	81	5	14	39	11	50
Sweden	79	9	12	22	19	59
Switzerland	81	5	14	43	17	40
Turkey	71	28	1	53	45	2
United Kingdom	75	6	19	22	13	65

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: Numbers might not sum to totals because of rounding.

Appendix B. Supplemental Results

Tables B.1 and B.2 list calculated price indexes for each bilateral comparison (that is, the United States versus each comparison country individually and the United States versus all comparison countries combined). The tables cover each set of results summarized in the body of the report. Table B.2 focuses on different sensitivity analyses around the extreme price outlier exclusion criteria.

Table B.1. Calculated U.S. Versus Other Countries' Price Indexes, 2022

Country	Main Results	Brand-Name Originator Drugs	Top 60 Drugs by U.S. Sales	Unbranded Generics Without Biologics	Unbranded Generics and Brand-Name Non-Originators	Biologics	Nonbiologics	Other Country Weights	Fisher Index	Active Ingredient Level	Retail Prices	U.S. Net Price Adjustment	Brand-Name Originators with Net Price Adjustment
United States	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
All countries excluding the United States	277.59	422.23	504.32	66.83	99.59	359.27	226.29	458.10	356.60	320.24	172.94	277.59	380.81
Australia	369.89	500.45	590.91	62.92	80.34	416.68	334.69	518.89	438.10	305.03	230.44	369.89	437.95
Austria	276.24	378.71	462.88	37.95	69.39	324.28	237.16	385.41	326.29	219.49	172.10	276.24	377.21
Belgium	320.61	414.46	477.76	49.06	89.79	355.23	288.23	363.11	341.20	282.19	199.74	320.61	434.95
Canada	228.92	324.00	374.37	39.11	58.49	272.06	195.55	318.42	269.99	214.97	142.62	228.92	276.03
Chile	259.87	748.46	716.18	76.42	40.23	530.55	205.91	439.00	337.77	267.09	161.90	259.87	499.89
Colombia	267.00	1,164.92	1,138.24	48.50	41.66	916.35	189.10	451.40	347.17	251.57	166.34	267.00	778.85
Czechia	353.72	453.29	552.98	54.38	106.33	393.79	314.16	489.54	416.13	317.49	220.37	353.72	534.56
Estonia	503.15	1,073.82	1,251.75	50.80	69.65	1,110.83	352.62	787.85	629.61	418.40	313.46	503.15	743.49
Finland	322.81	422.05	471.98	65.30	88.92	353.54	294.84	530.21	413.71	271.52	201.11	322.81	444.07
France	326.41	445.02	516.14	52.52	88.71	374.01	280.21	394.26	358.73	275.28	203.35	326.41	426.01
Germany	294.18	387.00	441.34	56.44	86.97	326.46	264.22	419.83	351.43	255.42	183.27	294.18	320.30
Greece	406.79	870.84	829.62	52.63	81.98	630.31	325.17	586.31	488.37	347.75	253.43	406.79	598.49
Hungary	388.73	513.11	551.52	64.30	112.37	417.40	363.87	521.37	450.19	360.34	242.18	388.73	500.67
Ireland	291.64	396.62	422.42	43.89	78.26	324.25	264.05	456.43	364.85	249.49	181.69	291.64	396.00
Italy	268.03	355.29	406.30	46.00	93.26	307.00	234.13	352.61	307.42	241.21	166.98	268.03	568.77
Japan	347.07	464.34	591.11	48.60	94.74	446.75	268.40	587.67	451.62	327.84	216.22	347.07	390.57
Korea	391.29	702.71	837.19	24.96	52.62	572.87	293.49	523.26	452.49	373.72	243.77	391.29	707.92
Latvia	495.01	747.29	842.14	55.44	78.31	714.55	383.58	673.32	577.32	406.18	308.39	495.01	659.51
Lithuania	426.50	624.65	666.72	62.93	106.03	518.91	354.26	615.37	512.30	369.03	265.71	426.50	605.23
Luxembourg	413.56	660.86	709.53	48.10	81.42	585.01	321.40	524.61	465.79	318.65	257.65	413.56	442.69
Mexico	172.16	401.52	425.52	50.59	45.50	325.93	122.32	244.18	205.03	186.24	107.25	172.16	311.10
Netherlands	333.17	589.15	627.21	66.11	93.67	400.25	303.53	570.50	435.97	281.58	207.57	333.17	432.88
New Zealand	288.07	371.51	394.21	84.52	121.97	299.19	279.95	503.68	380.91	278.03	179.46	288.07	378.05
Norway	248.17	417.11	441.24	42.69	57.24	330.61	196.87	476.98	344.05	218.00	154.61	248.17	408.35
Poland	403.68	525.16	649.87	79.41	118.83	481.49	343.38	540.51	467.11	420.50	251.49	403.68	603.32
Portugal	402.04	518.49	602.17	74.06	112.85	443.55	365.83	544.12	467.72	328.99	250.47	402.04	635.49

Country	Main Results	Brand-Name Originator Drugs	Top 60 Drugs by U.S. Sales	Unbranded Generics Without Biologics	Unbranded Generics and Brand-Name Non-Originators	Biologics	Nonbiologics	Other Country Weights	Fisher Index	Active Ingredient Level	Retail Prices	U.S. Net Price Adjustment	Brand-Name Originators with Net Price Adjustment
Slovakia	442.07	565.88	626.36	83.08	136.42	484.93	398.37	597.13	513.79	330.45	275.41	442.07	519.69
Slovenia	423.92	582.82	691.25	51.68	87.87	514.75	355.14	538.60	477.83	329.54	264.10	423.92	518.86
Spain	284.22	361.86	447.95	44.45	80.48	322.56	249.66	402.01	338.02	267.67	177.07	284.22	620.93
Sweden	333.19	418.15	466.45	71.48	98.81	336.89	329.19	505.86	410.55	293.90	207.58	333.19	392.85
Switzerland	218.87	339.33	376.04	19.07	38.07	282.31	172.73	317.71	263.70	195.68	136.36	218.87	293.30
Turkey	1,028.36	1,580.84	1,456.68	178.27	235.60	1,069.64	985.05	1,489.05	1,237.45	996.16	640.67	1,028.36	1,611.12
United Kingdom	270.04	384.80	438.75	46.85	79.11	326.27	226.04	392.42	325.53	273.55	168.23	270.04	434.47

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: We did not calculate a retail price comparison for the U.S. versus Colombia because we did not have a separate IQVIA manufacturer-to-retail conversion factor for Colombia.

**Table B.2. Calculated Price Indexes, U.S. Versus Other Countries' Drugs, Exclusion Criteria
Sensitivity Analyses, 2022**

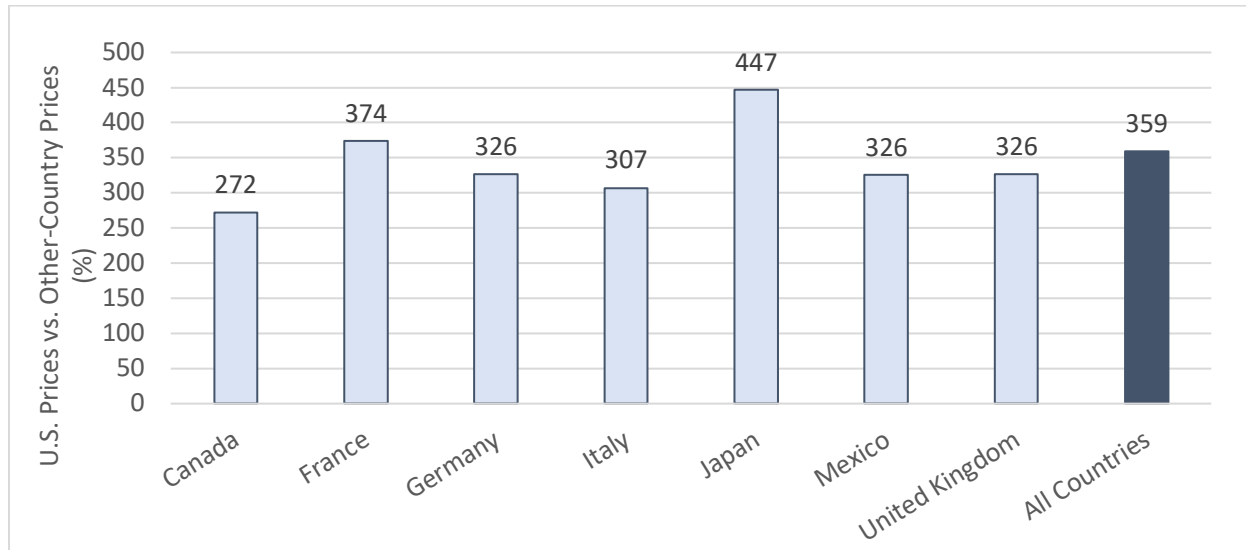
Country	Scenario 1: No Cleaning Steps	Scenario 2: Volume or Sales (\$) > 1,000; No Other Exclusions	Scenario 3: Volume or Sales (\$) > 1,000; 0.1%–1,000x Price Ratio Exclusion	Scenario 4: Main Results	Scenario 5: Volume or Sales (\$) > 1,000; 10%–10x Price Ratio Exclusion
United States	100.00	100.00	100.00	100.00	100.00
All countries excluding the United States	237.22	232.19	231.20	229.39	227.96
Australia	291.79	277.64	275.99	275.47	255.51
Austria	228.57	224.42	224.42	223.16	207.17
Belgium	269.34	257.08	257.06	256.45	226.29
Canada	221.74	210.78	210.78	209.95	206.24
Chile	192.15	182.49	182.38	182.36	224.24
Colombia	211.06	150.40	150.40	157.14	200.11
Czechia	327.44	300.12	300.08	299.30	259.45
Estonia	470.96	351.03	351.03	348.93	259.92
Finland	264.81	240.52	240.52	237.15	221.99
France	263.38	248.82	248.82	247.91	233.23
Germany	229.98	223.84	223.82	222.91	212.83
Greece	382.86	343.19	343.19	340.95	260.23
Hungary	315.23	271.68	271.68	270.84	251.69
Ireland	283.79	248.23	248.23	247.00	234.40
Italy	257.14	250.80	250.80	250.16	236.14
Japan	224.58	196.28	196.28	195.97	224.21
Korea	327.73	298.53	298.38	297.25	257.84
Latvia	405.47	326.19	326.19	325.12	266.54
Lithuania	429.17	326.76	326.76	326.61	271.46
Luxembourg	345.60	310.52	310.52	309.26	264.30
Mexico	184.23	166.91	166.91	177.24	221.06
Netherlands	291.82	279.57	279.57	278.02	256.87
New Zealand	279.69	262.44	262.44	259.48	240.62
Norway	237.35	224.22	224.22	223.30	226.45
Poland	373.99	302.49	302.49	301.63	254.16
Portugal	324.73	307.47	307.46	305.65	279.76
Slovakia	357.99	367.12	367.12	366.45	313.16
Slovenia	332.06	303.39	303.39	303.17	260.55
Spain	266.15	256.08	256.06	254.56	227.55
Sweden	272.49	270.87	270.87	270.19	247.16
Switzerland	182.79	179.53	179.52	179.39	191.93
Turkey	760.48	704.40	703.20	699.48	336.45
United Kingdom	278.19	263.60	263.58	261.72	252.81

SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

Biologics and Nonbiologics

Figures B.1 and B.2 illustrate compared prices for biologics and nonbiologics, respectively.⁶² U.S. prices are higher than prices in all comparison countries for both biologics and nonbiologics, at 359 percent and 226 percent, respectively, of prices in all other countries combined; these higher prices are likely driven by brand-name originator drugs.

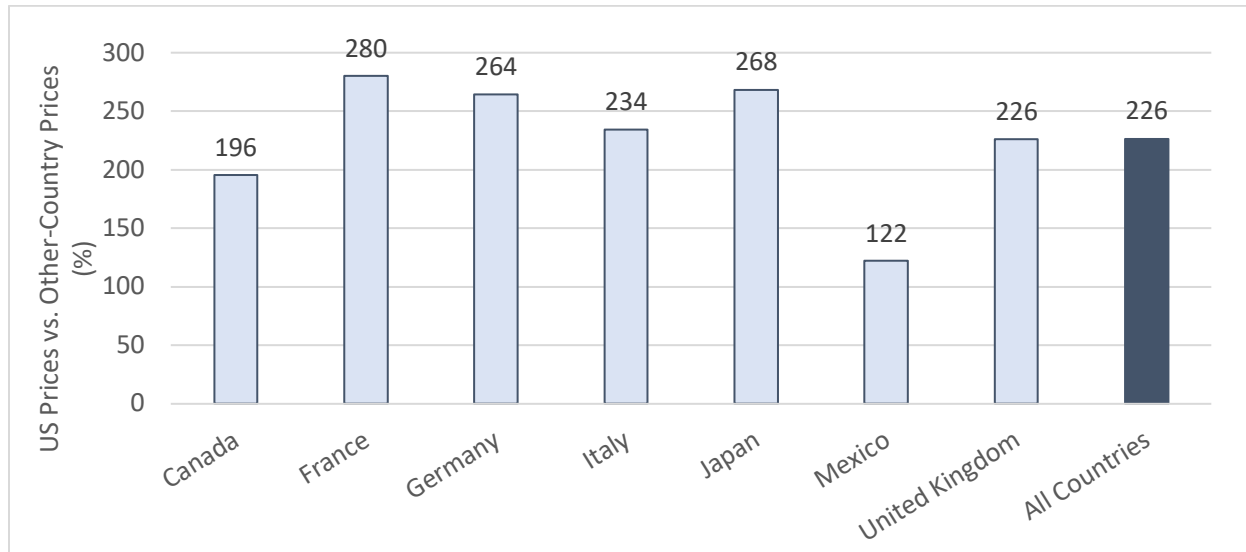
Figure B.1. U.S. Biologic Prices as a Percentage of Other Countries' Prices, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

⁶² We rely on the assignment of each active ingredient to a biologic and nonbiologic category in MIDAS. Biosimilars are categorized as biologics. Small-molecule brand and generic drugs that are not biologics are categorized as nonbiologics.

Figure B.2. U.S. Nonbiologic Drug Prices as a Percentage of Other Countries' Prices, 2022

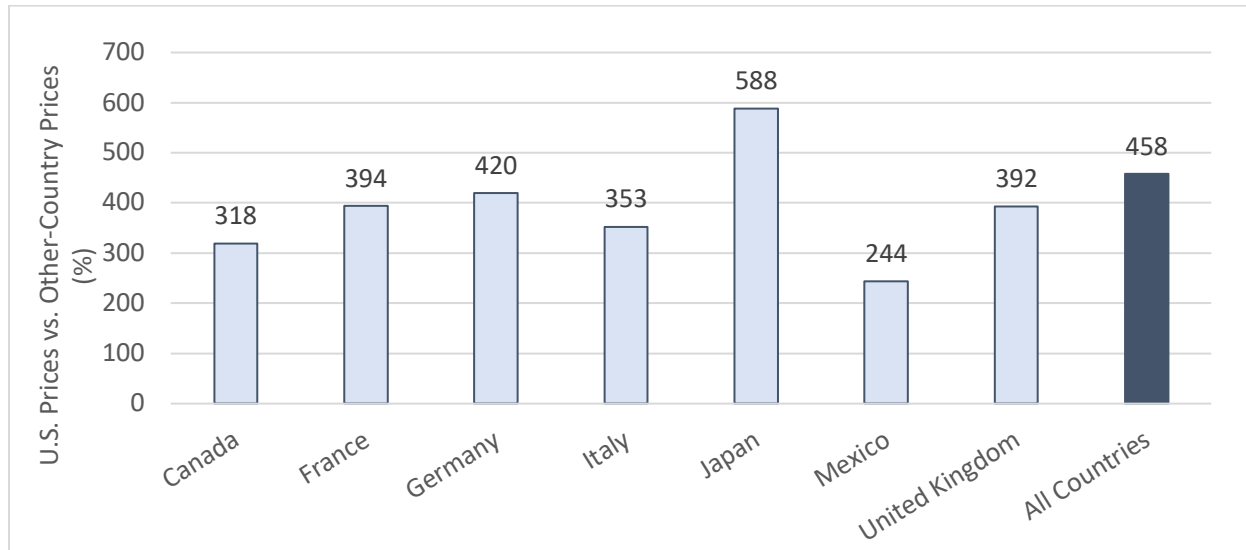


SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Results from Robustness Checks

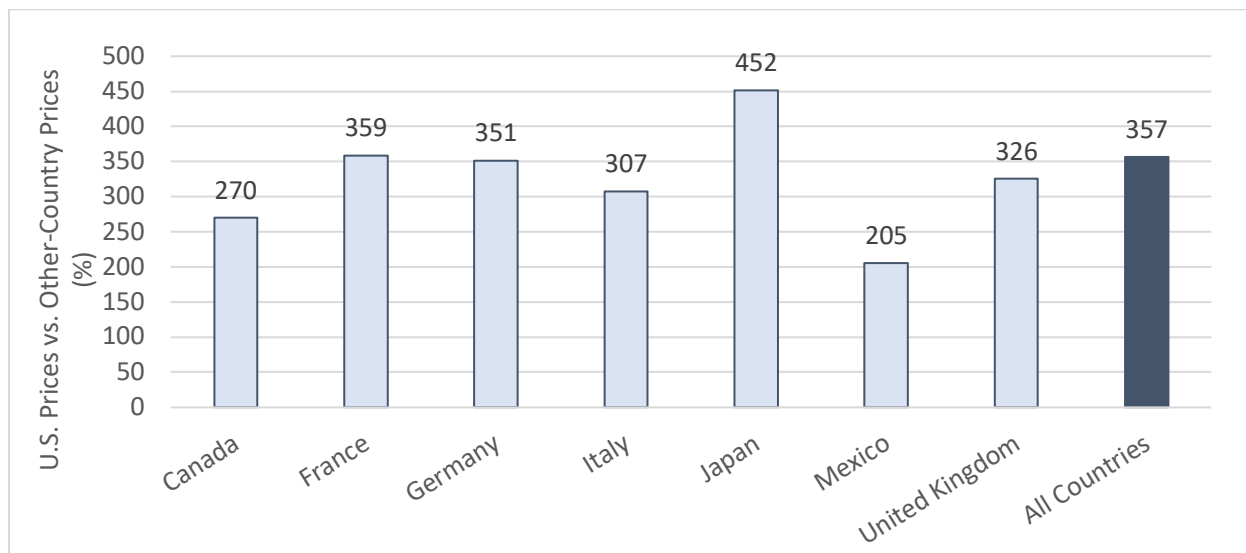
Figures B.3 and B.4 present results from a sensitivity analysis using other countries' volume weights (Figure B.3) and blended volume weights (Figure B.4) rather than U.S. volume weights. Compared with the main results, U.S. prices are even higher than other countries' prices in these sensitivity analyses. U.S. prices were 458 percent of prices in other countries when using other countries' weights and 357 percent of prices in other countries when using a blended rate (the geometric mean to calculate what is called the Fisher index), compared with 278 percent in our main results. When using other countries' weights, higher U.S. prices are expected if prescribing patterns outside the United States are skewed toward drugs with favorable prices in individual countries because of price controls and/or volume purchasing.

Figure B.3. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, Other Countries' Volume Weights, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

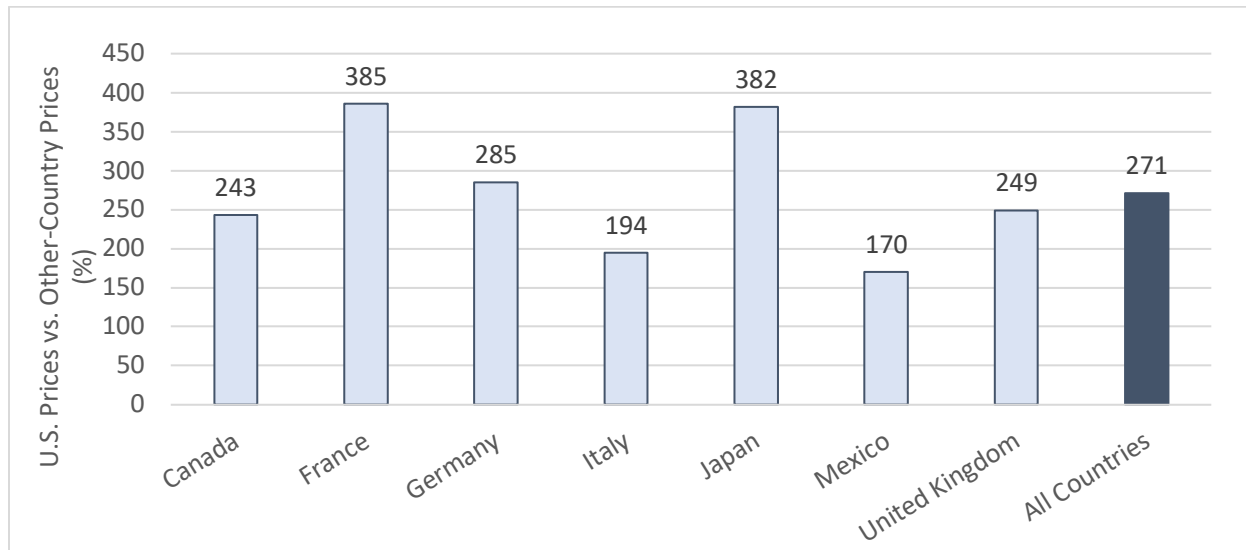
Figure B.4. U.S. Prescription Drug Prices as a Percentage of Other Countries' Prices, Blended Volume Weights (Fisher Index), 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).
NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Figure B.5 presents price comparisons using retail prices rather than manufacturer prices. U.S. prices are still notably higher than prices in other countries (271 percent, compared with 278 percent in our main results using manufacturer prices). Other countries' prices increase when using retail prices rather than manufacturer prices in some bilateral comparisons (for example, for Germany, Italy, Mexico, and the United Kingdom), likely because of higher wholesale and retail markups in these countries.

Figure B.5. U.S. Prescription Drug Retail Prices as a Percentage of Other Countries' Prices, 2022



SOURCE: Authors' analysis of 2022 sales and volume data from IQVIA, undated (run date May 19, 2023).

