



COLORADO

**Prescription Drug
Affordability Board**

Division of Insurance

Health & Insurance Committee
House of Representatives
Colorado General Assembly
200 East Colfax
Denver, Colorado 80203

Health & Human Services Committee
Colorado State Senate
Colorado General Assembly
200 East Colfax
Denver, Colorado 80203

Governor Jared Polis
Colorado Governor's Office
200 East Colfax, Room 136
Denver, Colorado 80203

July 1, 2023

Dear Governor Polis, Representatives, and Senators,

Excessive costs for prescription drugs negatively impact the health and safety of Coloradans and contribute to rising health care costs. The Prescription Drug Affordability Board continues to make progress in its efforts to ensure that Colorado consumers have access to affordable prescription drugs. The Board is pleased to share this report that summarizes the Board's activities in 2022. Pursuant to §10-16-1414, C.R.S., this report addresses various activities conducted by the Prescription Drug Affordability Board and Prescription Drug Affordability Advisory Council in 2022.

Thank you for the opportunity to share with you our efforts to increase the affordability of prescription drugs and reduce the effects of excess costs.

Sincerely,

Dr. Gail Mizner
Chair, Colorado Prescription Drug Affordability Board



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Prescription Drug Affordability Board

2022 Activities Summary Report



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Introduction and Background

Pursuant to Section 10-16-1414, C.R.S., the Colorado Prescription Drug Affordability Board (PDAB, the Board) is pleased to submit the 2022 PDAB Activities Summary Report. Formed in October 2021, the PDAB is a type 1 board¹ which is tasked with protecting Colorado consumers from excessive prescription drug costs pursuant to Section 10-16-1403, C.R.S. In its first full calendar year, the Board established the rules, policies, and norms to create a robust, stakeholder- and expert-informed, and thoughtful program to guide future prescription drug affordability work. This is the first report submitted to the Governor and the General Assembly's Health and Insurance Committee of the House of Representatives, and the Health and Human Services Committee of the Senate. More information about the Board is found on the Division of Insurance's [Colorado Prescription Drug Affordability Review Board & Advisory Council](#) webpage. Additionally, the Division published a [Frequently Asked Questions document](#) about the PDAB. The report and recommendations reflect the statements of the Board and do not necessarily reflect the ideas or intentions of the Division of Insurance.

In 2021, the General Assembly understood it was imperative to create a prescription drug affordability board with the authority to review prescription drug costs and protect Colorado

¹ A type 1 board exists from a type 1 transfer that denotes a relationship in which the subordinate board (PDAB) exercises its powers, duties, and functions independently of the executive director of the department within the agency in which it is placed (DORA).



residents and entities who purchase or reimburse for prescription drugs from excessive costs. As set forth in the legislative declaration, the General Assembly acknowledged that excessive prescription drug costs:

- Negatively impact the ability of Coloradans to obtain prescription drugs, and price increases that exceed reasonable levels endanger the health and safety of Coloradans;
- 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;
- 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;
- Pose a threat to the health and safety of all Coloradans but disproportionately harm people of color and Coloradans with low incomes; and
- 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.²

The General Assembly also acknowledged that a lack of prescription drug transparency prevents policymakers and the public from gaining a true understanding of the costs of prescription drugs and that information relating to the prescription drugs' costs is necessary to provide accountability to the state and to all Coloradans.³

Prescription Drug and Affordability Board Members

The five (5)-member Prescription Drug and Affordability Board (the Board) was appointed by Governor Polis on September 27, 2021 and confirmed by the Colorado Senate. Formed in 2021, the Board's duties include collecting and evaluating data to identify drugs that may be subject to an affordability review, performing affordability reviews if certain statutory triggers occur, determining whether a prescription drug is unaffordable for Colorado consumers, setting upper payment limits on prescription drugs the Board has found to be unaffordable, and making policy recommendations to the General Assembly. All Board members have an advanced degree and experience or expertise in clinical medicine or health care economics, as required by Section 10-16-1402, C.R.S. The five current Board members are:

- Dr. Sami Diab, MD of Greenwood Village, Colorado, is appointed for a term expiring September 27, 2024. Dr. Diab is a medical oncologist and serves as an Associate Professor of Medicine at the University of Colorado and Medical Director of Oncology at the UHealth's Lone Tree Medical Center. Dr. Diab's expertise in oncology and financial toxicity provide a clinical perspective to cost analysis and evaluating a drug's value to patients.
- Dr. Amy Gutierrez, PharmD of Aurora, Colorado, is appointed for a term expiring September 27, 2023. Dr. Gutierrez is the Vice President and Chief Pharmacy Officer for UHealth, overseeing medication management practice, strategy and policy across the healthcare system. She is also a Clinical Associate Professor at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences and an Adjunct Assistant Professor of Clinical Pharmacy at the University of Southern California School of Pharmacy and Chapman University's School of Pharmacy. Dr. Gutierrez is passionate

² Legislative declaration, SB21-175, Prescription Drug Affordability Review Board (2021).