NOTE: *All Countries* refers to all 33 OECD comparison countries combined. Other countries' prices are set to 100. Only some presentations sold in each country contribute to bilateral comparisons.

Abbreviations

CMS	Centers for Medicare & Medicaid Services
G7	Group of Seven (Canada, France, Germany, Italy, Japan, the United Kingdom, and the United States)
OECD	Organisation for Economic Co-operation and Development
PBM	pharmacy benefit manager
WAC	wholesale acquisition cost

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NHE Fact Sheet

Historical NHE, 2024:

- NHE grew 7.2% to \$5.3 trillion in 2024, or \$15,474 per person, and accounted for 18.0% of Gross Domestic Product (GDP).
- Medicare spending grew 7.8% to \$1,118.0 billion in 2024, or 21 percent of total NHE.
- Medicaid spending grew 6.6% to \$931.7 billion in 2024, or 18 percent of total NHE.
- Private health insurance spending grew 8.8% to \$1,644.6 billion in 2024, or 31 percent of total NHE.
- Out of pocket spending grew 5.9% to \$556.6 billion in 2024, or 11 percent of total NHE.
- Other Third Party Payers and Programs and Public Health Activity spending declined 7.0% in 2024 to \$590.5 billion, or 11 percent of total NHE.
- Hospital expenditures grew 8.9% to \$1,634.7 billion in 2024, slower than the 10.6% growth in 2023.

- Physician and clinical services expenditures grew 8.1% to \$1,109.7 billion in 2024, faster growth than the 7.4% in 2023.
- Prescription drug spending increased 7.9% to \$467.0 billion in 2024, slower than the 10.8% growth in 2023.
- The largest shares of total health spending were sponsored by the federal government (31 percent) and the households (28 percent). The private business share of health spending accounted for 18 percent of total health care spending, state and local governments accounted for 16 percent, and other private revenues accounted for 6 percent.

For further detail see NHE Tables in downloads below.

Projected NHE, 2024-2033:

- Over 2024-33 average NHE growth (5.8 percent) is projected to outpace that of average Gross Domestic Product (GDP) growth (4.3 percent), resulting in an increase in the health spending share of GDP from 17.6 percent in 2023 to 20.3 percent in 2033.
- 2024 NHE growth is projected to have been 8.2 percent and to have reflected a continued rebound in the growth of use of services and goods, as well as the high insured share of the population.
- The insured share of the population in 2024 is projected to have remained high, at 92.1 percent, despite Medicaid enrollment projected to have declined by 7.9 percent (to 84.5 million) following

the expiration of the Families First Coronavirus Response Act's (FFCRA) continuous enrollment provision.

- Direct-purchase enrollment is expected to decline by 4.7 million in 2026 (-12.3 percent) due to the expiration of the Inflation Reduction Act's (IRA) temporary extension of enhanced subsidies and associated temporary Special Enrollment Period (SEP).

For further detail see NHE projections 2024-2033 in downloads below.

NHE by Age Group and Sex, Selected Years 2002, 2004, 2006, 2008, 2010, 2012, 2014, 2016, 2018, and 2020:

- Per person personal health care spending for the 65 and older population was \$22,356 in 2020, over 5 times higher than spending per child (\$4,217) and almost 2.5 times the spending per working-age person (\$9,154).
- In 2020, children accounted for approximately 23 percent of the population and about 10 percent of all PHC spending.
- The working-age group comprised the majority of spending and population in 2014, 53 percent and over 60 percent respectively.
- Older Adults (aged 65 and older) were the smallest population group, about 17 percent of the population, and accounted for approximately 37 percent of all spending in 2020.

- Per person spending for females (\$10,887) was 14 percent more than males (\$9,554) in 2020.
- In 2020, per person spending for male children (0-18) was 10 percent more than females. However, for working age adults per person spending for females was 20 percent more than for males. For older adults, spending for males was 2 percent more than for females.

For further detail see health expenditures by age in downloads below.

NHE by State of Residence, 1991-2020:

- In 2020, per capita personal health care spending ranged from \$7,522 in Utah to \$14,007 in New York. Per capita spending in New York state was 37 percent higher than the national average (\$10,191) while spending in Utah was about 26 percent lower.
- Health care spending by region continued to exhibit considerable variation. In 2020, the New England and Mideast regions had the highest levels of total per capita personal health care spending (\$12,728 and \$12,577, respectively), or 25 and 23 percent higher than the national average. In contrast, the Rocky Mountain and Southwest regions had the lowest levels of total personal health care spending per capita (\$8,497 and \$8,587, respectively) with average spending 17 and 16 percent lower than the national average, respectively.

- Between 2014 and 2020, average growth in per capita personal health care spending was highest in New York at 6.1 percent per year and lowest in Wisconsin at 3.0 percent per year (compared with average growth of 4.3 percent nationally).
- The spread between the highest and the lowest per capita personal health spending across the states has remained relatively stable over 2014-20. Accordingly, the highest per capita spending levels were 90 to 100 percent higher per year than the lowest per capita spending levels during the period.
- Medicare expenditures per beneficiary were highest in Florida (\$13,652) and lowest in Vermont (\$8,726) in 2020.
- Medicaid expenditures per enrollee were highest in North Dakota (\$12,314) and lowest in Georgia (\$4,754) in 2020.

For further detail, see health expenditures by state of residence in downloads below.

NHE by State of Provider, 1980-2020:

- Between 2014 and 2020, U.S. personal health care spending grew, on average, 4.8 percent per year, with spending in Arizona growing the fastest (6.6 percent) and spending in Vermont growing the slowest (2.7 percent).
- In 2020, California's personal health care spending was highest in the nation (\$410.9 billion), representing 12.2 percent of total U.S. personal health care spending. Comparing historical state rankings

through 2020, California consistently had the highest level of total personal health care spending, together with the highest total population in the nation. Other large states, New York, Texas, Florida, and Pennsylvania, also were among the states with the highest total personal health care spending.

- Wyoming's personal health care spending was lowest in the nation (as has been the case historically), representing just 0.1 percent of total U.S. personal health care spending in 2020. Vermont, North Dakota, Alaska, and Montana were also among the states with the lowest personal health care spending in both 2020 and historically. All these states have smaller populations.
- Gross Domestic Product (GDP) by state measures the value of goods and services produced in each state. Health spending as a share of a state's GDP shows the importance of the health care sector in a state's economy. As a share of GDP, West Virginia ranked the highest (28.7 percent) and Washington state the lowest (11.7 percent) in 2020.

For further detail, see health expenditures by state of provider in downloads below.



Downloads

[Health expenditures by state of residence:
summary tables \(ZIP\)](#)

[Health expenditures by state of provider: summary
tables \(ZIP\)](#)

[NHE Tables \(ZIP\)](#)

[Age and Sex Tables \(ZIP\)](#)

[NHE Projections - Tables \(ZIP\)](#)

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Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026



CENTERS FOR MEDICARE & MEDICAID SERVICES

In August 2022, President Biden signed the Inflation Reduction Act of 2022 (P.L. 117-169) into law. The law makes improvements to Medicare by expanding benefits, lowering drug costs, and improving the sustainability of the Medicare program for generations to come. The law provides meaningful financial relief for millions of people with Medicare by improving access to affordable treatments and strengthening Medicare, both now and in the long run.

For the first time, the law provides Medicare the ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition. The Centers for Medicare & Medicaid Services (CMS) **selected** ten drugs covered under Medicare Part D for the first cycle of negotiations for initial price applicability year 2026 and engaged in voluntary negotiations with the drug companies for the selected drugs. Below is the list of negotiated prices, which the statute refers to as Maximum Fair Prices (MFPs), for 10 drugs covered under Medicare Part D that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies.

CMS negotiated in good faith consistent with the requirements of the law on behalf of people with Medicare and the Medicare program. Throughout the negotiation process, the CMS team took into account the factors outlined in the law in negotiating these prices, which supports the need for innovation and drug development with better prices for people with Medicare and the Medicare program.

CMS engaged in genuine, thoughtful negotiations with each participating drug company. CMS developed an initial offer for each drug, consistent with the process described in the statute and the agency's guidance, and each manufacturer responded with a counteroffer. CMS held three meetings with each participating drug company to discuss the offers and counteroffers, discuss evidence, and attempt to arrive at a mutually acceptable price for the drug. During the course of the negotiation process, CMS revised its offers for each of the drugs upward in response to these discussions. Likewise, many drug companies revised their counteroffers for their drugs downward, based on the discussions with CMS. For five of the selected drugs, this process of exchanging revised offers and counteroffers resulted in CMS and the drug company reaching an agreement on a negotiated price for the drug in association with a negotiation meeting. In four of these cases, CMS accepted a revised counteroffer proposed by the drug company. For the remaining five selected drugs, CMS sent a written final offer to those drug companies, consistent with the process described in its guidance, and in each instance, the drug company accepted CMS's offer on or before the statutory deadline.

Impact of the Negotiated Prices

Overall Medicare Spending and Out-of-Pocket Spending in 2023:

For the time period between January 1, 2023, and December 31, 2023, about 8.8 million of the 54 million people with Medicare Part D coverage were dispensed these drugs to treat a variety of conditions, such as cardiovascular disease, diabetes, autoimmune diseases, and cancer. These selected drugs accounted for \$56.2 billion in total Part D gross covered prescription drug costs, or about 20% of total Part D gross covered prescription drug costs during 2023. During that same time period, people with Medicare Part D prescription drug coverage spent \$18.9 billion in out-of-pocket costs for all drugs covered under Part D, including \$3.9 billion out-of-pocket for these drugs selected for negotiation.

Case
1:25-cv-3452-DDD-
STV

Exhibit
36

Estimated Medicare Net Savings in 2023:

Compared to 2023 Medicare spending net of all rebates and certain fees and payments, if the prices agreed to between CMS and participating drug companies under the Negotiation Program had been in effect during 2023, the negotiated prices would have saved an estimated \$6 billion in net covered prescription drug costs, which would have represented 22% lower net spending in aggregate.

Projected Savings for People with Medicare Part D Coverage:

When the negotiated prices go into effect in 2026, people enrolled in Medicare prescription drug coverage would save under the projected defined standard benefit design an estimated \$1.5 billion. These savings from the Negotiation Program are in addition to savings from other cost saving provisions in the Inflation Reduction Act, such as the first ever cap on out-of-pocket drug costs for people with Medicare.

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	\$113.00	\$527.00	79%	\$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	\$119.00	\$495.00	76%	\$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	\$178.50	\$556.00	68%	\$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	\$2,355.00	\$7,106.00	67%	\$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	\$197.00	\$573.00	66%	\$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	\$4,695.00	\$13,836.00	66%	\$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	\$197.00	\$517.00	62%	\$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	\$231.00	\$521.00	56%	\$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	\$295.00	\$628.00	53%	\$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	\$9,319.00	\$14,934.00	38%	\$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

Key Milestones for the First Cycle of Negotiations:

-  **On February 1, 2024** – CMS sent an initial offer for each selected drug, with a concise justification for the initial offer, to each respective participating drug company.
-  **By March 2, 2024** – Each participating drug company responded to the initial offer for a negotiated price with a counteroffer.
-  **Spring/Summer 2024** – CMS and participating drug companies conducted in-person and hybrid negotiation meetings, through which an agreement for a negotiated price was reached for several of the selected drugs.
-  **July 15, 2024** – CMS sent final offers to any participating drug company where an agreement was not reached in connection with the negotiation meetings.
-  **July 15-July 31, 2024** – Participating drug companies where an agreement was not reached in connection with the negotiation meetings had the opportunity to review CMS' final offers and respond to CMS.
-  **August 1, 2024** – The negotiation period ended with agreement reached for negotiated prices between CMS and participating drug companies for 10 selected drugs.

Q: How did CMS structure the negotiation process with the drug companies of selected drugs?

CMS is implementing the new drug law, including the Negotiation Program, with the goal of promoting transparency and engagement. As discussed in detail in the [revised guidance for initial price applicability year 2026](#), CMS set out a process for the first cycle of negotiations that engaged drug companies and the public throughout. The process included several steps, such as:

- Drug companies and the public had an opportunity to submit data and information on the selected drugs to CMS by October 2, 2023.

- During the Fall of 2023, CMS invited each participating drug company to engage in a meeting on its data submission. Additionally, CMS held public Patient-Focused Listening Sessions for each selected drug with patients and other interested parties.
- CMS sent an initial offer to the participating drug company reflecting CMS' proposal for a negotiated price and a concise justification of the initial offer on February 1, 2024. In developing an initial offer, CMS considered the factors set out by the statute, including evidence related to therapeutic alternatives as well as other factors, such as costs of research and development and production and distribution of the selected drug.
- Participating drug companies had 30 days to respond to the initial offer by accepting the offer or providing a counteroffer, if desired.
- After receiving counteroffers from participating drug companies, CMS and each participating drug company conducted three negotiation meetings during Spring and Summer 2024.
- The negotiation period ended on August 1, 2024.

Q: What information did CMS consider during the negotiations with participating drug companies?

In accordance with the Inflation Reduction Act, CMS considered the statutory factors listed at section 1194(e) of the Social Security Act in determining its initial offers, revised offers, and final offers.

Specifically, for the factors listed at section 1194(e)(1), CMS considered information reported by participating drug companies. This included manufacturer-submitted data on research and development costs, prior federal financial support, unit costs of production and distribution, market/revenue/sales data, and information on patents, FDA exclusivities, and FDA applications and approvals. For the factors listed at section 1194(e)(2) related to evidence about alternative treatments (including therapeutic advances, prescribing information, comparative effectiveness, and unmet medical need), CMS considered information from a wide variety of sources, including: information submitted by participating drug companies, people with Medicare, academic experts, clinicians, caregivers, and other interested parties in response to Information

Collection Requests issued for the Negotiation Program; information provided at the Patient-Focused Listening Sessions hosted by CMS in the Fall of 2023; information shared by participating drug companies during meetings with CMS; and information CMS identified from its own literature searches, including from clinical guidelines and published studies.

Q: How did CMS reach an agreement with participating drug companies on negotiated prices?

CMS engaged in good-faith negotiations with participating drug companies throughout the negotiation period, including through written offers, counteroffer exchanges, and three negotiation meetings for each drug. For certain selected drugs, negotiation meetings resulted in CMS' agreement to the drug company's proposal for a negotiated price or the drug company's agreement to CMS' proposal for a negotiated price, whereas for other selected drugs, agreement was reached with the written final offer.

Q: How does the Medicare program benefit from these negotiations?

Medicare's new ability to negotiate prices for selected drugs will improve drug affordability for people with Medicare, improving access to innovative life-saving treatments for people who need them. If the negotiated prices had been in effect during 2023, compared to the 2023 Medicare prices net of all rebates and certain fees and payments, the negotiated prices would have saved an estimated \$6 billion in 2023 across the 10 drugs, which would have amounted to approximately 22% in savings.

Q: How will people with Medicare get access to these prices? When will these prices be effective?

These negotiated prices will become effective on January 1, 2026. A participating drug company with a selected drug is required to ensure the negotiated price is made available to eligible individuals and to the pharmacies, mail-order services, and other entities that dispense the selected drug to such individuals.

As required by law, Medicare prescription drug plans, including standalone Part D plans and Medicare Advantage-prescription drug plans, must include in their formularies the selected drugs for which CMS and the participating drug company have agreed to a negotiated

price. CMS will use its comprehensive formulary review process for Medicare prescription drug plans to assess any practices that may undermine access to selected drugs for people with Medicare.

CMS will make public an explanation of the agreed-upon negotiated prices by March 2025.

Q: How long do these Negotiated Prices apply? Are they adjusted over time?

In accordance with the Inflation Reduction Act, the negotiated price will apply to a selected drug so long as the selected drug remains in the Medicare Drug Price Negotiation Program. For each year after the first initial price applicability year, CMS will publish an updated negotiated price for each selected drug. The updated price will be equal to the negotiated price that was published for such drug for the previous year, increased by the annual percentage increase in the Consumer Price Index for all urban consumers (United States city average) (CPI-U). The negotiated price of a selected drug would also be updated should CMS and the Primary Manufacturer renegotiate the negotiated price of the selected drug.

Q: How will these negotiated prices impact drugs selected for the second cycle of negotiations?

On May 3, 2024, CMS published **draft guidance for initial price applicability year 2027 (the "draft guidance")**. This draft guidance details requirements and parameters for the second cycle of negotiations for the Negotiation Program, which will occur during 2025 and may result in negotiated prices that would be effective beginning in 2027. If a drug selected for the first cycle of negotiations has a negotiated price and is subsequently identified as a therapeutic alternative to a drug selected for the second cycle of negotiations, the agreed-upon negotiated price from this first cycle of negotiations could serve as an input into the initial offer development process for the drug selected for the second cycle of negotiations. CMS solicited comment on this policy in the draft guidance.



THE WHITE HOUSE
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FACT SHEETS

Fact Sheet: President Donald J. Trump Launches TrumpRx.gov to Bring Lower Drug Prices to American Patients

The White House

February 5, 2026

Case
1:25-cv-3452-DDD-
STV

Exhibit
37

HISTORIC LAUNCH TO LOWER DRUG PRICES FOR AMERICAN PATIENTS: Today, President Donald J. Trump announced the launch of TrumpRx.gov. Through the website, patients will be able to access large discounts on many of the most popular and highest-priced medicines in the country, paying prices in line with the lowest paid by other developed nations (known as the most-favored-nation, or MFN, price).

- Today's launch features drugs made by the first five manufacturers to reach MFN pricing deals with the Trump Administration: AstraZeneca, Eli Lilly, EMD Serono, Novo Nordisk, and Pfizer.
- Additional drugs from other companies that have signed MFN pricing deals will be made available through TrumpRx.gov in the coming months.
- TrumpRx.gov provides patients with access to a world-class experience for accessing deep discounts on the medicines they need. Depending on the manufacturer of a given drug, patients with valid prescriptions will be able to access savings through user-friendly coupons that can be printed or downloaded onto their phones or through channels set up by the manufacturer and integrated into TrumpRx.gov.

DELIVERING LOWER COSTS ON THE MOST POPULAR DRUGS: As of today, patients purchasing directly through TrumpRx.gov will be able to see massive price reductions on 40 of the most popular and expensive branded medicines in the nation. Select examples include:

- Historic price reductions for Americans on the two drugs with the highest annual expenditures in the United States, which help adults struggling with diabetes, heart disease (Ozempic and Wegovy only), obesity, and other conditions.
 - The monthly prices of Ozempic and injectable Wegovy will fall from \$1,028 and \$1,349, respectively, to an average price of \$350 and as low as \$199, depending on dosage

strength. The monthly price of the Wegovy pill will fall from \$1,349 to as low as \$149, depending on dosage strength.

- The monthly price of Zepbound will fall from \$1,088 to an average price of \$346 and as low as \$299, depending on dosage strength.
- Massive savings on some of the most commonly used fertility medications in the country to help families grow. Many patients struggling with infertility pay for their medicines out-of-pocket, meaning they will stand to save more than \$2,000 per cycle of fertility drugs, on average.
 - Gonal-F, one of the most commonly-used fertility drugs, will see its price reduced to as low as \$168 per pen, depending on dosage strength.
 - The price of Cetrotide, another commonly used fertility medicine, will drop from \$316 to \$22.50.
 - The price of Ovidrel will fall from \$251 to \$84.
- Discounts on numerous other high-cost drugs, including:
 - Bevespi Aerosphere, an inhaler used to treat chronic obstructive pulmonary disease (COPD), will be discounted from \$458 to \$51.
 - Airsupra, an inhaler used to treat asthma symptoms and attacks, will see a price drop from \$504 to \$201.
 - Eucrisa, a topical ointment for atopic dermatitis, will be discounted from \$792 to \$158.
 - Insulin Lispro will be available for as low as \$25 per month.
 - Duavee, a medication used to treat hot flashes and osteoporosis, will see its price cut from \$202 to \$30.

DELIVERING ON PROMISES TO PUT AMERICAN PATIENTS FIRST: President Trump is delivering on promises to ensure American patients no longer pay high prices to subsidize low prices in the rest of the world, something the political establishment did not believe was possible.

- On May 12, 2025, President Trump signed an Executive Order titled: “Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients” directing the Administration to take numerous actions to bring American drug prices in line with those paid by similar nations.
- On July 31, 2025, President Trump sent letters to leading pharmaceutical manufacturers outlining the steps they must take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations.
- Since September 30, 2025, President Trump has announced 16 deals with major pharmaceutical manufacturers to bring prices in line with those paid in other developed nations, which will provide substantial price relief on numerous products taken by millions of Americans.

- On December 1, 2025, the Office of the United States Trade Representative, the Department of Commerce, and the Department of Health and Human Services announced an agreement with the United Kingdom (U.K.) that will increase the net price of new prescription drugs by 25% in the U.K., helping ensure that they pay their fair share for innovative medicines.
- On January 15, 2026, President Trump called on Congress to enact The Great Healthcare Plan, which would lower drug prices by codifying the savings from his Most-Favored-Nation pricing initiative, lower insurance premiums, hold insurance companies accountable, and maximize price transparency.

Related

President Trump Launches TrumpRx.gov, Delivering Massive, Immediate Savings to Millions of Americans

Releases | February 6, 2026

Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most-Favored-Nation Pricing to American Patients

Fact Sheets | November 6, 2025

Fact Sheet: President Donald J. Trump Announces Largest Developments to Date in Bringing Most-Favored-Nation Pricing to American Patients

Fact Sheets | December 19, 2025

Fact Sheet: President Donald J. Trump Announces Actions to Lower Costs and Expand Access to In Vitro Fertilization (IVF) and High-Quality Fertility Care

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Fact Sheet: President Donald J. Trump Announces Second Deal to Bring Most-Favored-Nation Pricing to American Patients

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An Act

SENATE BILL 21-175

BY SENATOR(S) Jaquez Lewis and Gonzales, Buckner, Bridges, Moreno; also REPRESENTATIVE(S) Caraveo and Kennedy, Amabile, Bacon, Bernett, Bird, Boesenecker, Cutter, Duran, Esgar, Exum, Froelich, Gonzales-Gutierrez, Herod, Hooton, Jackson, Jodeh, Kipp, Lontine, McCluskie, McCormick, Michaelson Jenet, Mullica, Ortiz, Roberts, Sirota, Sullivan, Titone, Valdez A., Weissman, Woodrow, Garnett.

CONCERNING THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD, AND, IN CONNECTION THEREWITH, DIRECTING THE BOARD TO REVIEW THE AFFORDABILITY OF CERTAIN DRUGS AND ESTABLISH UPPER PAYMENT LIMITS FOR CERTAIN DRUGS; PROHIBITING CERTAIN ENTITIES FROM PURCHASING OR REIMBURSING FOR ANY DRUG FOR DISTRIBUTION IN THE STATE AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT ESTABLISHED FOR THE PRESCRIPTION DRUG; ESTABLISHING PENALTIES FOR VIOLATIONS; AND MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly finds that:

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(a) Excessive costs for prescription drugs:

(I) Negatively impact the ability of Coloradans to obtain prescription drugs, and price increases that exceed reasonable levels endanger the health and safety of Coloradans;

(II) Threaten the economic well-being of Coloradans and endanger their ability to pay for other necessary and essential goods and services, including housing, food, and utilities;

(III) Contribute significantly to a dramatic and unsustainable rise in health-care costs and health insurance premiums that threatens the financial health of Coloradans and their ability to maintain their physical health;

(IV) Pose a threat to the health and safety of all Coloradans but disproportionately harm people of color and Coloradans with low incomes; and

(V) Contribute significantly to rising costs for health care that is provided to public employees, including employees of state, county, and local governments, school districts, and institutions of higher education, and to public retirees whose health-care costs are funded by public programs, thereby threatening the ability of state and local governments to adequately fund those programs and other important services, such as public education and public safety;

(b) Lack of transparency in health insurance costs and wholesaler and pharmacy benefits manager discounts and margins prevents policymakers and the public from gaining a true understanding of the costs of prescription drugs; and

(c) Information relating to the cost of prescription drugs in Colorado is necessary to provide accountability to the state and to all Coloradans for prescription drug pricing.

(2) The general assembly therefore declares that in exercise of its police powers and responsibility for the public health, safety, and general welfare of Colorado residents, it is imperative that Colorado take measures to reduce excessive prescription drug costs for Coloradans who cannot afford prescription drugs and create a prescription drug affordability board

with the authority to review prescription drug costs and protect Colorado residents and entities who purchase or reimburse for prescription drugs from the excessive costs of prescription drugs, including but not limited to state and local governments, contractors and vendors, commercial health plans, providers, and pharmacies.

SECTION 2. In Colorado Revised Statutes, **add** part 14 to article 16 of title 10 as follows:

PART 14
COLORADO PRESCRIPTION DRUG
AFFORDABILITY REVIEW BOARD

10-16-1401. Definitions. AS USED IN THIS PART 14, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(1) "ADVISORY COUNCIL" MEANS THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION 10-16-1409.

(2) "AFFORDABILITY REVIEW" MEANS AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG PERFORMED BY THE BOARD PURSUANT TO SECTION 10-16-1406.

(3) "ALL-PAYER HEALTH CLAIMS DATABASE" MEANS THE ALL-PAYER HEALTH CLAIMS DATABASE DESCRIBED IN SECTION 25.5-1-204.

(4) "AUTHORIZED GENERIC DRUG" HAS THE MEANING SET FORTH IN 42 CFR 447.502.

(5) "BIOLOGICAL PRODUCT" HAS THE MEANING SET FORTH IN 42 U.S.C. SEC. 262 (i)(1).

(6) "BIOSIMILAR DRUG" MEANS A PRESCRIPTION DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICAL PRODUCT LICENSE ISSUED PURSUANT TO 42 U.S.C. SEC. 262 (k)(3).

(7) "BOARD" MEANS THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402.

(8) "BRAND-NAME DRUG" MEANS A PRESCRIPTION DRUG THAT IS

PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH AN ORIGINAL NEW DRUG APPLICATION APPROVED PURSUANT TO 21 U.S.C. SEC. 355. "BRAND-NAME DRUG" DOES NOT INCLUDE AN AUTHORIZED GENERIC DRUG.

(9) "CARRIER" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (8).

(10) "CONFLICT OF INTEREST" MEANS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR APPEAR TO BIAS AN INDIVIDUAL'S DECISIONS IN MATTERS RELATED TO THE BOARD OR THE ADVISORY COUNCIL OR THE CONDUCT OF THE ACTIVITIES OF THE BOARD OR THE ADVISORY COUNCIL. "CONFLICT OF INTEREST" INCLUDES ANY INSTANCE IN WHICH A BOARD MEMBER; AN ADVISORY COUNCIL MEMBER; A STAFF MEMBER; A CONTRACTOR OF THE DIVISION, ON BEHALF OF THE BOARD; OR AN IMMEDIATE FAMILY MEMBER OF A BOARD MEMBER, AN ADVISORY COUNCIL MEMBER, A STAFF MEMBER, OR A CONTRACTOR OF THE DIVISION, ON BEHALF OF THE BOARD, HAS RECEIVED OR COULD RECEIVE:

(a) A FINANCIAL BENEFIT OF ANY AMOUNT DERIVED FROM THE RESULTS OR FINDINGS OF A STUDY OR DETERMINATION THAT IS REACHED BY OR FOR THE BOARD; OR

(b) A FINANCIAL BENEFIT FROM AN INDIVIDUAL OR COMPANY THAT OWNS OR MANUFACTURES A PRESCRIPTION DRUG, SERVICE, OR ITEM THAT IS BEING OR WILL BE STUDIED BY THE BOARD.

(11) "FINANCIAL BENEFIT" MEANS HONORARIA, FEES, STOCK, OR ANY OTHER FORM OF COMPENSATION, INCLUDING INCREASES TO THE VALUE OF EXISTING STOCK HOLDINGS.

(12) "GENERIC DRUG" MEANS:

(a) A PRESCRIPTION DRUG THAT IS MARKETED OR DISTRIBUTED IN ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION APPROVED PURSUANT TO 21 U.S.C. SEC. 355 (j);

(b) AN AUTHORIZED GENERIC DRUG; OR

(c) A PRESCRIPTION DRUG THAT WAS INTRODUCED FOR RETAIL SALE

BEFORE 1962 THAT WAS NOT ORIGINALLY MARKETING UNDER A NEW DRUG APPLICATION.

(13) "HEALTH BENEFIT PLAN" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (32).

(14) "INFLATION" MEANS THE ANNUAL PERCENTAGE CHANGE IN THE UNITED STATES DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR INDEX.

(15) (a) "LARGE EMPLOYER" MEANS ANY PERSON, FIRM, CORPORATION, PARTNERSHIP, OR ASSOCIATION THAT:

(I) IS ACTIVELY ENGAGED IN BUSINESS;

(II) EMPLOYED AN AVERAGE OF MORE THAN ONE HUNDRED ELIGIBLE EMPLOYEES ON BUSINESS DAYS DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, EXCEPT AS PROVIDED IN SUBSECTION (15)(c) OF THIS SECTION; AND

(III) WAS NOT FORMED PRIMARILY FOR THE PURPOSE OF PURCHASING INSURANCE.

(b) FOR PURPOSES OF DETERMINING WHETHER AN EMPLOYER IS A "LARGE EMPLOYER", THE NUMBER OF ELIGIBLE EMPLOYEES IS CALCULATED USING THE METHOD SET FORTH IN 26 U.S.C. SEC. 4980H (c)(2)(E).

(c) IN THE CASE OF AN EMPLOYER THAT WAS NOT IN EXISTENCE THROUGHOUT THE PRECEDING CALENDAR QUARTER, THE DETERMINATION OF WHETHER THE EMPLOYER IS A LARGE EMPLOYER IS BASED ON THE AVERAGE NUMBER OF EMPLOYEES THAT THE EMPLOYER IS REASONABLY EXPECTED TO EMPLOY ON BUSINESS DAYS IN THE CURRENT CALENDAR YEAR.

(16) "MANUFACTURER" MEANS A PERSON THAT:

(a) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG THAT IS SOLD TO PURCHASERS LOCATED IN THIS STATE; OR

(b) (I) ENTERS INTO A LEASE OR OTHER CONTRACTUAL AGREEMENT WITH A MANUFACTURER TO MARKET AND DISTRIBUTE A PRESCRIPTION DRUG IN THIS STATE UNDER THE PERSON'S OWN NAME; AND

(II) SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG IN THIS STATE.

(17) "OPTIONAL PARTICIPATING PLAN" MEANS A SELF-FUNDED HEALTH BENEFIT PLAN OFFERED IN COLORADO THAT ELECTS TO SUBJECT ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR PRESCRIPTION DRUGS FOR ITS MEMBERS IN COLORADO TO THE REQUIREMENTS OF THIS PART 14, AS DESCRIBED IN SECTION 10-16-1407 (8).

(18) "PRACTITIONER" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (40).

(19) "PRESCRIPTION DRUG" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (42); EXCEPT THAT THE TERM INCLUDES ONLY PRESCRIPTION DRUGS THAT ARE INTENDED FOR HUMAN USE.

(20) "PRICING INFORMATION" MEANS INFORMATION ABOUT THE PRICE OF A PRESCRIPTION DRUG, INCLUDING INFORMATION THAT EXPLAINS OR HELPS EXPLAIN HOW THE PRICE WAS DETERMINED.

(21) "SMALL EMPLOYER" HAS THE MEANING SET FORTH IN SECTION 10-16-102 (61).

(22) "STATE ENTITY" MEANS ANY AGENCY OF STATE GOVERNMENT THAT PURCHASES OR REIMBURSES PAYERS FOR PRESCRIPTION DRUGS ON BEHALF OF THE STATE FOR A PERSON WHOSE HEALTH CARE IS PAID FOR BY THE STATE, INCLUDING ANY AGENT, VENDOR, CONTRACTOR, OR OTHER PARTY ACTING ON BEHALF OF THE STATE.

(23) "UPPER PAYMENT LIMIT" MEANS THE MAXIMUM AMOUNT THAT MAY BE PAID OR BILLED FOR A PRESCRIPTION DRUG THAT IS DISPENSED OR DISTRIBUTED IN COLORADO IN ANY FINANCIAL TRANSACTION CONCERNING THE PURCHASE OF OR REIMBURSEMENT FOR THE PRESCRIPTION DRUG.

(24) "WHOLESALE ACQUISITION COST" HAS THE MEANING SET FORTH IN 42 U.S.C. SEC. 1395w-3a (c)(6)(B).

(25) "WHOLESALE" HAS THE MEANING SET FORTH IN SECTION 12-280-103 (55).

10-16-1402. Colorado prescription drug affordability review board - created - membership - terms - conflicts of interest. (1) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD IS CREATED IN THE DIVISION. THE BOARD IS A BODY POLITIC AND CORPORATE AND IS AN INSTRUMENTALITY OF THE STATE. THE BOARD IS AN INDEPENDENT UNIT OF STATE GOVERNMENT, AND THE EXERCISE BY THE BOARD OF ITS AUTHORITY UNDER THIS PART 14 IS AN ESSENTIAL PUBLIC FUNCTION.

(2) (a) THE BOARD CONSISTS OF FIVE MEMBERS, WHO MUST EACH HAVE AN ADVANCED DEGREE AND EXPERIENCE OR EXPERTISE IN HEALTH-CARE ECONOMICS OR CLINICAL MEDICINE.

(b) THE GOVERNOR SHALL APPOINT EACH BOARD MEMBER, SUBJECT TO CONFIRMATION BY THE SENATE. ALL OF THE INITIAL MEMBERS OF THE BOARD MUST BE APPOINTED BY OCTOBER 1, 2021.

(c) THE TERM OF OFFICE OF EACH BOARD MEMBER IS THREE YEARS; EXCEPT THAT, AS TO THE TERMS OF THE MEMBERS WHO ARE FIRST APPOINTED TO THE BOARD, TWO SUCH MEMBERS SHALL SERVE THREE-YEAR INITIAL TERMS, TWO SUCH MEMBERS SHALL SERVE TWO-YEAR INITIAL TERMS, AND ONE SUCH MEMBER SHALL SERVE A ONE-YEAR INITIAL TERM, TO BE DETERMINED BY THE GOVERNOR. THE GOVERNOR MAY REMOVE ANY APPOINTED MEMBER OF THE BOARD FOR MALFEASANCE IN OFFICE, FOR FAILURE TO REGULARLY ATTEND MEETINGS, OR FOR ANY CAUSE THAT RENDERES THE MEMBER INCAPABLE OR UNFIT TO DISCHARGE THE DUTIES OF THE MEMBER'S OFFICE, AND ANY SUCH REMOVAL IS NOT SUBJECT TO REVIEW.

(d) THE GOVERNOR SHALL DESIGNATE ONE MEMBER OF THE BOARD TO SERVE AS THE CHAIR. A MAJORITY OF THE BOARD CONSTITUTES A QUORUM. THE CONCURRENCE OF A MAJORITY OF THE BOARD IN ANY MATTER WITHIN ITS POWERS AND DUTIES IS REQUIRED FOR ANY DETERMINATION MADE BY THE BOARD.

(3) (a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR APPOINTMENT TO THE BOARD SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE INDIVIDUAL'S POTENTIAL APPOINTING AUTHORITY. WHEN APPOINTING A MEMBER OF THE BOARD, AN APPOINTING AUTHORITY SHALL CONSIDER ANY

CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE MEMBER.

(b) A BOARD MEMBER MUST NOT BE AN EMPLOYEE, BOARD MEMBER, OR CONSULTANT OF:

(I) A MANUFACTURER OR A TRADE ASSOCIATION OF MANUFACTURERS;

(II) A CARRIER OR A TRADE ASSOCIATION OF CARRIERS; OR

(III) A PHARMACY BENEFIT MANAGER OR A TRADE ASSOCIATION OF PHARMACY BENEFIT MANAGERS.

(c) BOARD MEMBERS, STAFF MEMBERS, AND CONTRACTORS OF THE DIVISION, ON BEHALF OF THE BOARD, SHALL RECUSE THEMSELVES FROM ANY BOARD ACTIVITY IN ANY CASE IN WHICH THEY HAVE A CONFLICT OF INTEREST.

(d) ON AND AFTER JANUARY 1, 2022, THE DIVISION SHALL MAINTAIN A PAGE ON ITS PUBLIC WEBSITE FOR THE BOARD TO USE FOR ITS PURPOSES. THE BOARD SHALL DISCLOSE ON THE PAGE EACH CONFLICT OF INTEREST THAT IS DISCLOSED TO THE BOARD PURSUANT TO SUBSECTION (3)(c) OF THIS SECTION AND SECTION 10-16-1409 (5)(b).

(e) BOARD MEMBERS, STAFF MEMBERS, CONTRACTORS OF THE DIVISION, ON BEHALF OF THE BOARD, AND IMMEDIATE FAMILY MEMBERS OF BOARD MEMBERS, STAFF MEMBERS, OR CONTRACTORS SHALL NOT ACCEPT A FINANCIAL BENEFIT OR GIFTS, BEQUESTS, OR DONATIONS OF SERVICES OR PROPERTY THAT SUGGEST A CONFLICT OF INTEREST OR HAVE THE APPEARANCE OF CREATING BIAS IN THE WORK OF THE BOARD.

(4) THE ATTORNEY GENERAL SHALL ASSIGN AN ASSISTANT ATTORNEY GENERAL TO PROVIDE LEGAL COUNSEL TO THE BOARD. ANY ASSISTANT ATTORNEY GENERAL ASSIGNED TO THE BOARD PURSUANT TO THIS SUBSECTION (4) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

10-16-1403. Colorado prescription drug affordability review board - powers and duties - rules. (1) TO PROTECT COLORADO CONSUMERS FROM EXCESSIVE PRESCRIPTION DRUG COSTS, THE BOARD SHALL:

(a) COLLECT AND EVALUATE INFORMATION CONCERNING THE COST OF PRESCRIPTION DRUGS SOLD TO COLORADO CONSUMERS, AS DESCRIBED IN SECTION 10-16-1405;

(b) PERFORM AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS, AS DESCRIBED IN SECTION 10-16-1406;

(c) ESTABLISH UPPER PAYMENT LIMITS FOR PRESCRIPTION DRUGS, AS DESCRIBED IN SECTION 10-16-1407; AND

(d) MAKE POLICY RECOMMENDATIONS TO THE GENERAL ASSEMBLY TO IMPROVE THE AFFORDABILITY OF PRESCRIPTION DRUGS FOR COLORADO CONSUMERS, AS DESCRIBED IN SECTION 10-16-1414 (1)(h).

(2) THE BOARD MAY ESTABLISH AD HOC WORK GROUPS TO CONSIDER MATTERS RELATED TO THE WORK OF THE BOARD PURSUANT TO THIS PART 14. AD HOC WORK GROUPS MAY INCLUDE MEMBERS OF THE PUBLIC.

(3) THE DIVISION, ON BEHALF OF THE BOARD, MAY ENTER INTO A CONTRACT WITH A QUALIFIED, INDEPENDENT THIRD PARTY FOR ANY SERVICE NECESSARY TO CARRY OUT THE POWERS AND DUTIES OF THE BOARD. A THIRD PARTY WITH WHICH THE DIVISION CONTRACTS PURSUANT TO THIS SUBSECTION (3), INCLUDING ANY OF THE THIRD PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, CONTRACTORS, OR AGENTS, SHALL NOT RELEASE OR PUBLISH ANY INFORMATION THAT THE THIRD PARTY ACQUIRES PURSUANT TO ITS PERFORMANCE UNDER THE CONTRACT. ANY THIRD PARTY WITH WHICH THE DIVISION CONTRACTS PURSUANT TO THIS SUBSECTION (3) SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD.

(4) IN CARRYING OUT ITS DUTIES PURSUANT TO THIS PART 14, THE DIVISION, WHEN PERFORMING ITS DUTIES ON BEHALF OF THE BOARD, IS EXEMPT FROM THE STATE "PROCUREMENT CODE", ARTICLES 101 TO 112 OF TITLE 24.

(5) THE BOARD SHALL PROMULGATE RULES AS NECESSARY, PURSUANT TO ARTICLE 4 OF TITLE 24, FOR THE IMPLEMENTATION OF THIS PART 14.

(6)(a) THE DIVISION, ON BEHALF OF THE BOARD, MAY SEEK, ACCEPT, AND EXPEND GIFTS, GRANTS, AND DONATIONS FROM PRIVATE OR PUBLIC

SOURCES FOR THE PURPOSES OF THIS PART 14, AND ANY SUCH GIFTS, GRANTS, AND DONATIONS ARE CONTINUOUSLY APPROPRIATED TO THE DEPARTMENT OF REGULATORY AGENCIES; EXCEPT THAT THE DIVISION SHALL NOT ACCEPT ANY GIFT, GRANT, OR DONATION THAT CREATES A CONFLICT OF INTEREST OR THE APPEARANCE OF ANY CONFLICT OF INTEREST FOR ANY BOARD MEMBER.

(b) THE GENERAL ASSEMBLY FINDS THAT THE IMPLEMENTATION OF THIS PART 14 DOES NOT RELY ENTIRELY ON THE RECEIPT OF ADEQUATE FUNDING THROUGH GIFTS, GRANTS, OR DONATIONS. THEREFORE, THE BOARD IS NOT SUBJECT TO THE REPORTING REQUIREMENTS DESCRIBED IN SECTION 24-75-1303.

10-16-1404. Colorado prescription drug affordability review board meetings - required to be public - exceptions. (1) THE BOARD SHALL HOLD ITS FIRST MEETING WITHIN SIX WEEKS AFTER ALL OF THE BOARD MEMBERS ARE APPOINTED AND SHALL MEET AT LEAST EVERY SIX WEEKS THEREAFTER TO REVIEW PRESCRIPTION DRUGS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A MEETING IF THE BOARD HAS NO PRESCRIPTION DRUGS TO REVIEW.

(2) THE BOARD IS A STATE PUBLIC BODY FOR PURPOSES OF SECTION 24-6-402, AND THE BOARD'S MEETINGS AND THE MEETINGS OF AD HOC WORK GROUPS OF THE BOARD ARE PUBLIC MEETINGS.

(3) THE BOARD SHALL MEET IN EXECUTIVE SESSION TO DISCUSS PROPRIETARY INFORMATION. THE BOARD AND ANY BOARD MEMBERS, OFFICERS, DIRECTORS, EMPLOYEES, CONTRACTORS, AND AGENTS SHALL NOT DISCLOSE OR OTHERWISE MAKE AVAILABLE TO THE PUBLIC ANY MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA THAT IS NOT OTHERWISE AVAILABLE TO THE PUBLIC. ELECTRONIC RECORDINGS OF SUCH EXECUTIVE SESSIONS ARE NOT PERMITTED IF THEY WOULD RESULT IN THE DISCLOSURE OF ANY MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA, AND IN NO CASE SHALL MINUTES FROM SUCH EXECUTIVE SESSIONS DISCLOSE OR INCLUDE MATERIALS OR INFORMATION CONTAINING TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY DATA. THE BOARD SHALL NOT TAKE ANY OF THE FOLLOWING ACTIONS WHILE MEETING IN EXECUTIVE SESSION:

(a) DELIBERATIONS CONCERNING WHETHER TO SUBJECT A

PRESCRIPTION DRUG TO AN AFFORDABILITY REVIEW AS DESCRIBED IN SECTION 10-16-1406;

(b) VOTES CONCERNING WHETHER TO ESTABLISH AN UPPER PAYMENT LIMIT ON A PRESCRIPTION DRUG; OR

(c) ANY FINAL DECISION OF THE BOARD.

10-16-1405. Colorado prescription drug affordability review board - reports from carriers and pharmacy benefit management firms required - confidential materials. (1) BEGINNING IN THE 2022 CALENDAR YEAR, FOR ALL PRESCRIPTION DRUGS DISPENSED AT A PHARMACY IN THIS STATE AND PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR, INCLUDING BRAND-NAME DRUGS, AUTHORIZED GENERIC DRUGS, BIOLOGICAL PRODUCTS, AND BIOSIMILAR DRUGS:

(a) EACH CARRIER AND EACH PHARMACY BENEFIT MANAGEMENT FIRM ACTING ON BEHALF OF A CARRIER SHALL REPORT TO THE ALL-PAYER HEALTH CLAIMS DATABASE THE FOLLOWING INFORMATION:

(I) THE TOP FIFTEEN PRESCRIPTION DRUGS BY VOLUME, CALCULATED BY UNIT, FOR WHICH THE CARRIER PAID;

(II) THE FIFTEEN COSTLIEST PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID, AS DETERMINED BY TOTAL ANNUAL PLAN SPENDING;

(III) THE FIFTEEN PRESCRIPTION DRUGS PAID FOR BY THE CARRIER THAT ACCOUNTED FOR THE HIGHEST INCREASE IN TOTAL ANNUAL PLAN SPENDING WHEN COMPARED WITH THE TOTAL ANNUAL PLAN SPENDING FOR THE SAME PRESCRIPTION DRUGS IN THE YEAR IMMEDIATELY PRECEDING THE YEAR FOR WHICH THE INFORMATION IS REPORTED;

(IV) THE FIFTEEN PRESCRIPTION DRUGS THAT CAUSED THE GREATEST INCREASES IN THE CARRIER'S PREMIUMS;

(V) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER PAID MOST FREQUENTLY AND FOR WHICH THE CARRIER RECEIVED A REBATE FROM MANUFACTURERS;

(VI) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE HIGHEST REBATES, AS DETERMINED BY PERCENTAGES OF THE PRICE OF THE PRESCRIPTION DRUG;

(VII) THE FIFTEEN PRESCRIPTION DRUGS FOR WHICH THE CARRIER RECEIVED THE LARGEST REBATES;

(VIII) THE TOTAL SPENDING FOR EACH OF THE FOLLOWING CATEGORIES OF PRESCRIPTION DRUGS:

(A) BRAND-NAME DRUGS PURCHASED FROM RETAIL PHARMACIES;

(B) AUTHORIZED GENERIC DRUGS PURCHASED FROM RETAIL PHARMACIES;

(C) BRAND-NAME DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;

(D) AUTHORIZED GENERIC DRUGS PURCHASED FROM MAIL-ORDER PHARMACIES;

(E) PRESCRIPTION DRUGS DISPENSED BY A PRACTITIONER IN ACCORDANCE WITH SECTION 12-280-120 (6);

(F) PRESCRIPTION DRUGS ADMINISTERED IN AN INPATIENT HOSPITAL SETTING; AND

(G) PRESCRIPTION DRUGS ADMINISTERED IN AN OUTPATIENT HOSPITAL SETTING; AND

(IX) THE TOTAL SPENDING FOR THE PRESCRIPTION DRUGS DESCRIBED IN SUBSECTION (1)(a)(VIII) OF THIS SECTION PAID FOR BY A CARRIER PURSUANT TO A HEALTH BENEFIT PLAN ISSUED UNDER PART 2, 3, OR 4 OF THIS ARTICLE 16 DURING THE IMMEDIATELY PRECEDING CALENDAR YEAR FOR EACH OF THE FOLLOWING MARKET SECTORS:

(A) INDIVIDUAL;

(B) SMALL EMPLOYER; AND

(C) LARGE EMPLOYER.

(b) IF THE ALL-PAYER HEALTH CLAIMS DATABASE DOES NOT COLLECT AND MAINTAIN THE DATA THAT IS REQUIRED TO BE REPORTED TO THE DATABASE PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION, THE ADMINISTRATOR OF THE ALL-PAYER HEALTH CLAIMS DATABASE SHALL AMEND THE REQUIREMENTS REGARDING THE DATA TO BE SUBMITTED TO THE DATABASE PURSUANT TO SECTION 25.5-1-204 (5) TO INCLUDE THE DATA REQUIRED BY SUBSECTION (1)(a) OF THIS SECTION DURING THE NEXT UPDATE OF SUCH REQUIREMENTS, BUT NO LATER THAN JUNE 1, 2022.

(2) THE ADMINISTRATOR OF THE ALL-PAYER HEALTH CLAIMS DATABASE SHALL PROVIDE TO THE COMMISSIONER, IN A FORM AND MANNER DETERMINED BY THE COMMISSIONER, THE INFORMATION THAT IS REPORTED TO THE DATABASE BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO SUBSECTION (1)(a) OF THIS SECTION.

(3) (a) EXCEPT AS PROVIDED IN SUBSECTION (3)(b) OF THIS SECTION, THE COMMISSIONER SHALL:

(I) POST THE INFORMATION REPORTED BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION ON THE DIVISION'S WEBSITE; AND

(II) PROVIDE THE INFORMATION REPORTED BY CARRIERS AND PHARMACY BENEFIT MANAGEMENT FIRMS PURSUANT TO THIS SECTION TO THE BOARD, IN A FORM AND MANNER PRESCRIBED BY THE BOARD.

(b) IF A CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM CLAIMS THAT INFORMATION SUBMITTED PURSUANT TO THIS SECTION IS CONFIDENTIAL OR PROPRIETARY, THE COMMISSIONER SHALL REVIEW THE INFORMATION AND REDACT SPECIFIC ITEMS THAT THE CARRIER OR PHARMACY BENEFIT MANAGEMENT FIRM DEMONSTRATES TO BE CONFIDENTIAL OR PROPRIETARY. THE COMMISSIONER SHALL NOT DISCLOSE REDACTED ITEMS TO ANY PERSON; EXCEPT THAT THE COMMISSIONER MAY DISCLOSE REDACTED ITEMS:

(I) AS MAY BE REQUIRED PURSUANT TO THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24; AND

(II) TO EMPLOYEES OF THE DIVISION, AS NECESSARY.

(4) THE REQUIREMENT IN THIS SECTION TO REPORT INFORMATION RELATING TO THE COST OF PRESCRIPTION DRUGS IS INTENDED TO CREATE TRANSPARENCY IN PRESCRIPTION DRUG PRICING AND DOES NOT:

(a) PROHIBIT A MANUFACTURER OF A PRESCRIPTION DRUG FROM MAKING PRICING DECISIONS ABOUT ITS PRESCRIPTION DRUGS; OR

(b) PROHIBIT PURCHASERS, BOTH PUBLIC AND PRIVATE, OR PHARMACY BENEFIT MANAGEMENT FIRMS FROM NEGOTIATING DISCOUNTS AND REBATES CONSISTENT WITH EXISTING STATE AND FEDERAL LAW.

10-16-1406. Colorado prescription drug affordability review board - affordability reviews of prescription drugs. (1) THE BOARD MAY CONDUCT AFFORDABILITY REVIEWS OF PRESCRIPTION DRUGS IN ACCORDANCE WITH THIS SECTION. THE BOARD SHALL IDENTIFY, FOR PURPOSES OF DETERMINING WHETHER TO CONDUCT AN AFFORDABILITY REVIEW, ANY PRESCRIPTION DRUG THAT IS:

(a) A BRAND-NAME DRUG OR BIOLOGICAL PRODUCT THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS:

(I) AN INITIAL WHOLESALE ACQUISITION COST OF THIRTY THOUSAND DOLLARS OR MORE FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION; OR

(II) AN INCREASE IN THE WHOLESALE ACQUISITION COST OF TEN PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS FOR A TWELVE-MONTH SUPPLY OR FOR A COURSE OF TREATMENT THAT IS LESS THAN TWELVE MONTHS IN DURATION;

(b) A BIOSIMILAR DRUG THAT HAS AN INITIAL WHOLESALE ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN THE CORRESPONDING BIOLOGICAL PRODUCT; OR

(c) A GENERIC DRUG:

(I) THAT, AS ADJUSTED ANNUALLY FOR INFLATION, HAS A WHOLESALE ACQUISITION COST OF ONE HUNDRED DOLLARS OR MORE FOR:

(A) A THIRTY-DAY SUPPLY BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA;

(B) A SUPPLY THAT LASTS LESS THAN THIRTY DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE FDA; OR

(C) ONE DOSE OF THE GENERIC DRUG IF THE LABELING APPROVED BY THE FDA DOES NOT RECOMMEND A FINITE DOSAGE; AND

(II) FOR WHICH THE WHOLESALE ACQUISITION COST INCREASED BY TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS, AS DETERMINED BY COMPARING THE CURRENT WHOLESALE ACQUISITION COST TO THE AVERAGE WHOLESALE ACQUISITION COST REPORTED DURING THE IMMEDIATELY PRECEDING TWELVE MONTHS.

(2) AFTER IDENTIFYING PRESCRIPTION DRUGS AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER TO CONDUCT AN AFFORDABILITY REVIEW FOR EACH IDENTIFIED PRESCRIPTION DRUG BY:

(a) EVALUATING THE CLASS OF THE PRESCRIPTION DRUG AND WHETHER ANY THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS ARE AVAILABLE FOR SALE;

(b) EVALUATING AGGREGATED DATA;

(c) SEEKING AND CONSIDERING INPUT FROM THE ADVISORY COUNCIL ABOUT THE PRESCRIPTION DRUG; AND

(d) CONSIDERING THE AVERAGE PATIENT'S OUT-OF-POCKET COST FOR THE PRESCRIPTION DRUG.

(3) IF THE BOARD CONDUCTS AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG, THE AFFORDABILITY REVIEW MUST DETERMINE WHETHER USE OF THE PRESCRIPTION DRUG IS CONSISTENT WITH THE LABELING APPROVED FOR THE PRESCRIPTION DRUG BY THE FDA OR WITH STANDARD MEDICAL PRACTICE IS UNAFFORDABLE FOR COLORADO CONSUMERS.

(4) IN PERFORMING AN AFFORDABILITY REVIEW, TO THE EXTENT PRACTICABLE, THE BOARD SHALL CONSIDER:

- (a) THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG;
- (b) THE COST AND AVAILABILITY OF THERAPEUTIC ALTERNATIVES TO THE PRESCRIPTION DRUG IN THE STATE;
- (c) THE EFFECT OF THE PRICE ON COLORADO CONSUMERS' ACCESS TO THE PRESCRIPTION DRUG;
- (d) THE RELATIVE FINANCIAL EFFECTS ON HEALTH, MEDICAL, OR SOCIAL SERVICES COSTS, AS THE EFFECTS CAN BE QUANTIFIED AND COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC ALTERNATIVES TO THE PRESCRIPTION DRUG;
- (e) THE PATIENT COPAYMENT OR OTHER COST SHARING THAT IS ASSOCIATED WITH THE PRESCRIPTION DRUG AND TYPICALLY REQUIRED PURSUANT TO HEALTH BENEFIT PLANS ISSUED BY CARRIERS IN THE STATE;
- (f) THE IMPACT ON SAFETY NET PROVIDERS IF THE PRESCRIPTION DRUG IS AVAILABLE THROUGH SECTION 340B OF THE FEDERAL "PUBLIC HEALTH SERVICE ACT", PUB.L. 78-410;
- (g) ORPHAN DRUG STATUS;
- (h) INPUT FROM:
- (I) PATIENTS AND CAREGIVERS AFFECTED BY THE CONDITION OR DISEASE THAT IS TREATED BY THE PRESCRIPTION DRUG THAT IS UNDER REVIEW BY THE BOARD; AND
- (II) INDIVIDUALS WHO POSSESS SCIENTIFIC OR MEDICAL TRAINING WITH RESPECT TO A CONDITION OR DISEASE TREATED BY THE PRESCRIPTION DRUG THAT IS UNDER REVIEW BY THE BOARD;
- (i) ANY OTHER INFORMATION THAT A MANUFACTURER, CARRIER, PHARMACY BENEFIT MANAGEMENT FIRM, OR OTHER ENTITY CHOOSES TO PROVIDE; AND
- (j) ANY OTHER FACTORS AS DETERMINED BY RULES PROMULGATED BY THE BOARD PURSUANT TO SECTION 10-16-1403 (5).

(5) TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY INFORMATION OBTAINED BY THE BOARD PURSUANT TO THIS SECTION MAY BE ACCESSED ONLY BY BOARD MEMBERS AND STAFF OR BY A QUALIFIED INDEPENDENT THIRD PARTY THAT HAS CONTRACTED WITH THE DIVISION PURSUANT TO SECTION 10-16-1403 (3) AND IS SUBJECT TO A NONDISCLOSURE AGREEMENT PROHIBITING DISCLOSURE OF SUCH INFORMATION. ANY PERSON WITH ACCESS TO SUCH INFORMATION SHALL PROTECT THE INFORMATION FROM DIRECT OR INDIRECT PUBLICATION OR RELEASE TO ANY PERSON.

(6) IN PERFORMING AN AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG, THE BOARD MAY CONSIDER ANY DOCUMENTS AND INFORMATION RELATING TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE OF THE PRESCRIPTION DRUG, INCLUDING DOCUMENTS AND INFORMATION RELATING TO:

- (a) LIFE-CYCLE MANAGEMENT;
- (b) THE AVERAGE COST OF THE PRESCRIPTION DRUG IN THE STATE;
- (c) MARKET COMPETITION AND CONTEXT;
- (d) PROJECTED REVENUE;
- (e) THE ESTIMATED COST-EFFECTIVENESS OF THE PRESCRIPTION DRUG; AND
- (f) OFF-LABEL USAGE OF THE PRESCRIPTION DRUG.

(7) (a) TO THE EXTENT PRACTICABLE, THE BOARD MAY ACCESS PRICING INFORMATION FOR PRESCRIPTION DRUGS BY:

(I) ACCESSING PUBLICLY AVAILABLE PRICING INFORMATION FROM A STATE TO WHICH MANUFACTURERS REPORT PRICING INFORMATION;

(II) ACCESSING AVAILABLE PRICING INFORMATION FROM THE ALL-PAYER HEALTH CLAIMS DATABASE AND FROM STATE ENTITIES; AND

(III) ACCESSING INFORMATION THAT IS AVAILABLE FROM OTHER COUNTRIES.

(b) TO THE EXTENT THAT THERE IS NO PUBLICLY AVAILABLE INFORMATION WITH WHICH TO CONDUCT AN AFFORDABILITY REVIEW, THE BOARD MAY REQUEST THAT A MANUFACTURER, CARRIER, OR PHARMACY BENEFIT MANAGEMENT FIRM PROVIDE PRICING INFORMATION FOR ANY PRESCRIPTION DRUG IDENTIFIED PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE FAILURE OF AN ENTITY TO PROVIDE PRICING INFORMATION TO THE BOARD FOR AN AFFORDABILITY REVIEW DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO CONDUCT THE AFFORDABILITY REVIEW, AS DESCRIBED IN THIS SECTION.

10-16-1407. Colorado prescription drug affordability review board - upper payment limits for certain prescription drugs - rules - severability. (1) THE BOARD MAY ESTABLISH AN UPPER PAYMENT LIMIT FOR ANY PRESCRIPTION DRUG FOR WHICH THE BOARD HAS PERFORMED AN AFFORDABILITY REVIEW PURSUANT TO SECTION 10-16-1406 AND DETERMINED THAT THE USE OF THE PRESCRIPTION DRUG IS UNAFFORDABLE FOR COLORADO CONSUMERS; EXCEPT THAT THE BOARD MAY NOT ESTABLISH AN UPPER PAYMENT LIMIT FOR MORE THAN TWELVE PRESCRIPTION DRUGS IN EACH CALENDAR YEAR FOR THREE YEARS BEGINNING APRIL 1, 2022. THE FAILURE OF AN ENTITY TO PROVIDE INFORMATION TO THE BOARD PURSUANT TO SECTION 10-16-1406 (7)(b) DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO ESTABLISH AN UPPER PAYMENT LIMIT FOR THE PRESCRIPTION DRUG.

(2) THE BOARD SHALL DETERMINE BY RULE THE METHODOLOGY FOR ESTABLISHING AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG TO PROTECT CONSUMERS FROM THE EXCESSIVE COST OF PRESCRIPTION DRUGS AND ENSURE THEY CAN ACCESS PRESCRIPTION DRUGS NECESSARY FOR THEIR HEALTH. THE METHODOLOGY MUST INCLUDE CONSIDERATION OF:

(a) THE COST OF ADMINISTERING OR DISPENSING THE PRESCRIPTION DRUG;

(b) THE COST OF DISTRIBUTING THE PRESCRIPTION DRUG TO CONSUMERS IN THE STATE;

(c) THE STATUS OF THE PRESCRIPTION DRUG ON THE DRUG SHORTAGE LIST PUBLISHED BY THE DRUG SHORTAGE PROGRAM WITHIN THE FDA; AND

(d) OTHER RELEVANT COSTS RELATED TO THE PRESCRIPTION DRUG.

(3) THE METHODOLOGY DETERMINED BY THE BOARD PURSUANT TO SUBSECTION (2) OF THIS SECTION MUST CONSIDER THE IMPACT TO OLDER ADULTS AND PERSONS WITH DISABILITIES AND SHALL NOT PLACE A LOWER VALUE ON THEIR LIVES.

(4) THE METHODOLOGY DETERMINED BY THE BOARD PURSUANT TO SUBSECTION (2) OF THIS SECTION:

(a) SHALL NOT CONSIDER RESEARCH OR METHODS THAT EMPLOY A DOLLARS-PER-QUALITY ADJUSTED LIFE YEAR, OR SIMILAR MEASURE, THAT DISCOUNTS THE VALUE OF A LIFE BECAUSE OF AN INDIVIDUAL'S DISABILITY OR AGE; AND

(b) MUST AUTHORIZE A PHARMACY LICENSED BY THE STATE BOARD OF PHARMACY TO CHARGE REASONABLE FEES, TO BE PAID BY THE PROVIDING HEALTH BENEFIT PLAN OF THE CONSUMER, FOR DISPENSING OR DELIVERING A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT.

(5) AN UPPER PAYMENT LIMIT APPLIES TO ALL PURCHASES OF AND PAYER REIMBURSEMENTS FOR A PRESCRIPTION DRUG THAT IS DISPENSED OR ADMINISTERED TO INDIVIDUALS IN THE STATE IN PERSON, BY MAIL, OR BY OTHER MEANS AND FOR WHICH AN UPPER PAYMENT LIMIT IS ESTABLISHED. THE BOARD SHALL PROMULGATE RULES THAT ESTABLISH THE EFFECTIVE DATE OF ANY UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD, WHICH EFFECTIVE DATE IS AT LEAST SIX MONTHS AFTER THE ADOPTION OF THE UPPER PAYMENT LIMIT BY THE BOARD AND APPLIES ONLY TO PURCHASES, CONTRACTS, AND PLANS THAT ARE ISSUED ON OR RENEWED AFTER THE EFFECTIVE DATE.

(6) THE BOARD SHALL PROMULGATE RULES TO NOTIFY CONSUMERS OF ANY DECISION TO ESTABLISH AN UPPER PAYMENT LIMIT PURSUANT TO THIS SECTION.

(7) ANY INFORMATION SUBMITTED TO THE BOARD IN ACCORDANCE WITH THIS SECTION OR SECTION 10-16-1405 OR 10-16-1406 IS SUBJECT TO PUBLIC INSPECTION ONLY TO THE EXTENT ALLOWED UNDER THE "COLORADO OPEN RECORDS ACT", PART 2 OF ARTICLE 72 OF TITLE 24, AND IN NO CASE SHALL TRADE-SECRET, CONFIDENTIAL, OR PROPRIETARY INFORMATION BE DISCLOSED TO ANY PERSON WHO IS NOT AUTHORIZED TO ACCESS SUCH

INFORMATION PURSUANT TO SECTION 10-16-1406.

(8) NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, WITH RESPECT TO AN ENTITY PROVIDING OR ADMINISTERING A SELF-FUNDED HEALTH BENEFIT PLAN AND ITS PLAN MEMBERS, THE REQUIREMENTS OF THIS PART 14 APPLY ONLY IF THE PLAN ELECTS TO BE SUBJECT TO THIS PART 14 FOR ITS MEMBERS IN COLORADO. SUCH A PLAN IS AN OPTIONAL PARTICIPATING PLAN FOR THE PURPOSES OF THIS PART 14.

(9) IF ANY PROVISION OF THIS SECTION OR ITS APPLICATION TO ANY PERSON OR CIRCUMSTANCE IS HELD INVALID, THE INVALIDITY DOES NOT AFFECT OTHER PROVISIONS OR APPLICATIONS OF THIS SECTION THAT CAN BE GIVEN EFFECT WITHOUT THE INVALID PROVISION OR APPLICATION, AND TO THIS END THE PROVISIONS OF THIS SECTION ARE SEVERABLE.

(10) FOR ANY UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO THIS SECTION, THE BOARD SHALL:

(a) INQUIRE OF MANUFACTURERS OF THE PRESCRIPTION DRUG AS TO WHETHER EACH SUCH MANUFACTURER IS ABLE TO MAKE THE PRESCRIPTION DRUG AVAILABLE FOR SALE IN THE STATE AND REQUEST THE RATIONALE FOR THE MANUFACTURER'S RESPONSE; AND

(b) SUBMIT ANNUALLY TO THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR TO ANY SUCCESSOR COMMITTEES, THE RESPONSE OF EACH MANUFACTURER TO THE INQUIRY DESCRIBED IN SUBSECTION (10)(a) OF THIS SECTION.

10-16-1408. Colorado prescription drug affordability review board - appeals - rules - judicial review. (1) A PERSON AGGRIEVED BY A DECISION OF THE BOARD MAY APPEAL THE DECISION WITHIN SIXTY DAYS AFTER THE DECISION IS MADE. THE BOARD SHALL CONSIDER THE APPEAL AND ISSUE A FINAL DECISION CONCERNING THE APPEAL WITHIN SIXTY DAYS AFTER THE BOARD RECEIVES THE APPEAL.

(2) NOT LATER THAN MARCH 31, 2022, THE BOARD SHALL PROMULGATE RULES ESTABLISHING A PROCESS AND TIMELINE FOR THE CONSIDERATION BY THE BOARD OF ANY APPEAL THAT IS SUBMITTED TO THE BOARD PURSUANT TO SUBSECTION (1) OF THIS SECTION. THE PROCESS AND

TIMELINE MUST COMPORT WITH THE "STATE ADMINISTRATIVE PROCEDURE ACT", ARTICLE 4 OF TITLE 24.

(3) IN THE ABSENCE OF AN APPEAL, A DECISION OF THE BOARD BECOMES FINAL AND RIPE FOR JUDICIAL REVIEW AFTER SIXTY DAYS. ANY PERSON AGGRIEVED BY A FINAL DECISION OF THE BOARD MAY PETITION FOR JUDICIAL REVIEW PURSUANT TO SECTION 24-4-106.

(4) NOTWITHSTANDING ANY PROVISION OF LAW TO THE CONTRARY:

(a) AN INDIVIDUAL MAY REQUEST AN EXPEDITED REVIEW, AS DESCRIBED IN SECTION 10-16-113.5, OF ACCESS TO A PRESCRIPTION DRUG THAT IS UNAVAILABLE TO THE INDIVIDUAL BECAUSE A MANUFACTURER REFUSES TO MAKE THE DRUG AVAILABLE AS A RESULT OF AN UPPER PAYMENT LIMIT ESTABLISHED FOR THE PRESCRIPTION DRUG BY THE BOARD; AND

(b) A CARRIER MAY DISREGARD THE UPPER PAYMENT LIMIT IF THE INDEPENDENT EXTERNAL REVIEW ENTITY THAT PERFORMS THE EXPEDITED REVIEW DETERMINES PURSUANT TO SUCH REVIEW THAT THE PRESCRIPTION DRUG SHOULD BE COVERED FOR AND AVAILABLE TO THAT INDIVIDUAL.

10-16-1409. Colorado prescription drug affordability advisory council - created - membership - powers and duties. (1) (a) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL IS CREATED IN THE DIVISION TO PROVIDE STAKEHOLDER INPUT TO THE BOARD REGARDING THE AFFORDABILITY OF PRESCRIPTION DRUGS. THE ADVISORY COUNCIL INCLUDES FIFTEEN MEMBERS AS FOLLOWS:

(I) THE EXECUTIVE DIRECTOR OF THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING OR THE EXECUTIVE DIRECTOR'S DESIGNEE; AND

(II) FOURTEEN MEMBERS APPOINTED BY THE BOARD AS FOLLOWS:

(A) TWO MEMBERS WHO ARE HEALTH-CARE CONSUMERS OR WHO REPRESENT HEALTH-CARE CONSUMERS;

(B) ONE MEMBER REPRESENTING A STATEWIDE HEALTH-CARE CONSUMER ADVOCACY ORGANIZATION;

(C) ONE MEMBER REPRESENTING HEALTH-CARE CONSUMERS WHO ARE LIVING WITH CHRONIC DISEASES;

(D) ONE MEMBER REPRESENTING A LABOR UNION;

(E) ONE MEMBER REPRESENTING EMPLOYERS;

(F) ONE MEMBER REPRESENTING CARRIERS;

(G) ONE MEMBER REPRESENTING PHARMACY BENEFIT MANAGEMENT FIRMS;

(H) ONE MEMBER REPRESENTING HEALTH-CARE PROFESSIONALS WITH PRESCRIBING AUTHORITY;

(I) ONE MEMBER WHO IS EMPLOYED BY AN ORGANIZATION THAT PERFORMS RESEARCH CONCERNING PRESCRIPTION DRUGS, INCLUDING RESEARCH CONCERNING PRICING INFORMATION;

(J) ONE MEMBER REPRESENTING MANUFACTURERS OF BRAND-NAME DRUGS;

(K) ONE MEMBER REPRESENTING MANUFACTURERS OF GENERIC DRUGS;

(L) ONE MEMBER REPRESENTING PHARMACISTS; AND

(M) ONE MEMBER REPRESENTING WHOLESALERS.

(b) TO THE EXTENT POSSIBLE, THE BOARD SHALL APPOINT COUNCIL MEMBERS WHO HAVE EXPERIENCE SERVING UNDERSERVED COMMUNITIES AND REFLECT THE DIVERSITY OF THE STATE WITH REGARD TO RACE, ETHNICITY, IMMIGRATION STATUS, INCOME, WEALTH, DISABILITY, AGE, GENDER IDENTITY, AND GEOGRAPHY. IN CONSIDERING GEOGRAPHIC DIVERSITY, THE BOARD SHALL ENSURE AT LEAST ONE COUNCIL MEMBER RESIDES ON THE EASTERN PLAINS AND ONE MEMBER RESIDES ON THE WESTERN SLOPE, AND THE BOARD SHALL ATTEMPT TO APPOINT MEMBERS FROM EACH CONGRESSIONAL DISTRICT IN THE STATE.

(c) ALL OF THE INITIAL MEMBERS OF THE ADVISORY COUNCIL MUST

BE APPOINTED BY JANUARY 1, 2022.

(2) EACH MEMBER OF THE ADVISORY COUNCIL MUST POSSESS KNOWLEDGE OF AT LEAST ONE OF THE FOLLOWING SUBJECT MATTERS:

- (a) THE PHARMACEUTICAL BUSINESS MODEL;
- (b) SUPPLY CHAIN BUSINESS MODELS;
- (c) THE PRACTICE OF MEDICINE OR CLINICAL TRAINING;
- (d) HEALTH-CARE CONSUMER OR PATIENT PERSPECTIVES;
- (e) HEALTH-CARE COST TRENDS AND DRIVERS;
- (f) CLINICAL AND HEALTH SERVICES RESEARCH; OR
- (g) THE STATE'S HEALTH-CARE MARKETPLACE.

(3) THE TERM OF EACH MEMBER OF THE ADVISORY COUNCIL IS THREE YEARS; EXCEPT THAT THE MEMBERS INITIALLY APPOINTED TO THE ADVISORY COUNCIL PURSUANT TO SUBSECTIONS (1)(a)(II)(A) TO (1)(a)(II)(E) OF THIS SECTION SHALL EACH SERVE INITIAL TERMS OF TWO YEARS.

(4) THE CHAIR OF THE BOARD SHALL DESIGNATE ONE MEMBER OF THE ADVISORY COUNCIL TO SERVE AS CHAIR OF THE ADVISORY COUNCIL.

(5)(a) AN INDIVIDUAL WHO IS BEING CONSIDERED FOR APPOINTMENT TO THE ADVISORY COUNCIL SHALL DISCLOSE ANY CONFLICT OF INTEREST TO THE BOARD IN A FORM AND MANNER PRESCRIBED BY THE BOARD. WHEN APPOINTING A MEMBER OF THE ADVISORY COUNCIL, THE BOARD SHALL CONSIDER ANY CONFLICT OF INTEREST DISCLOSED BY THE PROSPECTIVE MEMBER.

(b) THE CHAIR OF THE ADVISORY COUNCIL SHALL REPORT TO THE BOARD ANY CONFLICT OF INTEREST THAT IS DISCLOSED TO THE ADVISORY COUNCIL. THE BOARD SHALL INCLUDE INFORMATION CONCERNING SUCH DISCLOSURES ON ITS PUBLIC WEBSITE PURSUANT TO SECTION 10-16-1402 (3)(d).

(6) THE ADVISORY COUNCIL SHALL MEET AT LEAST ONCE EVERY THREE MONTHS; EXCEPT THAT THE CHAIR MAY CANCEL OR POSTPONE A MEETING.

(7)(a) EXCEPT AS DESCRIBED IN SUBSECTION (7)(b) OF THIS SECTION, THE ADVISORY COUNCIL SHALL CONDUCT ALL OF ITS MEETINGS IN PUBLIC.

(b) NOTWITHSTANDING SECTION 24-6-402, THE ADVISORY COUNCIL MAY MEET PRIVATELY IN GROUPS OF THREE OR FEWER MEMBERS FOR THE FOLLOWING PURPOSES, SO LONG AS NO FORMAL ACTION IS TAKEN AT THE MEETING:

(I) TO GATHER AND UNDERSTAND DATA; OR

(II) TO ESTABLISH, ORGANIZE, AND PLAN FOR THE BUSINESS OF THE ADVISORY COUNCIL.

10-16-1410. Use of savings - report - rules. (1) ANY SAVINGS GENERATED FOR A HEALTH BENEFIT PLAN THAT ARE ATTRIBUTABLE TO THE ESTABLISHMENT OF AN UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1407 MUST BE USED BY THE CARRIER THAT ISSUES THE HEALTH BENEFIT PLAN TO REDUCE COSTS TO CONSUMERS, PRIORITIZING THE REDUCTION OF OUT-OF-POCKET COSTS FOR PRESCRIPTION DRUGS.

(2) ON OR BEFORE MARCH 15, 2023, AND ON OR BEFORE MARCH 15 EACH YEAR THEREAFTER, EACH STATE ENTITY AND EACH CARRIER THAT ISSUES A HEALTH BENEFIT PLAN OR OPTIONAL PARTICIPATING PLAN SHALL SUBMIT TO THE BOARD A REPORT DESCRIBING THE SAVINGS ACHIEVED DURING THE PRECEDING PLAN YEAR FOR EACH PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE PRECEDING YEAR AND HOW THOSE SAVINGS WERE USED TO SATISFY THE REQUIREMENT DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

(3) ON OR BEFORE NOVEMBER 1, 2022, THE BOARD SHALL PROMULGATE RULES ESTABLISHING A FORMULA FOR CALCULATING SAVINGS FOR THE PURPOSE OF COMPLYING WITH SUBSECTION (1) OF THIS SECTION.

10-16-1411. Unlawful acts - enforcement - penalties. (1) ON AND AFTER JANUARY 1, 2022, IT IS UNLAWFUL FOR ANY PERSON TO PURCHASE OR

REIMBURSE A PAYER FOR A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 AT AN AMOUNT THAT EXCEEDS THE UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD FOR THAT PRESCRIPTION DRUG, REGARDLESS OF WHETHER THE PRESCRIPTION DRUG IS DISPENSED OR DISTRIBUTED IN PERSON, BY MAIL, OR BY OTHER MEANS.

(2) ON AND AFTER JANUARY 1, 2023, EACH STATE ENTITY, CARRIER, AND OPTIONAL PARTICIPATING PLAN SHALL REQUIRE COMPLIANCE WITH AN UPPER PAYMENT LIMIT ESTABLISHED BY THE BOARD.

(3) THE ATTORNEY GENERAL IS AUTHORIZED TO ENFORCE THIS PART 14 ON BEHALF OF ANY STATE ENTITY OR ANY CONSUMER OF PRESCRIPTION DRUGS.

(4) NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, AS USED IN THIS SECTION, "PERSON" DOES NOT INCLUDE AN INDIVIDUAL WHO ACQUIRES A PRESCRIPTION DRUG FOR THE INDIVIDUAL'S OWN USE OR FOR A FAMILY MEMBER'S USE.

(5) NOTWITHSTANDING ANY PROVISION OF THIS SECTION TO THE CONTRARY, A CARRIER OR STATE AGENCY THAT IS REQUIRED PURSUANT TO STATE OR FEDERAL LAW TO PURCHASE OR REIMBURSE A PAYER FOR A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 IS NOT SUBJECT TO AN ENFORCEMENT ACTION FOR A VIOLATION OF SUBSECTION (1) OR (2) OF THIS SECTION FOR THAT PARTICULAR PRESCRIPTION DRUG.

10-16-1412. Notice of withdrawal of prescription drugs with upper payment limits required - rules - penalty. (1) ANY MANUFACTURER THAT INTENDS TO WITHDRAW FROM SALE OR DISTRIBUTION WITHIN THE STATE A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407 SHALL PROVIDE A NOTICE OF WITHDRAWAL IN WRITING AT LEAST ONE HUNDRED EIGHTY DAYS BEFORE THE WITHDRAWAL TO:

- (a) THE COMMISSIONER;
- (b) THE ATTORNEY GENERAL; AND

(c) EACH ENTITY IN THE STATE WITH WHICH THE MANUFACTURER HAS CONTRACTED FOR THE SALE OR DISTRIBUTION OF THE PRESCRIPTION DRUG.

(2) THE BOARD SHALL PROMULGATE RULES TO NOTIFY CONSUMERS OF THE INTENT OF ANY MANUFACTURER TO WITHDRAW A PRESCRIPTION DRUG FROM SALE OR DISTRIBUTION WITHIN THE STATE, AS DESCRIBED IN SUBSECTION (1) OF THIS SECTION.

(3) AFTER PROVIDING NOTICE AND A HEARING AS DESCRIBED IN SECTION 24-4-105, THE COMMISSIONER MAY REQUIRE A MANUFACTURER TO PAY A PENALTY NOT TO EXCEED FIVE HUNDRED THOUSAND DOLLARS IF THE COMMISSIONER DETERMINES THAT THE MANUFACTURER FAILED TO PROVIDE THE NOTICE REQUIRED BY SUBSECTION (1) OF THIS SECTION BEFORE WITHDRAWING FROM SALE OR DISTRIBUTION WITHIN THE STATE A PRESCRIPTION DRUG FOR WHICH THE BOARD HAS ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407.

10-16-1413. Optional participating plans - notice of election to participate required. AN OPTIONAL PARTICIPATING PLAN THAT ELECTS TO SUBJECT ITS PURCHASES OF OR PAYER REIMBURSEMENTS FOR PRESCRIPTION DRUGS IN COLORADO TO THE REQUIREMENTS OF THIS PART 14 SHALL NOTIFY THE COMMISSIONER IN WRITING WITHIN THIRTY DAYS AFTER SUCH ELECTION.

10-16-1414. Reports. (1) NOTWITHSTANDING SECTION 24-1-136 (11)(a), ON OR BEFORE JULY 1, 2023, AND ON OR BEFORE JULY 1 EACH YEAR THEREAFTER, THE BOARD SHALL SUBMIT A REPORT TO THE GOVERNOR, THE HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR TO ANY SUCCESSOR COMMITTEES, SUMMARIZING THE ACTIVITIES OF THE BOARD DURING THE PRECEDING CALENDAR YEAR. AT A MINIMUM, THE REPORT MUST INCLUDE:

(a) PUBLICLY AVAILABLE DATA CONCERNING PRICE TRENDS FOR PRESCRIPTION DRUGS;

(b) THE NUMBER OF PRESCRIPTION DRUGS THAT WERE SUBJECTED TO AN AFFORDABILITY REVIEW BY THE BOARD PURSUANT TO SECTION 10-16-1406, INCLUDING THE RESULTS OF EACH AFFORDABILITY REVIEW AND THE NUMBER AND DISPOSITION OF ANY APPEALS OR JUDICIAL REVIEWS OF

THE BOARD'S DECISIONS;

(c) A LIST OF EACH PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407, INCLUDING THE AMOUNT OF THE UPPER PAYMENT LIMIT;

(d) THE IMPACT OF ANY UPPER PAYMENT LIMITS ESTABLISHED BY THE BOARD PURSUANT TO SECTION 10-16-1407 ON HEALTH-CARE PROVIDERS, PHARMACIES, AND PATIENTS' ABILITY TO ACCESS ANY PRESCRIPTION DRUGS FOR WHICH THE BOARD HAS ESTABLISHED UPPER PAYMENT LIMITS;

(e) A SUMMARY OF ANY APPEALS OF BOARD DECISIONS THAT WERE CONSIDERED BY THE BOARD PURSUANT TO SECTION 10-16-1408, INCLUDING AN INDICATION OF THE OUTCOME OF ANY SUCH APPEAL;

(f) A DESCRIPTION OF EACH CONFLICT OF INTEREST THAT WAS DISCLOSED TO THE BOARD DURING THE PRECEDING YEAR;

(g) A DESCRIPTION OF ANY VIOLATIONS OF ANY OF THE PROVISIONS OF THIS PART 14, INCLUDING AN INDICATION OF ANY ENFORCEMENT ACTION TAKEN IN RESPONSE TO ANY SUCH VIOLATION; AND

(h) ANY RECOMMENDATIONS THE BOARD MAY HAVE FOR THE GENERAL ASSEMBLY CONCERNING LEGISLATIVE AND REGULATORY POLICY CHANGES TO INCREASE THE AFFORDABILITY OF PRESCRIPTION DRUGS AND REDUCE THE EFFECTS OF EXCESS COSTS ON CONSUMERS AND COMMERCIAL HEALTH INSURANCE PREMIUMS IN THE STATE.

(2) THE BOARD SHALL POST THE REPORT DESCRIBED IN SUBSECTION (1) OF THIS SECTION ON THE PUBLIC WEB PAGE MAINTAINED BY THE DIVISION FOR THE BOARD PURSUANT TO SECTION 10-16-1402 (3)(d).

(3) (a) THE CHAIR OF THE BOARD SHALL PRESENT TO THE JOINT HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES AND HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR ANY SUCCESSOR COMMITTEES, WHICH PRESENTATION OCCURS PURSUANT TO THE "STATE MEASUREMENT FOR ACCOUNTABLE, RESPONSIVE, AND TRANSPARENT (SMART) GOVERNMENT ACT", PART 2 OF ARTICLE 7 OF TITLE 2, INFORMATION CONCERNING ANY PRESCRIPTION DRUG FOR WHICH

THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT DURING THE PRECEDING CALENDAR YEAR. THE CHAIR SHALL SUMMARIZE FOR THE COMMITTEE MEMBERS:

(I) THE AFFORDABILITY REVIEW OF THE PRESCRIPTION DRUG, INCLUDING THE RESULTS OF THE BOARD'S CONSIDERATIONS AS DESCRIBED IN SECTION 10-16-1406 (4) AND, IF APPLICABLE, SECTION 10-16-1406 (6); AND

(II) THE ESTABLISHMENT OF THE UPPER PAYMENT LIMIT, INCLUDING A SUMMARY OF THE METHODOLOGY USED TO ESTABLISH THE UPPER PAYMENT LIMIT.

(b) BASED ON THE INFORMATION PRESENTED IN SUBSECTION (3)(a) OF THIS SECTION, MEMBERS OF THE JOINT HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES AND HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE, OR ANY SUCCESSOR COMMITTEES, MAY PURSUE LEGISLATION, IF THE MAJORITY OF COMMITTEE MEMBERS VOTE TO PURSUE SUCH LEGISLATION, TO DISCONTINUE THE UPPER PAYMENT LIMIT FOR ANY PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHED AN UPPER PAYMENT LIMIT. ANY SUCH LEGISLATION SHALL NOT COUNT AGAINST ANY LIMITATION UPON THE NUMBER OF BILLS THAT A MEMBER OF THE GENERAL ASSEMBLY MAY INTRODUCE EACH REGULAR LEGISLATIVE SESSION, WHICH LIMITATION MAY EXIST PURSUANT TO RULES ADOPTED BY THE GENERAL ASSEMBLY.

10-16-1415. Exemption - prescription drugs derived from cannabis. NOTWITHSTANDING ANY PROVISION OF THIS PART 14 TO THE CONTRARY, THE BOARD HAS NO AUTHORITY TO PERFORM AN AFFORDABILITY REVIEW OF, OR TO ESTABLISH AN UPPER PAYMENT LIMIT FOR, ANY PRESCRIPTION DRUG THAT IS DERIVED IN WHOLE OR IN PART FROM CANNABIS.

10-16-1416. Repeal of part. THIS PART 14 IS REPEALED, EFFECTIVE SEPTEMBER 1, 2026. BEFORE THE REPEAL, THE FUNCTIONS OF THE BOARD ARE SCHEDULED FOR REVIEW IN ACCORDANCE WITH SECTION 24-34-104.

SECTION 3. In Colorado Revised Statutes, 24-1-122, add (6) as follows:

24-1-122. Department of regulatory agencies - creation.

(6)(a) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402 IS TRANSFERRED BY A **TYPE 1** TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND ALLOCATED TO THE DIVISION OF INSURANCE.

(b) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY ADVISORY COUNCIL CREATED IN SECTION 10-16-1409 IS TRANSFERRED BY A **TYPE 2** TRANSFER TO THE DEPARTMENT OF REGULATORY AGENCIES AND ALLOCATED TO THE DIVISION OF INSURANCE.

SECTION 4. In Colorado Revised Statutes, 24-34-104, **add** (27)(a)(XIX) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (27) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2026:

(XIX) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402.

SECTION 5. Appropriation. (1) For the 2021-22 state fiscal year, \$730,711 is appropriated to the department of regulatory agencies. This appropriation is from the division of insurance cash fund created in section 10-1-103 (3), C.R.S. To implement this act, the department may use this appropriation as follows:

(a) \$325,297 for use by the division of insurance for personal services, which amount is based on an assumption that the division will require an additional 3.0 FTE;

(b) \$22,650 for use by the division of insurance for operating expenses; and

(c) \$382,824 for the purchase of legal services.

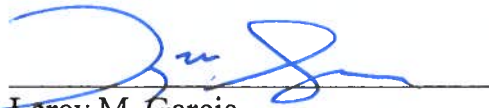
(2) For the 2021-22 state fiscal year, \$382,824 is appropriated to the department of law. This appropriation is from reappropriated funds received from the department of regulatory agencies under subsection (1)(c) of this section and is based on an assumption that the department of law will

require an additional 2.0 FTE. To implement this act, the department of law may use this appropriation to provide legal services for the department of regulatory agencies.

SECTION 6. Severability. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity does not affect other provisions or applications of this act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.

SECTION 7. Safety clause. The general assembly hereby finds,

determines, and declares that this act is necessary for the immediate preservation of the public peace, health, or safety.



Leroy M. Garcia
PRESIDENT OF
THE SENATE



Alec Garnett
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

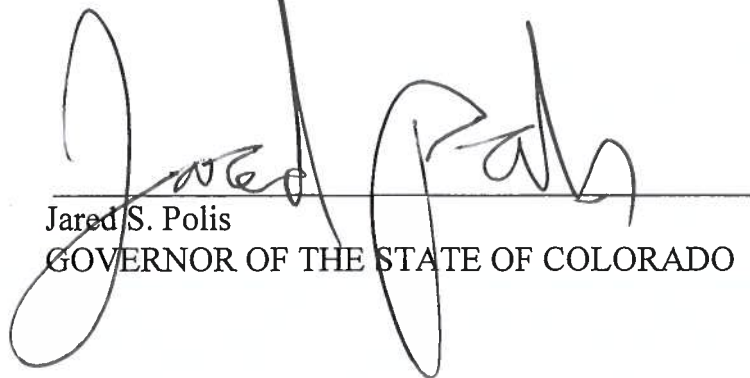


Cindi L. Markwell
SECRETARY OF
THE SENATE



Robin Jones
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED June 16, 2021 at 9:36am
(Date and Time)



Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

**Prescription Drug Affordability Board Policy and
Procedure**

Policy Number: 01

Title: Delegation to Division of Insurance Staff Policy and Procedure

Date Issued: November 12, 2021

Dates Reviewed: June 3, 2022

Purpose

1. To clarify when Staff within the Colorado Division of Insurance (“Division”) may perform work on behalf of the Colorado Prescription Drug Affordability Board (“Board”).
2. To provide guidance to Board Members regarding their duties and responsibilities with respect to Staff.

Background

The Board is an independent unit of state government, created by a Type 1 transfer, in the Division. The Board exercises its statutory powers, duties, and functions, including the promulgation of rules, regulations, and standards, and the rendering of findings, orders, and adjudications, independently of the Division and the Commissioner of Insurance (“Commissioner”). The Division performs any powers, duties, and functions not specifically vested by statute in the Board, including but not limited to, all budgeting, purchasing, planning, and related management functions of the Board. The Commissioner is the head of the Division pursuant to section 10-1-104(1), C.R.S.

The Division is further authorized by statute to provide specific support services to the Board, including but not limited to: maintaining a public website for the Board (§ 10-16-1402(3)(d), C.R.S.); entering into contracts with qualified, independent third parties for any service necessary to carry out the powers and duties of the Board (§ 10-16-1403(3), C.R.S.); and seeking and accepting gifts, grants, and donations from private or public sources that do not create a conflict of interest or appearance of conflict of interest for the Board (§ 10-16-1403(6)(a), C.R.S.).

The Board adopts this policy regarding the scope of assistance that may be properly provided by Staff so Staff may assist in the Board’s expedient and informed performance of its statutory duties and obligations.

Definitions

“Advisory Council” means the Colorado Prescription Drug Affordability Advisory

Council created in section 10-16-1409, C.R.S.

“Counsel” means any assistant attorneys general assigned by the Attorney General to provide legal counsel to the Board (§ 10-16-1402(4), C.R.S.).

“Staff” means any individual employed by the Division of Insurance providing support to and/or doing work on behalf of the Board.

Policy Statement

The Board delegates its authority to Staff to perform the following functions on the Board’s behalf. The Board may also delegate its authority to Staff in other specific policies and procedures, or during meetings through oral direction or by written resolution. The Board may elect to perform any of these duties at its discretion, including to delegate any of these duties to an individual Board Member.

Board Meetings

- a. Facilitate meetings of the Board and ad hoc committees, including scheduling meetings, arranging meeting platforms and/or locations, and sending calendar invitations and Board-related notices.
- b. Provide public notice of Board meetings and agenda items on the Board’s website.
- c. Develop agendas for Board meetings in coordination with the Board Chair.
- d. Serve as the recording secretary for the Board and prepare meeting minutes for consideration by the Board.
- e. Prepare Board materials.
- f. Distribute agenda and materials in support of the Board’s agenda to each Board Member, in accordance with Board Policy No. ***.** [COI Policy].
- g. Review meeting materials and agenda items with Counsel prior to the Board meeting.
- h. Record all meetings.
- i. Record and securely store recordings of all executive sessions entered into by the Board at Board meetings in compliance with sections 10-16-1404(3) and 24-6-402(1)(d.5)(1)(A), C.R.S.

Contracts

- a. Pursuant to section 10-16-1403(3), C.R.S., and in compliance with any procurement policies developed by the Board, facilitate contracts for work deemed necessary by the Board to carry out its powers and duties and ensure contract deliverables requested by the Board, if any, are prepared and presented to the Board.
- b. The Board determines that to necessarily carry out its powers and duties, the Division is authorized to contract on its behalf for work

related to the following: Data identification, collection, and analysis related to pharmaceutical markets and supply chains, prescription drug pricing, and other state and federal programs related to prescription drug pricing;

- i. Data, research, analysis, and supporting materials to inform the process for and conducting of affordability reviews;
- ii. Data, research, analysis, and supporting materials to inform the methodology and process for and consideration of whether to set an upper payment limit;
- iii. Data, research, analysis, and initial recommendations related to the development of a formula to calculate savings pursuant to section 10-16-1410, C.R.S.;
- iv. Equity and cultural responsiveness related to the Board's activities; and
- v. Data, research, analysis, and supporting materials for the Board's consideration in identifying potential policy recommendations to the Governor and General Assembly and compiling the Board's recommendations.

Administration

- a. Serve as the custodian of record for the Board.
- b. Maintain records for the Board in accordance with the Board's retention policies and all applicable laws and regulations, including but not limited to securely storing information, documents, and records received by the Board and executing the Board's destruction policy.
- c. Establish and maintain an electronic mail account for the Board for submission of public comment, public inquiries, or submissions of information for the Board's consideration.
- d. Receive and respond to requests made pursuant to the Colorado Open Records Act related to the Board in accordance with any applicable Board policies and all applicable laws and regulations and seek assistance of Counsel in connection with any such request, if necessary.
- e. The Program Director or any other Staff for the Board may accept service on behalf of the Board.
- f. Draft and issue correspondence on behalf of the Board, including with stakeholders, to communicate the Board's positions and determinations, provide notice of Board activities, respond to administrative or ministerial requests made to the Board, and/or seek additional information on behalf of the Board.
- g. Receive and maintain documents and correspondence addressed or submitted to the Board and ensure Board review of such materials, if necessary.
- h. Draft reports and memoranda pertaining to work completed by or on

behalf of the Board.

- i. Collect and distribute any moneys received for the Board pursuant to section 10-16-1403(6)(a), C.R.S.
- j. Maintain the Board's public webpage and ensure the webpage contains the following:
 - i. Conflicts of interest disclosed to the Board pursuant to sections 10-16-1402(3) and 10-16-1409(5)(b), C.R.S.
 - ii. Reports prepared for the General Assembly pursuant to section 10-16-1414, C.R.S.
 - iii. Notice of Board meetings and hearings.
 - iv. All agendas, non-confidential and non-privileged meeting materials, and Board-approved meeting minutes.
 - v. List of Board Members.
 - vi. List of Advisory Council Members.
 - vii. Instructions for submitting materials for the Board's consideration.
 - viii. Contact information for submitting requests pursuant to the Colorado Open Records Act.
 - ix. Policies and procedures adopted by the Board.
 - x. Resolutions, Orders, and any other memorialized decisions by the Board.
 - xi. Findings, reports, and studies conducted by the Board, redacted for confidential information as necessary.
 - xii. Notices of proposed rulemaking and rulemaking hearing information.
 - xiii. Regulations and guidance adopted by the Board.
 - xiv. List of all prescription drugs the Board determines to be unaffordable.
 - xv. List of all upper payment limits established by the Board.
 - xvi. Any material specifically requested by the Board.

Support for Performance of Board Duties

- a. Facilitate rulemaking conducted by the Board, including but not limited to:
 - i. Draft rules for consideration by the Board.
 - ii. Effectuate publication and/or filing of notices of draft proposed regulations on specific topics authorized by the Board, and adopted rules in the Colorado Register, on the Colorado Secretary of State's website, and to the DORA Office of Policy, Research and Regulatory Reforms.
 - iii. Submit requests for Attorney General opinions regarding adopted rules.
 - iv. Compile the official rulemaking record for all rulemaking conducted by the Board, including receipt and inclusion of any public comments.
- b. Collect and provide conflicts of interest to the Board:
 - i. Distribute conflict of interest forms and coordinate completion of

disclosures by prospective and active Board Members, Staff, contractors of the Division, prospective and active Advisory Council members, and Counsel.

- ii. Seek legal advice on behalf of the Board from Counsel concerning analysis related to conflicts of interest.
- c. Draft reports required by section 10-16-1414, C.R.S., and present drafts to the Board for review, amendment, and approval.
- d. Coordinate with legislative staff regarding any SMART Act or other legislative hearings or presentations.
- e. Coordinate data and information collection on behalf of the Board, including by working with other state agencies, stakeholders, and the Advisory Council, and present material received to the Board, including entering into a memorandum of understanding or data use agreement as needed and approved by the Board.
- f. Obtain legal advice from Counsel on behalf of the Board including but not limited to the following subjects: the Board or Staff's legal authority, rulemaking, engagement with stakeholders and regulated entities, Board processes, Board policies and procedures, contract management, Open Meetings Law, Colorado Open Records Act, confidentiality of information received by the Board, Board meetings and agenda items, executive session, and Board proceedings.
- g. Recruit potential Advisory Council members for consideration by the Board.
- h. Request notification and copies of any notices of withdrawal received by the Commissioner of Insurance pursuant to section 10-16-1412, C.R.S.
- i. Assist in the collection and presentation of data, information, or analysis necessary for the Board to perform its duties related to affordability reviews and establishing upper payment limits generally and as may be further specifically address in Board Policy **-*** [Affordability Review Policy] and Board Policy **-*** [Upper Payment Limit Policy].
- j. Facilitate the Board's annual training and review of the Board's policies and procedures pursuant to section 24-3.7-102(1), C.R.S., in coordination with Counsel.

Prescription Drug Affordability Board Policy and Procedures

Policy

Number: 02

Title: Policies and Procedures required by § 24-3.7-102, C.R.S.

Date Issued: November 12, 2021

Dates Reviewed: November 12, 2021

1. Statutory Authority.

The Prescription Drug Affordability Board is convened in the Division of Insurance as required by § 10-16-1402, C.R.S. Nothing in this document is intended to be contrary to these, or any, statutes, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, Constitution, and judicial decisions govern.

2. Purpose.

The Prescription Drug Affordability Board (the “Board”) is established by statute to protect Colorado residents from excessive prescription drug costs. The Board is directed to collect and evaluate information concerning the cost of Prescription Drugs purchased by Colorado consumers, perform Affordability Reviews of those Prescription Drugs, establish Upper Payment Limits where appropriate, and report annually to the Governor and General Assembly which may include policy recommendations to the General Assembly to improve the affordability of Prescription Drugs for Colorado consumers. For the initial Board, the Governor appointed five members on October 1, 2021, who are subject to Senate confirmation with staggered terms. Subsequent Board Members are appointed by the Governor with the consent of the Senate for three (3) year terms. Each Board Member must hold an advanced degree and have experience or expertise in health-care economics or clinical medicine. The Governor designates one Member of the Board to serve as the Chair of the Board.

3. Board Member Selection Process

Individuals interested in serving on the Board may apply through the Colorado State Boards and Commissions website. Openings will be communicated to the public through a notice or other consumer alert. The Board application process is open to the public at all times.

4. Term Length and Vacancies

The initial Board was appointed by the Governor by October 1, 2021. To ensure initial terms were staggered, two Members were appointed to serve three year terms, two Members were appointed to serve two year terms, and one Member was appointed to serve a one year term as determined by the Governor. Subsequent Board Members will be appointed by the Governor with the consent of the Senate for three year terms.

Except for the initial term for certain members, Board members will serve three year terms and may serve no more than two three year terms. Members seeking re-appointment for a second term should notify the Division and the Governor's Office sixty (60) days before the end of their term and will be required to complete a new application if more than two years have passed since they submitted an application for Board membership. Reappointments are not automatic and must be confirmed by the Colorado Senate. Members who are appointed to fill vacancies that occur mid-term shall serve the remainder of the unexpired term of the member whose vacancy is being filled. If more than half the term is remaining when a vacancy is filled, the partial term counts as a full term for purposes of reappointment.

5. Conflict of Interest

The Board's Conflict of Interest Policy is set forth in Prescription Drug Affordability Board, Policy No. ***-**.

6. Responsibilities of the Chair of the Board

The Governor delegates one Member to serve as the Chair of the Board. The Chair provides

leadership for the Board, presides over all Board meetings, and provides strategic planning to help the Board comply with its statutory duties and responsibilities. The Chair shall designate a Member to preside over a Board meeting in their absence. The Chair works with Board staff to develop Board meeting agendas as set forth in Section 8. The Chair also ensures Member compliance with the Conflict of Interest Policy, Policy No. ***-**.

7. Open Records and Open Meetings

The Board's activities are subject to the Colorado Open Records Act, § 24-72-201 *et seq.*, C.R.S., and the Open Meetings Law, § 24-6-402, C.R.S. Consistent with those laws, the

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Board's activities generally will be conducted in public pursuant to public notice, unless the Open Meetings Law permits particular matters to be discussed in executive session or as expressly required by § 10-16-1404(3), C.R.S. to consider trade secret, confidential, or proprietary data that is not otherwise available to the public. The Board's records are generally subject to the Colorado Open Records Act, subject to any exclusions from disclosure contained in that Act or exclusions provided under § 10-16-1401 *et seq.*, C.R.S. The Board adopts as its Colorado Open Records Act policy the Division's Colorado Open Records Act policy contained in Division of Insurance Bulletin 1.06. Under some circumstances, the Board may meet in Executive Session. See Section 11 below.

8. Meetings

The Board will hold meetings at least every six weeks. The Chair of the Board may decide to cancel or postpone a meeting when there are no prescription drugs to review whether as a result of incomplete data or the need for further analysis and no other Board business to conduct. The meetings may be referred to as meetings or hearings depending on what types of business the Board plans to conduct. The Board has discretion to set the time for its meetings. The Board may decide to adjourn a meeting or hearing to the next available day because a meeting or hearing is running long or for any other reason. A Member can participate in person, by phone, or virtually. Board meetings are broadcast live over the internet, other than executive sessions.

The Board will provide the opportunity for public comment at each meeting. Public comment can be submitted in writing or alternatively, given orally during the designated time and when speaking should introduce themselves with their name and affiliation, if any. The Board is not obligated to respond to comments.

9. Meeting Agendas, Materials, and Notes

Division staff will post Board meeting minutes, agendas, and notices of upcoming meetings on the Prescription Drug Affordability Board website. The meeting agenda will be designed,

among other things, to ensure the Board meets its statutory obligations. The Board Chair in collaboration with the Staff will prepare a draft agenda and provide it to the Members prior to the Board meeting or hearing. Each Member will review the draft agenda and notify the assigned Assistant Attorney(s) General at the Colorado Department of Law of any potential conflict of interest. Counsel will notify the Staff of whether Members have recused themselves from certain agenda items. Prior to the meeting or hearing, the Staff will provide each Member with a Board packet of items, excluding materials related to any agenda item from which a Member has recused themselves. The Board packet may include materials, information, and/or analysis from the Advisory Council, Staff, and any third-party contractors necessary for the Board to make informed decisions. The Agenda will be posted on the Board's website two days prior to the Board meeting or hearing.

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Staff will coordinate Board meeting times, location (virtual and/or in-person), materials, and other logistics including providing accommodations as requested.

10. Quorum, Decisions, and Voting

A majority of the five (5) person Board constitutes a quorum. Voting will be conducted by a Member roll call. Motions to conduct Board business should follow the processes set forth in Robert's Rules of Order (e.g. motion, second, discussion, vote).

11. Executive Session

The Board may, at any time, retire into executive session to consult with the assigned Assistant Attorney(s) General at the Colorado Department of Law or as permitted by section 24-6-402, C.R.S. The Board must retire into executive session to discuss proprietary, trade secret, or confidential information pursuant to section 10-16-1404(3), C.R.S.

To enter executive session, a Member will state the topic for discussion in the executive session and the statutory provision which authorizes the Board to meet in executive session. Upon a majority vote, the open meeting will be adjourned and the executive session will begin. No official Board business may be conducted during the executive session and the Board may only discuss the topic(s) announced during the open meeting. The Board will not deliberate concerning whether to subject a prescription drug to an affordability review, vote concerning whether to establish an upper payment limit on a prescription drug, or otherwise make any final decision of the Board in executive session.

Upon reconvening the open meeting at the conclusion of the executive session, all Members will maintain the confidentiality of the information discussed and/or legal advice provided in executive session. The Board will ensure that electronic recordings of executive sessions are securely stored and will not result in the disclosure of any material or information containing trade-secret, confidential, or proprietary data. The Board will also ensure that

no minutes from executive session disclose or include materials or information containing trade-secret, confidential, or proprietary data.

12. Meeting Attendance, Absences, and Participation

Board Members are expected to make every effort to attend Board meetings. Members may participate in a meeting in person, by telephone, or any other means of electronic communication by which all persons participating in the meeting can hear each other at the same time. If a Member is unable to attend a meeting, the Member must notify the Chair prior to the meeting. If a Member misses more than three consecutive meetings without

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informing the Chair, the Board may vote to recommend to the Governor that Member be removed.

13. Member Resignation and Replacement

Any Board Member who can no longer perform the responsibilities of the Board must notify the Chair (unless that Member is the Chair), Board Staff, and the Governor's Office in writing to resign from their position. Any such resignation shall take effect at the date of receipt of such notice or at any later date specified therein if the later date is acceptable to the Governor. The Governor, with the consent of the Senate, will appoint a replacement Member. The new Member will serve for the remainder of the resigning Member's term.

When a Member's term expires, the Member, at the Governor's discretion, may remain on the Board until a replacement is appointed by the Governor.

Please see "Member Selection Process" at Section 3 above.

14. Board Members are Public Representatives

Members of the Board are Public Representatives, appointed by the Governor, with the purpose of protecting Colorado consumers from excessive prescription drug costs. Members accept appointment to the Board with the understanding that they will represent the public interest in their actions and decisions on the Board. As such, it is imperative Members do not engage in any activity of the Board where there is a Conflict of Interest.

15. Coordinating with other Entities

The Board may, from time to time, coordinate with other boards, commissions, industry, educational institutions, and state agencies where the responsibilities and interests overlap in creating transparency for the cost of prescription drugs and determining the affordability

of prescription drugs for Colorado consumers.

16. Interaction with the Media and Lobbyists

Unless otherwise delegated to them by a majority vote of the Board, individual Board Members do not have the authority to speak on behalf of the Board. The Board operates as a single entity when communicating with external parties. If Board Members receive media requests related to their Board work and participation, they should notify Assistant Commissioner Vince Plymell at vincent.plymell@state.co.us.

17. Division of Insurance Staff

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Staff from the Division of Insurance (“Staff”) shall provide support to the Board including serving as the Recording Secretary for the Board; coordinating Board meeting times, location (virtual or otherwise), materials, and other logistics; compiling information necessary for the Board to conduct Affordability Reviews and setting Upper Payment Limits; tracking health benefit plan savings; and additional tasks as delegated by the Board. The Staff may also provide support to the Board in preparing policy recommendations to the General Assembly and preparation of annual reports to the General Assembly (pursuant to § 10-16-1407(10)(b) and § 10-16-1414, C.R.S.). The Division, on behalf of the Board, may enter into contracts with qualified, independent third parties for services necessary to carry out the powers and duties of the Board. All third-party contractors are required to enter into a nondisclosure agreement to protect trade-secret, confidential, or proprietary information. In retaining third-party contractors on behalf of the Board, the staff is exempt from the state “Procurement Code”, articles 101 to 112 of title 24 (pursuant to section 10-16-1403(4), C.R.S.). The Staff may be reached at ***_***_**** and *****@state.co.us. The Board’s standing authorization to the Division of Insurance may also be found at [location of adopted Staff delegation policy]. The Board may also delegate particular tasks to the Division of Insurance on a case-by-case basis to perform its duties. These particular delegations may be found at [“Resolutions” tab of PDAB website].

18. Advisory Council

The Board shall appoint an Advisory Council pursuant to § 10-16-1409, C.R.S., comprised of fifteen (15) members. The executive director of the Department of Health Care Policy and Financing or their designee shall serve as a member of the Council. The Board will appoint the members of the initial Advisory Council no later than January 1, 2022. The Advisory Council will provide stakeholder input to the Board regarding the affordability of prescription drugs for Colorado consumers.

19. Annual Review

The Board will review this Policy and the Conflict of Interest Policy at least annually. The Board will also receive annual training as required by section 24-3.7-102, C.R.S.

**Prescription Drug Affordability Board Policies and
Procedures**

Policy Number: 03

Title: Conflict of Interest Policy and Procedure

Date Issued: December 17, 2021

Dates Reviewed: February 17, 2023

Purpose

1. To ensure that the Colorado Prescription Drug Affordability Board (“Board”) conducts business for the benefit of the public, and in the absence of personal, financial, or otherwise improper interests.
2. To provide guidance to individual Board Members on how to identify and manage Conflicts of Interest in relation to their statutory obligations as Board Members.

Background

The Board consists of five (5) members and was created by a Type I transfer to the Division of Insurance within the Department of Regulatory Agencies. The Board is directed to collect and evaluate information concerning the cost of Prescription Drugs purchased by Colorado consumers, perform Affordability Reviews of Prescription Drugs, establish Upper Payment Limits where appropriate, and make policy recommendations to the General Assembly to improve the affordability of Prescription Drugs for Colorado consumers. Board Members are appointed by the Governor with the consent of the Senate for three (3) year terms. Each Board Member holds an advanced degree and has experience or expertise in health-care economics or clinical medicine.

Definitions

Terms used in this policy have the same meaning as set forth in Part 1 the Board’s Rules and section 10-16-1401, C.R.S., unless clarified further below.

“Advisory Council” means the Colorado Prescription Drug Affordability Advisory Council that was created in section 10-16-1401, C.R.S.

“Affordability Review” means the review by the Prescription Drug Affordability Board of specific Prescription Drugs to determine whether the drug is affordable for Coloradans pursuant to section 10-16-1406(3)-(7), C.R.S., to determine whether use of the Prescription Drug consistent with the labeling approved for Prescription Drug by the FDA or with standard medical practice is unaffordable for Colorado consumers. “Board Activity” means selecting Prescription Drugs for an Affordability Review; conducting an Affordability Review; selecting Prescription Drugs for an Upper Payment Limit; and establishing an Upper Payment Limit.

“Board activity” means selecting prescription drugs for an affordability review;

determining whether a prescription drug is unaffordable; selecting prescription drugs for an upper payment limit; and establishing an upper payment limit.

“Board member” or “member” means a person appointed by the Governor to serve on the Prescription Drug Affordability Board.

“Conflict of Interest” or “Conflict” means an association, including a Financial or Personal Association, that has the potential to bias or appear to bias an individual’s decisions in matters related to the Board or the Advisory Council or the conduct of the activities of the Board or the Advisory Council. “Conflict of Interest” includes any instance in which a Board Member; an Advisory Council member; a Board staff member; a contractor of the Division, on behalf of the Board; or an Immediate Family Member of a Board Member, an Advisory Council member, a Board staff member, or a contractor of the Division, on behalf of the Board, has received or could receive: (a) a Financial Benefit of any amount derived from the results or findings of a study or determination that is reached by or for the Board; or (b) a Financial Benefit from an individual or company that owns or manufactures a Prescription Drug, service, or item that is being or will be studied by the Board.

“Division” means the Colorado Division of Insurance.

“Financial Association” means a relationship, contract, or ownership interest over which the Board Member exercises meaningful control, which elicits a Financial Benefit relating to a Prescription Drug under consideration by the Board or Pharmaceutical Company associated with a Prescription Drug under consideration by the Board including employment, consultancy, direct stock ownership, affiliation with the patent for a Prescription Drug, or publication of written work or research involving a Prescription Drug under consideration by the Board that was partially or fully paid for by a Pharmaceutical Company. A Financial Association does not include a Board Member’s participation in the 340B Program on behalf of their employer, provided that the Board Member does not individually receive a Financial Benefit in the form of increased compensation, incentives, or other benefits from their employer because of the Member’s professional participation in the 340B Program.

“Financial Benefit” means honoraria, fees, stock, personal cost savings resulting from the Member or Member’s Immediate Family Member taking a Prescription Drug for which the Board is considering an Upper Payment Limit, patent royalties, or any other form of compensation, including increase to the value of existing stock holdings.

“Immediate Family Member” means a person living in the same household as a Board Member, Advisory Council Member, a staff member, and/or a contractor of the Division working on behalf of the Board.

“Personal Association” means taking the Prescription Drug that is the subject of a Board Activity, currently participating in pharmaceutical-sponsored clinical trials for the Prescription Drug or testifying in a judicial proceeding without compensation either for or against the Prescription Drug or Pharmaceutical Company associated with the Prescription Drug that is the subject of a Board Activity.

“Pharmaceutical Company” means a company that owns or manufactures a prescription

drug, service, or item that is being or will be studied by the Board and includes manufacturers as defined by section 10-16-1401(16), C.R.S.

“Prescription Drug” means a drug intended for human consumption that: (a) is required by any applicable federal or state law or rule to be dispensed only pursuant to an order; (b) is restricted by any applicable federal or state law or rule to use by practitioners only; or (c) prior to being dispensed or delivered, is required under federal law to be labeled with “Rx only.”

“Upper Payment Limit” means the maximum amount that may be paid or billed for a Prescription Drug that is dispensed or distributed in Colorado in any financial transaction concerning the purchase of or reimbursement for the Prescription Drug.

Policy Statement

Board Members must disclose any Conflict of Interest for which the Board Member is required to recuse from a Board Activity. An association or Financial Benefit that does not have the potential to bias or appear to bias a Board Member’s participation in a Board activity does not constitute a Conflict of Interest. All Board Member applicants must disclose conflicts of interest when being considered for appointment or re-appointment to the Board.

A Financial Benefit received more than five years prior to the Board Member’s appointment to the Board presumptively does not have the potential to bias or appear to bias a Board Member’s decision. Board Members may also choose to disclose to the Board a Financial Benefit received more than five years prior to the appointment to the Board, even if the member has determined it does not constitute a conflict. However, if a Board member determines that a financial benefit received more than five years prior to the appointment to the Board does constitute a Conflict, Board Members shall disclose and recuse from the Board activity with which that conflict applies.

The Board will strive to ensure that it acts impartially. To ensure impartiality, each Board Member is required to limit participation or recuse themselves from any Board Activity that involves a Prescription Drug or Pharmaceutical Company to which the member has a Conflict. To further ensure impartiality, staff and contractors of the Division engaged in a Board Activity may be required to recuse themselves from any Board Activity in which the individual has a Conflict. The Board and Division will ensure Board Members, staff, and contractors disclose Conflicts in accordance with this policy and its requirements.

The Board appoints the members of the Advisory Council and will ensure that all potential Advisory Council members disclose their Conflicts of Interest on a form provided by the Board. The Board will consider such disclosures prior to appointment of the applicant to the Advisory Council. The Board will also consider any Council member conflicts disclosed to the Board pursuant to section 10-16- 1409(5)(b), C.R.S., the Board will disclose Conflicts of Interest for the Board, Council, staff, and contractors working on behalf of the Board on its page of the Division’s website and in the annual report to the Governor and respective committees in the General Assembly.

Conflict of Interest

Board Members may have an actual Conflict of Interest or the appearance of a Conflict of Interest. An actual Conflict of Interest occurs when a Board Member or a Board Member's Immediate Family Member has a Financial or Personal Association that could influence the Board Member's opinion on a matter before the Board.

Appearance of Impropriety

Board Members should be aware of the appearance of impropriety and should take care to avoid any conduct that may appear improper and erode public confidence in the decisions of the Board. Pursuant to section 10-16-1402(3)(e), C.R.S., Board Members shall not accept a financial benefit, gift, bequest, or donations of services or property that suggests a Conflict of Interest or appears to create bias in the work of the Board.

Procedures for Identifying and Managing Conflicts of Interest

When the Board is selecting prescription drugs for affordability review, Board members will disclose conflicts of interest prior to deliberation concerning selection in the open meeting. The Board member will not participate in any deliberations concerning a specific prescription drug or pharmaceutical company with which they have a conflict of interest. The Board member may otherwise participate in deliberations related to selection of prescription drugs for which they do not have a conflict. A Board member with a conflict of interest will recuse themselves from any vote that involves only the prescription drug or pharmaceutical company with which they have a conflict when selecting prescription drugs for affordability review.

For all other Board activities, Board members will not participate in any Board activity in which a Board member has a Conflict of Interest. Prior to each Board meeting where the Board will engage in a Board activity, Board members will review the draft agenda and identify any potential Conflicts of Interest with a prescription drug or pharmaceutical company that is the subject of the Board activity. When a Board member determines they have a Conflict of Interest, the Board Member must disclose the conflict in an open meeting and recuse themselves. The Board Member will also notify Board staff to help ensure that the Member does not have access to confidential, proprietary, or trade secret information on matters for which the Member must recuse themselves.

For questions regarding conflicts of interest, the Board Members may seek the advice of the assistant attorney(s) general assigned to the Board.

As required by sections 10-16-1402(3)(d) and 10-16-1414(1)(f), C.R.S., the Board will disclose Conflicts of Interest for the Board, Advisory Council, Board staff, and contractors working on behalf of the Board on its page of the Division's website and in the annual report to the Governor and respective committees in the General Assembly. The Board will identify Conflicts of Interest on its website by identifying the person with the Conflict and the Prescription Drug or Pharmaceutical Company for which they have a Conflict and have recused. The Board will not identify the nature of the Conflict of Interest on the website.

Prescription Drug Affordability Board Policy and Procedures

Policy Number: 04

Title: Affordability Review Policy and Procedure

Date Issued: April 11, 2025

Dates Reviewed: August 30, 2024, November 20, 2024, January 10, 2025

Authority

The statutory authority for this policy is section 10-16-1406, C.R.S. Nothing in this document is intended to be contrary to any statutes, rules, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, rules, Constitution, and judicial decisions govern.

Scope and Purpose

The purpose of this policy is to further establish methodologies and processes for the Board to identify and select drugs eligible for affordability review, and conduct affordability reviews of prescription drugs to determine whether use of the prescription drug consistent with the labeling approved for the prescription drug by the U.S. Food and Drug Administration (FDA) or with standard medical practice is unaffordable for Colorado consumers in compliance with section 10-16-1406(3), C.R.S.

As directed by PDAB Policy 01, Delegation to Division of Insurance Staff Policy and Procedure, this policy outlines specific delegations to Board Staff (or “Staff”) associated with the affordability review process. In connection with the delegations and processes set forth below, Staff is authorized to perform these functions through whatever means Staff deems appropriate, whether by doing this work themselves, working with other state entities, other states, or stakeholders, or using a qualified third-party contractor pursuant to section 10-16-1403(3), C.R.S.

Further, this policy sets forth the interpretations employed by the Board in performing its work related to the affordability review, provides additional information regarding what types of data and information the Board will consider and how it will get or determine that information, and sets forth the Board’s processes and procedures for performing an affordability review. Terms used in this policy have the same meaning as set forth in Parts 1 and 3 of the Board’s Rules.

Identifying Prescription Drugs for Affordability Reviews

Staff will prepare a list of prescription drugs that meet the criteria set forth in section 10-16-1406(1), C.R.S., Part 3 of the Board’s Rules, 3 C.C.R. 702-9.

Once Staff has compiled the list of eligible prescription drugs as delegated by the Board, Staff will present the list to the Board. The Board will review the list and vote on whether to approve the list.

To the extent that Staff develops methodologies or draws from existing data sources to identify the drugs, the methodologies and sources will be publicly presented to the Board, or presented in executive session pursuant to section 10-16-1404(3), C.R.S., as applicable.

In accordance with the above parameters, Staff will identify drugs according to the criteria as outlined in 10-16-1406(1), C.R.S. Staff will utilize methodologies, including the following where practicable, to identify prescription drugs eligible for affordability reviews:

1. For all prescription drugs:
 - a. Wholesale Acquisition Costs (WAC), where the initial WAC means the earliest listed WAC for a prescription drug, and the current WAC means the most recently available WAC for a prescription drug in the relevant database.
 - b. Brand name drugs and biological products will be identified utilizing National Drug Code (NDC) identifications. Brand name drugs and biological products will be identified for eligibility by identifying, consolidating, and listing NDCs with the same brand name and active ingredient.
 - c. Twelve-month supply and course of treatment will be determined by multiplying the initial WAC/unit for a prescription drug by a measure of central tendency (e.g., mean, median, mode) as calculated from utilization data in Colorado's APCD. Staff may provide additional utilization statistics to provide more context regarding how actual utilization compares to common understandings of a twelve-month supply or course of treatment.
2. For a biosimilar product:
 - a. Biosimilar products will be identified utilizing National Drug Code (NDC) identifications. Biosimilar products will be identified for eligibility by identifying, consolidating, and listing NDCs for FDA-approved biosimilar drugs by manufacturer, brand name, and active ingredient.
 - b. Initial WAC amounts for biosimilars will be compared to the corresponding biological product's most recent WAC listed before the date when the initial biosimilar WAC was listed.

Selection of Eligible Prescription Drugs for Affordability Review

After approving the list of eligible prescription drugs, the Board will select which drug(s), if any, for which to conduct an affordability review. The affordability review will include consideration of statutory factors, as further described in Part 3, 3 C.C.R. 702-9.

Staff will prepare the following information, to the extent it is available, for the Board's consideration and deliberation as part of the selection process. After identifying prescription drugs as described in Section C above, the Board will determine whether to conduct an affordability review for an identified prescription drug by considering the following criteria.

The Board must examine all criteria for a prescription drug before deciding whether to conduct an affordability review for that drug.

1. Identifying the initial date of FDA approval of the eligible prescription drug, including whether the prescription drug was approved through an expedited pathway, and evaluating the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale by gathering:
 - a. Information on the class of the prescription drug, as identified in the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) Classification, US Pharmacopeia (USP) Drug Classification System, or other similar classification system.
 - b. Information on whether there are any therapeutically equivalent prescription drugs:
 - i. Are approved: therapeutic equivalent prescription drugs will be identified by examination of the FDA Orange Book, FDA Purple Book, or other therapeutic equivalence databases.
 - ii. Are for sale: information on the availability of therapeutic equivalents for sale, as opposed to therapeutic equivalents that are FDA approved but not currently marketed, will be gathered by examining information regarding utilization of the therapeutic equivalent prescription drug within the previous 12 months, in aggregate and by payer, as well as additional information gathered from experts regarding whether the therapeutically equivalent drug is for sale.
1. The following aggregated data sources may be utilized:
 - a. Pricing Information: Including WAC pricing trends over time, Average Sales Price trends over time, and National Average Drug Acquisition Cost trends over time.
 - b. Expenditures: APCD data showing spending amounts by line of business and payers, by consumers, and by total amounts, including data collected pursuant to section 10-16-1405, C.R.S.. Board staff will summarize required data submitted by carriers.
 - c. Utilization: APCD data showing claim counts, unit counts, and per person utilization.
 - d. Combined expenditure and utilization aggregated data: APCD data that incorporates both expenditure and utilization (e.g., cost per person, per member per month expenditure, etc.).
 - e. Health equity impact: information showing whether the prescription drug is utilized to treat a condition disproportionately experienced by priority populations, as such conditions are identified from sources like the Colorado Department of Public Health & Environment's Health Equity office, the Centers for Disease

Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion, and other sources.

- f. Information estimating manufacturer net-cost and net-sales amounts of an eligible drug.
 - g. Aggregated data analyses will examine up to five years of data for all categories and all prescription drugs.
2. Input from the Prescription Drug Affordability Advisory Council:
 - a. After presenting the list of identified prescription drugs to the Board, Staff will email the list to the Advisory Council and convey Board requests.
 - b. Before the next Board meeting, Staff will assist in convening an Advisory Council meeting to gather Advisory Council input.
 - c. Staff will present the Advisory Council input to the Board.
 - d. Nothing in this policy precludes the Advisory Council from identifying additional methods for delivering input to the Board (e.g., Advisory Council written or verbal reports directly to the Board).
3. Average patient's out-of-pocket cost for the prescription drug for up to five years for each prescription drug based on:
 - a. APCD data, in aggregate and by payer type, for out-of-pocket costs, and
 - b. Other data sources that approximate out-of-pocket costs not captured in APCD data.
4. Input regarding orphan drug designation: consideration of whether the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications. If the prescription drug has an approved orphan drug designation for one or more rare diseases and no other indications then the Board will consider input from consumers and the rare disease advisory council created in section 25-1-1503, C.R.S. Input sought may include:
 - a. Whether consumers and the Rare Disease Advisory Council have observed affordability concerns with the prescription drug,
 - b. Consumer and the Rare Disease Advisory Council observations regarding other selection criteria outlined in selection criteria outlined in Part 3, 3 C.C.R. 702-9 D.1-4.
5. The Board may use information from selection criteria to prioritize affordability goals in the selection of prescription drugs for an affordability review. Examples of affordability goals the Board may want to consider prioritizing in selecting prescription drugs for an affordability review include:
 - a. Price increases that exceed reasonable levels, as such levels are identified by the Board,

- b. Consumer costs that threaten Coloradans' economic well-being,
- c. Costs that contribute significantly to rises in health-care costs and health insurance premiums that threaten financial and physical health of Coloradans,
- d. Costs for prescription drugs for conditions and disease that disproportionately impact priority populations, and/or
- e. Excessive costs that contribute significantly to rising state budget costs.

To the extent permissible pursuant to section 10-16-1404(3), C.R.S, the Board will publicly deliberate over the selection criteria. The Board will deliberate over any information relating to the selection criteria containing trade-secret, confidential, or proprietary data that is not otherwise available to the public in executive session. The Board will take and consider public comment regarding its selection of eligible drugs for affordability review.

If the Board chooses to conduct an affordability review for a prescription drug, the Board will adopt a resolution, by majority vote, selecting the prescription drug and setting forth the selection criteria relied upon for its action. The Board will not deliberate concerning whether to subject a prescription drug to an affordability review in executive session, as required by section 10-16-1404(3)(a), C.R.S. All drugs for which the Board has determined to conduct an affordability review will be posted on the Board's website.

Conducting an Affordability Review

A. Assembling and Presenting Required Information to the Board

Staff shall compile information to support each of the factors identified in sections 10-16-1406(4) and (6), C.R.S., and Part 3, 3 C.C.R. 702-9. Staff may compile the information through internal analysis, engaging contractors, referencing the transparency reporting information pursuant to section 10-16-1405, C.R.S., accessing data sources, soliciting feedback from stakeholders, procuring pricing information from other states, the APCD and state entities, or other countries as appropriate.

Staff will draft a report for the Board's consideration detailing the information compiled to support each factor in the affordability review. Staff's draft report shall not contain a recommendation as to unaffordability. To the degree the Board has identified whether certain criteria should be weighted for consideration more strongly than other criteria, Staff will reflect this weighting in the draft report. Staff will identify in the draft report whether any information or data could not be obtained because it was not practicable. When all the information has been compiled, Staff shall present the draft report to the Board. The Board will consider the factual information presented by Staff in support of each factor in the affordability review. Staff may engage third party consultants to assist in compiling and/or analyzing the data. All third party contractors will be required to execute a nondisclosure agreement as required by section 10-16-1406(5), C.R.S. The Board will take and consider public comment regarding the factual information presented by Staff. The Board may request additional information from Staff.

Once the Board has established it has sufficient information, it will deliberate over the information to make a determination as to whether a prescription drug is unaffordable for

Colorado consumers. The Board will weigh the factors and information according to its expertise and discretion. All Board members will comply with the Board's Conflict of Interest Policy and recuse themselves from deliberations if required by the Policy.

The Board will take and consider public comment regarding its deliberations concerning whether a prescription drug is unaffordable for Colorado consumers. When the Board determines it has sufficiently considered the information, the Board will:

1. Vote to adopt the affordability review report, and
2. Vote to determine whether a prescription drug is unaffordable.

Staff will finalize the report, incorporating a summary of the Board's deliberations and identifying the Board's determination as to unaffordability. The final report will be made available to the public on the Board's website.

B. Compiling Supporting Evidence and Information for Required Factors

1. Wholesale Acquisition Cost: Information regarding the initial WAC, the current WAC, and changes to WAC over time.
2. Therapeutic Alternatives: Information containing a list of therapeutic alternatives for the Board's consideration through review and consultation of sources such as the Orange Book, the Purple Book, World Health Organization's anatomical therapeutic classification code system, and peer-reviewed research.

Information prepared for the Board's consideration includes:

- a. The cost of the therapeutic alternative in the state by examining APCD expenditure data or other data sources relevant to cost of the therapeutic alternatives in the state;
 - b. The availability of the therapeutic alternative in the state by examining APCD utilization data or other data sources relevant to the therapeutic alternatives in the state; and
 - c. Rebate, discount, and price concessions data for the therapeutic alternative(s) by examining external databases.
3. Price Effect on Colorado Consumer Access: Information regarding changes in pricing compared to changes in expenditure and utilization over the same time period to analyze potential correlation. Information will also be presented from APCD data and subject matter experts to better understand potential confounding variables, such as:
 - a. When therapeutic alternative(s) were available;
 - b. Changes to patents;
 - c. Changes in rebate amounts for the prescription drug or therapeutic alternative; and

- d. Utilization rate of the drug per approved indication.
 - e. The Board may consider the impact of the drug's price on insurance consumer premiums and out-of-pocket costs, the impacts of formulary placement on access, and the extent to which and manner in which rebates are shared with patients purchasing the drug.
4. Relative Financial Effects of the Prescription Drug on Health, Medical, or Social Services Costs: Information providing an overview of the research regarding the relative financial effects of the prescription drug on health, medical, or social services cost, or impacts on premiums, state expenditures on the drug or disease, and other broader system financial impacts. This will be done by reviewing research that is:
- a. Publicly available;
 - b. To the extent the Board has funding, data accessible from the Drug Effectiveness Review Project; or
 - c. Is voluntarily provided by manufacturers, PBMs, or carriers.
5. Patient Copayment or Other Cost Sharing: Information from:
- a. APCD data, in aggregate and by line of business, payer, and insurance plan type, for out-of-pocket costs;
 - b. Other data sources that approximate out-of-pocket costs not captured in APCD data; and
 - c. Out-of-pocket analyses will examine up to five years of data and will be consistent across all prescription drugs.
6. Impact on Safety Net Providers: As part of the Board's obligation to consider the impact of an affordability review of the cost of a prescription drug on safety net providers, Staff will request all safety net providers to voluntarily provide information to the Board. To facilitate gathering the information from safety net providers, Staff may request a list of 340B approved safety net providers from HCPF.
7. Orphan Drug Status: Information regarding the prescription drug's orphan drug status as designated by the FDA pursuant to the Orphan Drug Act (Pub.L. 97-414), including:
- a. Reviewing the Orphan Drug List for the quarter during which the affordability review begins.
 - b. Designation date of the prescription drug on the orphan drug list.
 - c. Treatment designation of the prescription drug on the orphan drug list as an indicator of the population the orphan drug serves.
 - d. Reviews of literature and patient, caregiver, and clinical expertise to understand the extent to which the prescription drug addresses and unmet need or treats a rare or serious disease for which limited therapeutic

alternatives are available.

8. Input from Specified Stakeholders

- a. Staff will gather input from patients and caregivers affected by a condition or disease that is treated by the prescription drug. To gather information from patients and caregivers, Board staff may:
 - i. Facilitate a public meeting(s) with patients, caregivers, and Board members.
 - ii. Facilitate individual or small group meetings with patients and caregivers.
 - iii. Conduct focus groups with patients and caregivers.
 - iv. Distribute a survey to gather information from patients and caregivers who were unable to attend public or small group meetings.
 - v. Patients and caregivers may continue to provide input via verbal public comment and written public comment.
 - vi. During the following Board meeting(s), Staff will present input provided by patients and caregivers and will report such information in their final report.
- b. Staff will gather input from individuals who possess scientific or medical training in regards to a prescription drug under review. To gather information from individuals with scientific and medical training, Board staff may:
 - i. Facilitate a public meeting(s) with individuals with scientific or medical training and Board members.
 - ii. Facilitate individual or small group meetings with individuals with scientific or medical training.
 - iii. Conduct focus groups.
 - iv. Distribute a survey to gather information from individuals with scientific or medical training who were not able to attend public or small group meetings.
 - v. Individuals who possess scientific or medical training with respect to the condition or disease may continue to provide input via verbal public comment and written public comment.
 - vi. Individuals who possess scientific or medical training with respect to the condition or disease will be asked to voluntarily disclose any conflicts of interest with the drug under review. At the request of the Board, Staff may further investigate the CMS Open Payments database for potential conflicts of interest.

- vii. During the following Board meeting(s), Staff will present input provided by individuals with scientific or medical training and will report such information in their final report.
 - c. Staff will gather input from the Rare Disease Advisory Council (RDAC). To gather information from the RDAC, Board staff will work with the RDAC Chair or RDAC staff, and may:
 - i. Facilitate a public meeting(s) with the RDAC.
 - ii. The RDAC may continue to provide input via verbal public comment and written public comment.
 - iii. During the following Board meeting(s), Staff will present input provided by the RDAC and will report such information in their final report.
 - d. Prior to or while gathering input from specified stakeholders, the Board may direct Board staff to facilitate a public meeting or workgroup with members of PDAAC, RDAC, or other stakeholders, including organizations representing or advocating for patients affected by a condition or disease treated by the prescription drug, to identify best practices regarding: gathering sensitive patient experience information, requesting voluntary disclosures of conflicts of interest; and determining preferred methods to gather information.
9. Information Voluntarily Submitted from a Manufacturer, Carrier, Pharmacy Benefit Management Firm, or Other Entity: Staff will prepare information voluntarily provided by a manufacturer, carrier, pharmacy benefit management firm, or other entity for the Board's consideration. This may include requests from manufacturers or PBMs to provide information on patient assistance programs, negotiated rebates, and 340B discounts.

After selection of a prescription drug for affordability review, the Board will notify interested parties, including members of the PDAAC, using its listserv and by posting on its website, of the ability to submit information pursuant to section 10-16-1406(4)(i), C.R.S., if such interested parties are manufacturers, carriers, pharmacy benefit management firms, or other entities.

10. Additional Factors:

- a. Rebates, Discounts, and Price Concessions: To the extent the Board has funding, information may be prepared from an external database regarding estimated manufacturer net sales net sales and net costs (including rebates, discounts, and price concessions) for the prescription drug under review and, to the extent practicable, for therapeutic alternatives under review. Board staff will include estimates that separate 340B discounts from negotiated rebates if data or estimates that separate 340B discounts from negotiated rebates if data or estimates become available.
- b. Health Equity Factors: Staff will prepare information regarding utilization and expenditures as identified in APCD data, attempting to understand utilization

by:

- i. People experiencing homelessness;
 - ii. People involved in the criminal justice system;
 - iii. Black people, indigenous people, and people of color;
 - iv. American Indians and Alaska natives;
 - v. Veterans;
 - vi. People who are lesbian, gay, bisexual, transgender, queer, or questioning;
 - vii. People of disproportionately affected sexual orientations, gender identities, or sex assigned at birth;
 - viii. People who have AIDs or HIV;
 - ix. Older adults;
 - x. Children and families;
 - xi. People with disabilities, including people who are deaf and hard of hearing, people who are blind and deafblind, people with brain injuries, people with intellectual and developmental disabilities, people with other co-occurring disabilities;
 - xii. Other populations as deemed appropriate by the Prescription Drug Affordability Board.
- c. Information from the Department of Health Care Policy and Financing: Staff will review any additional analyses conducted by HCPF relevant to the prescription drug or therapeutic alternative under review for presentation to the Board.
- d. Non-adherence and Utilization Management Information: To the extent such information is available, the Board may use information regarding non-adherence to the prescription drug, as well as information related to utilization management restrictions and prior authorization requirements placed on the prescription drug.
- e. Patient Assistance Program Information: Staff will gather information regarding patient assistance programs available to patients in Colorado, potentially including utilization, eligibility criteria, financial impacts, and ease of accessing assistance programs. Staff will accept information from:
- i. Manufacturers providing voluntarily submitted information regarding manufacturer assistance programs and other assistance programs affiliated with the manufacturer; and
 - ii. Other entities that provide financial assistance programs. Other entities may be identified by patients, caregivers, individuals with scientific and medical training, and the RDAC.

C. Compiling Supporting Evidence and Information for Permissive Factors

1. The Board may also consider documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug including information related to:
 - a. Life-cycle management;
 - b. Average cost of the prescription drug in Colorado;
 - c. Market competition;
 - d. Projected revenue;
 - e. Estimated cost-effectiveness of the prescription drug; and
 - f. Off-label usage of the prescription drug.
2. The Board may access pricing information for prescription drugs by:
 - a. Accessing publicly available pricing information from a state to which manufacturers report pricing information. Staff will review other state programs and provide such information to the extent it is available.
 - b. Accessing available pricing information from the APCD and from state entities.
 - c. Staff will review pricing information in the APCD and, to the extent such data has not already been utilized in the affordability review, provide such information.
 - d. Staff will review pricing information available from state entities and provide such information to the Board.
 - e. Accessing information that is available from other countries. Staff will review pricing information from other countries and provide such information to the extent it is available.

D. Notice and Submissions of Information

On an annual basis, Staff will conduct outreach to trade associations for manufacturers, carriers, pharmacy benefit management firms, providers, pharmacies, wholesalers, patients, consumers, and caregivers requesting the trade organizations notify members of the activities of the Board, including that the Board may conduct affordability reviews and potentially set upper payment limits pursuant to sections 10-16-1406 and 1407, C.R.S. All interested parties will be encouraged to provide information for the Board's listserv in order to ensure they receive notice of the Board's upcoming actions including specific affordability reviews and consideration of specific upper payment limits.

Staff will notify the public of the selection of the drug by posting the same to the Board's website and distributing an email on the listserv. Staff will provide guidance on how the public and interested persons may participate in the Board's affordability review and provide information on public meetings where the Board will be gathering input, and how to submit information for the Board's consideration. Staff will specifically provide information related

to how appropriate persons may submit information for the Board's consideration pursuant to subsections 10-16-1406(4)(f), (h), and (i), C.R.S.

Persons submitting information for the Board's consideration shall have 90 days from the commencement of an affordability review of the prescription drug to provide such information to the Board. Stakeholders are encouraged to disclose to the Board which type of specified stakeholder they are (e.g. patient, caregiver, or individual with scientific or medical training, etc.) and/or whether they are affiliated with an entity or organization that may have experience with or an interest in a specific position related to the prescription drug.

After determining there is no publicly available pricing information, Staff may seek pricing information from manufacturers, carriers, and PBMs pursuant to section 10-16-1406(7)(b), C.R.S. Staff will request information provided under section 10-16-1406(7)(b), C.R.S., in writing (by mail or electronic mail). Staff will inform the Board in the event a manufacturer, carrier, and/or PBM fails to voluntarily provide the requested pricing information. The Board will consider information provided within 30 days of the request from Staff. The Board will then conduct the affordability review without the requested information.

E. Maintaining Confidential Information

Staff will employ reasonable efforts to ensure confidential information can be securely submitted and maintained for the Board's consideration and is only accessible to authorized persons pursuant to sections 10-16-1404(3) and 10-16-1406(5), C.R.S. A person submitting information for the Board's consideration pursuant to Part 3 of the Board's rule shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary as "confidential". Staff will not disclose information marked as "confidential" in public Board materials, including public meeting packets. Staff will not share confidential information except with Board members, legal counsel, and qualified third-party contractors subject to a nondisclosure agreement pursuant to section 10-16-1406(5), C.R.S.

If information marked as confidential has been submitted for the Board's consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential, trade secret, or proprietary information. Staff may also determine that information submitted to the Board is confidential, trade secret, or proprietary. To the extent the Board deliberates such confidential information, the deliberations will take place in executive session pursuant to sections 10-16-1404(3). The Board will not disclose confidential, trade secret, or proprietary information in an open meeting, its public meeting materials, or its summary report. To the extent practicable, Staff will identify the need for an executive session for the Board's discussion and/or deliberation of trade-secret, proprietary, and confidential materials in advance of a public Board meeting as required by section 10-16-1404(3), C.R.S.

The Board will comply with the Colorado Open Records Act and all applicable state and federal laws in determining whether information is confidential. The Board, through Staff, will independently determine whether information otherwise identified as "confidential" by a party submitting the information is confidential pursuant to state and federal law for purposes of responding to requests for information or documents.

In responding to any requests for information or documents, Staff may request additional information from the person asserting confidentiality regarding the nature of the

confidentiality or, to the extent Staff is able to determine who created the document or information, the person who created the document or information. Staff may seek legal advice on behalf of the Board related to confidentiality of documents.

Prescription Drug Affordability Board Policy and Procedures

Policy Number: 05

Title: Upper Payment Limit Policy and Procedure

Date Issued: January 13, 2023

Dates Reviewed: July 19, 2024

Authority

The statutory authority for this policy is section 10-16-1407, C.R.S. Nothing in this document is intended to be contrary to any statutes, rules, constitutional provisions, or relevant judicial decisions. To the extent there is any inconsistency, the statutes, rules, Constitution, and judicial decisions govern.

Scope and Purpose

The purpose of this policy is to further establish the methodology and processes for the Board to establish upper payment limits for prescription drugs it has determined to be unaffordable pursuant to section 10-16-1407, C.R.S.

As directed by PDAB Policy 01, Delegation to Division of Insurance Staff Policy and Procedure, this policy outlines specific delegations to Board Staff (or “Staff”) associated with the upper payment limit process. In connection with the delegations and processes set forth below, Staff is authorized to perform these functions through whatever means Staff deems appropriate, whether by doing this work themselves, working with other state entities, other states, or stakeholders, or using a qualified third-party contractor pursuant to section 10-16-1403(3), C.R.S.

Further, this policy sets forth the interpretations employed by the Board in performing its work related to establishing an upper payment limit, provides additional information regarding what types of data and information the Board will consider and how it will get or determine that information, and sets forth the Board’s processes and procedures for establishing an upper payment limit. Terms used in this policy have the same meaning as set forth in Parts 1 and 4 of the Board’s Rules.

Upper Payment Limits Applicability

As set forth in 3 CCR 702-9, Part 4.2.C.1, an upper payment limit, plus any reasonable fees charged by the pharmacy (as defined by section 12-280-103(43), C.R.S.) or pharmacist for dispensing or delivering a prescription drug, applies to all purchases by a Colorado consumer from a pharmacy or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means. If the Colorado consumer is insured, the consumer’s portion of the payment together with the reimbursement to the pharmacy (as defined by section 12-280-103(43), C.R.S.) and provider by the carrier, state entity, or optional participating plan should not exceed the upper payment limit plus any reasonable fees charged by the pharmacy or pharmacist for dispensing or delivering a prescription drug. As set forth in 3 CCR 702-9, Part 4.2.C.2, an upper payment limit also

applies to all purchases by a pharmacy (as defined by section 12-280-103(43), C.R.S.) or provider of a prescription drug that is dispensed or administered to the Colorado consumer in person, by mail, or by other means.

An upper payment limit does not apply to the purchase or reimbursement by any federal agency, federal program, Indian Tribe, or non-participating self-funded health benefit plans, including but not limited to, purchases or reimbursements made by Medicare, TRICARE, or the Federal Employee Health Benefits program.

Methodology to Establish Upper Payment Limits

Upper Payment Limit Methodology: Staff will prepare the following information, to the extent it is available, for the Board to utilize to establish an upper payment limit. This information will be submitted to the Board as part of the rulemaking record for the rule establishing the upper payment limit for the prescription drug. To the degree the Board has identified whether certain factors in the methodology should be weighted, Staff will reflect this weighting in documents and data presented to the Board when establishing an upper payment limit.

1. Prescription Drug Costs: To approximate the cost of administering, dispensing, and distributing prescription drugs, as well as other relevant prescription drug costs, Staff may compile the following price and cost metrics for the Board's review. Staff may provide information on current metrics, metrics at the time when the prescription drug was identified as a prescription drug eligible for an affordability review, and historical information. Metrics include but are not limited to:
 - a. Wholesale Acquisition Cost: obtained via a third-party vendor or contractor.
 - b. Average Sales Price: if the prescription drug has an Average Sales Price (ASP), as reported by the Center for Medicare and Medicaid Services (CMS).
 - c. National Average Drug Acquisition Cost: if the prescription drug has a NADAC, as reported by CMS.
 - d. Out-of-pocket spending: Information regarding out-of-pocket costs for the prescription drug will be based on:
 - i. APCD data, and
 - ii. Other data sources that approximate out-of-pocket costs not captured in APCD data.
 - e. Carrier paid amounts: Information regarding carrier paid amounts will be based on APCD data.
 - f. Retail discount amounts: Information regarding retail discounting for the prescription drug from sources including Pharmacy Checker, Good Rx, and others.
 - g. Public program fee schedules: Information regarding public program fee schedules may include fee schedules from: Colorado Medicaid, Colorado Children's Health Plan Plus, Medicare, Veterans Affairs, and other state and national fee schedules.
 - h. Estimates of manufacturer net-cost and net-sales amounts: To the extent the Board has funding, information may be prepared from an external database regarding estimated rebates, discounts, and price concessions for the prescription drug under review.

- i. Medicare's Maximum Fair Price: Information regarding the price negotiated as determined by section 42 U.S.C. § 1320f(c)(3).
 - j. Cost information voluntarily provided by a wholesaler, pharmacist, or provider.
2. Drug Shortage List: Staff will prepare information regarding a prescription drug's status on the Drug Shortage List on the day the Board adopts an upper payment limit for the prescription drug, as reported by the Food and Drug Administration (FDA) and the American Society for Health System Pharmacists.
3. Impact to Older Adults and Persons with Disabilities: Staff will prepare information related to the impact of the upper payment limit methodology to older adults and persons with disabilities and shall not place a lower value on their lives.
 - a. Impact to Older Adults: The Board will consider the following metrics for individuals 65 years and older: =
 - i. To the extent such information is available in the APCD:
 - (a) Utilization of the prescription drug;
 - (b) Cost of the prescription drug; and
 - (c) Insurance coverage type for individuals utilizing the prescription drug; and
 - ii. Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to older adults. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age. When applicable, stakeholders will disclose if cost-per-QALY or similar measure was used in research submitted.
 - b. Impact to Persons with Disabilities: The Board will consider the following metrics for persons with disabilities:
 - i. Therapeutic classification of the prescription drug, including the prescription drug's therapeutic purpose and any conditions or diseases the prescription drug may treat,
 - ii. To the extent it is known that any conditions or diseases the prescription drug may treat are considered disabilities and to the extent such information is available in the APCD, the Board may consider:
 - (a) Utilization of the prescription drug;
 - (b) Cost of the prescription drug; and

- (c) Insurance coverage type for individuals utilizing the prescription drug; and
 - iii. Qualitative or quantitative analyses and information submitted by stakeholders with lived experience or expertise of the prescription drug's impact to persons with disabilities. The Board will not consider any analyses or information submitted that utilizes a cost-per-QALY or similar measure that discounts the value of life because of an individual's disability or age. When applicable, stakeholders will disclose if cost-per-QALY or similar measure was used in research submitted.
- 4. Reasonable Pharmacy Fees: Staff will prepare information regarding the requirement to ensure an upper payment limit established by the Board does not preclude a pharmacist or pharmacy (as defined by section 12-280-103(43), C.R.S.) licensed by the State Board of Pharmacy to charge reasonable fees, to be paid by the providing health benefit plan of the consumer, for dispensing or delivering a prescription drug for which the Board has established an upper payment limit.
- 5. Research and Methods that Employ a Dollars-per-QALY: Staff will prepare information regarding the requirement that the Board shall not consider research or methods that employ a dollars-per-QALY or similar measure in estimating impact to older adults and persons with disabilities, or in any other upper payment limit methodology considerations.
- 6. Stakeholder Input: The Board shall receive stakeholder information submitted through an upper payment limit rulemaking, containing information relevant to any of these considerations that the Board may take into account in establishing an upper payment limit. Stakeholders are encouraged to disclose to the Board which type of stakeholder they are and/or whether they are affiliated with an entity or organization that may have experience with or an interest in a specific position related to the prescription drug.

Process for Establishing an Upper Payment Limit Through Rulemaking

1. The Board will establish upper payment limits through rulemaking, in compliance with sections 10-16-1407(5) and 24-4-103, C.R.S.
2. The Board will publicly deliberate over which prescription drugs it has determined to be unaffordable pursuant to section 10-16-1406, C.R.S. and part 3 of the Board's rules to select for establishment of an upper payment limit.
3. The Board will take and consider public comment regarding its selection of eligible prescription drugs to be subject to an upper payment limit prior to voting whether to select a prescription drug for establishment of an upper payment limit.
4. The Board will select a prescription drug for establishment of an upper payment limit by a majority vote to initiate rulemaking to establish an upper payment limit for that drug. The upper payment limit will be established through the Board's adoption of a rule that identifies the upper payment limit for that prescription drug.
5. The Board will not vote whether to set an upper payment limit for a prescription drug in executive session, as required by section 10-16-1404(3)(a), C.R.S.

6. All drugs for which the Board has determined to establish an upper payment limit and filed notice for rulemaking with the Colorado Secretary of State will be posted on the Board's website.
7. Once a notice of rulemaking has been filed with the Colorado Secretary of State, Staff will make available the Affordability Review Report for that prescription drug.
8. Stakeholders can submit written comments to the Board at dora_ins_pdab@state.co.us or provide testimony at the noticed rulemaking hearing for that prescription drug in accordance with the Colorado Administrative Procedures Act. Subject to any confidentiality, all written stakeholder input will be published and become part of the rulemaking record.
9. The Board will encourage stakeholders to identify which of the considerations set forth above and in Part 4 of its rules the submitted information will assist and/or inform the Board of in its deliberations.
10. Nothing precludes the Board from terminating a rulemaking to establish an upper payment limit.

Process for Prescription Drug Availability Inquiries and Reporting

1. Withdrawal Information from Manufacturers:
 - a. Inquiry process:
 - i. For any upper payment limit established, the Board shall inquire of manufacturers:
 - (a) Whether the manufacturer is able to make the prescription drug available for sale in the State of Colorado, and
 - (b) The rationale for the manufacturer's response.
 - ii. Manufacturers shall have 30 days to respond.
 - b. Notification to Consumers: If the Board receives notification that a manufacturer intends to withdraw a prescription drug for which the Board has established an upper payment limit from the sale or distribution within Colorado, the Board will notify consumers within ten days, as required by section 10-16-1412(2), C.R.S.
2. Reporting to the General Assembly: The Board shall submit the manufacturer's inquiry response annually to the Health and Human Services Committee of the Senate and the Health and Insurance Committee of the House of Representatives, or to any successor committees.

Confidentiality

Staff will employ reasonable efforts to ensure confidential information can be securely submitted and maintained for the Board's consideration and is only accessible to authorized persons pursuant to sections 10-16-1404(3) and 10-16-1406(5), C.R.S. A person submitting information for the Board's consideration pursuant to Part 4 of the Board's rule shall clearly designate the specific information it deems to be confidential, trade secret, or proprietary as

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“confidential”. Staff will not disclose information marked as “confidential” in public Board materials, including public meeting packets. Staff will not share confidential information except with Board members, legal counsel, and qualified third-party contractors subject to a nondisclosure agreement pursuant to section 10-16-1406(5), C.R.S.

If information marked as confidential has been submitted for the Board’s consideration, Staff will separately distribute a confidential Board meeting packet containing materials identified as having confidential, trade secret, or proprietary information. The Board may also determine that information submitted to it is confidential, trade secret, or proprietary. To the extent the Board deliberates such confidential information, the deliberations will take place in executive session pursuant to sections 10-16-1404(3) and 10-16-1407(7), C.R.S. The Board will not disclose confidential, trade secret, or proprietary information in an open meeting or its public meeting materials. To the extent practicable, Staff will identify the need for an executive session for the Board’s discussion and/or deliberation of trade-secret, proprietary, and confidential materials in advance of a public Board meeting as required by section 10-16-1404(3), C.R.S., and section 10-16-1407(7), C.R.S.

The Board will comply with the Colorado Open Records Act and all applicable state and federal laws in determining whether information is confidential. The Board, through Staff will independently determine whether information otherwise identified as “confidential” by a party submitting the information is confidential pursuant to state and federal law for purposes of responding to requests for information or documents.

In responding to any requests for information or documents, Staff may request additional information from the person asserting confidentiality or, to the extent Staff is able to determine who created the document or information, the person who created the document or information, regarding the nature of the confidentiality. Staff may seek legal advice on behalf of the Board related to confidentiality of documents.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:24-cv-00810-NYW-SBP

AMGEN INC., et al.

Plaintiffs,

v.

GAIL MIZNER, MD, in her official
capacity as Chair of the Colorado
Prescription Drug Affordability Review
Board, et al.,

Defendants.

DECLARATION OF NATHAN BLAKE

I, Nathan Blake, pursuant to 28 U.S.C. § 1746, state as follows:

1. I am the Deputy Attorney General for the Consumer Protection Section in the Colorado Attorney General's Office. Attorney General Philip Weiser has granted me authority to testify on his behalf regarding the above-captioned lawsuit's challenge to the constitutionality sections 10-16-1401 to 10-16-1416, C.R.S.

2. Pursuant to section 10-16-1411(3), C.R.S., the Colorado Attorney General is authorized to enforce part 14, title 10, C.R.S., on behalf of any state entity or any consumer of prescription drugs.

3. Pursuant to sections 10-16-1406 and 10-16-1407, C.R.S., the Prescription Drug Affordability Review Board is the agency charged with conducting affordability reviews and setting upper payment limits. Further the Prescription Drug Affordability

Review Board is the agency responsible for interpreting the statutes governing affordability reviews and upper payment limits.

4. The statements in this declaration are all based upon my own personal knowledge or information.

5. As of the date of this declaration the Colorado Attorney General's office has not taken or initiated any enforcement actions under section 10-16-1411(3), C.R.S.

6. The Colorado Attorney General's Office will only enforce part 14, title 10, C.R.S., in accordance with the regulations and policies adopted by the Prescription Drug Affordability Review Board.

7. The Colorado Attorney General does not intend to enforce part 14, title 10, C.R.S., against Plaintiffs in the above-captioned matter, or against any others similarly situated to Plaintiffs, in a manner that is inconsistent with the regulations and policies adopted by the Prescription Drug Affordability Review Board.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 7th day of August, 2024.

s/ Nathan Blake

Nathan Blake