³ *Id.*



about leading strategies to improve medication access and outcomes, as well as leveraging the value of pharmacists to drive improved health outcomes.

- Catherine Harshbarger, RN, MHA of Holyoke, Colorado, is appointed for a term expiring September 27, 2023. Ms. Harshbarger has worked as a nurse for nearly 40 years and has experience with retail, hospital, and clinic pharmacies. Representing the eastern plains of Colorado, Ms. Harshbarger has an acute awareness of the needs and barriers facing rural Coloradans and is skilled in recommending more affordable therapeutic alternatives.
- Dr. Gail Mizner, MD, FACP, AAHIVS of Snowmass Village, Colorado, is appointed Board Chair with a term expiring September 27, 2024 and is the Board Chair. She is the Internal Medicine Consultant and Director of Clinical Education at Mountain Family Health Centers, a Federally Qualified Health Center on the western slope of Colorado that serves 22,000 uninsured and underinsured patients. She is a former full time assistant professor at the University of Colorado School of Medicine and a current clinical faculty member. Dr. Mizner is a board-certified internist, an American Academy of HIV Medicine certified HIV specialist, and a Fellow with the American College of Physicians.
- Dr. James Justin Vandenberg, PharmD, BCPS of Denver, Colorado, is reappointed for a second term expiring September 27, 2026. Dr. Vandenberg is the Pharmacy Business Services Manager at Denver Health. He has served as a clinical pharmacist, and has expertise in financial management and the 340B program. This broad pharmacy experience allows Dr. Vandenberg to understand cost drivers and identify opportunities to minimize drug costs while providing optimal patient care.

The Board meets every six weeks and met twice in 2021 and ten times in 2022. Board meeting materials can be found [here](#). Typical attendance at Board meetings ranges from 50-70 people.

Prescription Drug Affordability Advisory Council Members

In December of 2021, the Board appointed the fifteen (15)-member Prescription Drug Affordability Advisory Council (PDAAC, Advisory Council), as required by Section 10-16-1409, C.R.S. The Advisory Council's role is to provide general input to the Board and provide insights and expertise to the Board during the Board's selection of prescription drugs for affordability reviews.

In selecting Advisory Council members, the Board reviewed over 50 applications from Coloradans across the state who represent different interests including patients, providers, and participants in the pharmaceutical supply chain. Pursuant to statute, the PDAAC must be composed of individuals who reflect the diversity of the state with regard to race, ethnicity, disability, age, gender identity, and geography, as well as individuals who have experience serving underserved communities. The fifteen PDAAC members are:

- Kim Bimestefer, Executive Director of the Colorado Department of Health Care Policy and Financing
- Gail deVore, representing health care consumers
- Sarita Parikh, representing health care consumers
- Edward A. Dauer, LL.B., M.P.H., representing statewide health care advocacy organizations
- Kimberley Jackson, DO (PDAAC Chair) representing consumers with chronic diseases
- Maria Fenwick, representing a labor union
- Nathan Wilkes, representing employers



- Chad Friday, representing carriers
- Marc Reece, representing pharmacy benefit managers
- Thomas Tobin, MD, MBA, representing health care professionals with prescribing authority
- R. Brett McQueen, PhD, representing an organization that researches prescription drugs
- Katelin Lucariello, MPH, representing manufacturers of brand name drugs
- Neal Miller, representing manufacturers of generic drugs
- Andrew Gonzales, PharmD, representing pharmacists
- Jason Atlas, RPh, MBA, representing wholesalers

The Advisory Council met nine (9) times since their inaugural meeting in February 2022 and has been instrumental in providing advice and insights to inform the Board's policy development and rulemaking. The Advisory Council's in-depth knowledge regarding the pharmaceutical business model, supply chain business models, medical and clinical practice, health care consumer and patient perspectives, health care cost trends and drivers, clinical and health services research, and Colorado's health care marketplace has greatly informed the Board's work. Advisory Council meeting materials can be found [here](#).

2022 PDAB Accomplishments

Prescription Drug Affordability Learning Series

The Board hosted a five-part learning series in spring 2022 to allow Board members, Advisory Council members, and interested stakeholders to build upon foundational knowledge necessary to implement a successful new prescription drug affordability program. The Board heard from over twenty (20) state and national experts to learn more about:

- [Understanding Prescription Drug Data](#) - Presenters from the [Program on Regulation, Therapeutics, and Law \(PORTAL\)](#) from Harvard and Brigham Women's Hospital, the [Center for Improving Value in Health Care \(CIVHC\)](#), and the [Colorado Health Institute \(CHI\)](#) discussed data considerations the PDAB will need to conduct its duties.
- [Gathering and Measuring Patient Perspectives](#) - Presenters from the [Colorado Consumer Health Initiative \(CCHI\)](#) and the [Chronic Care Collaborative \(CCC\)](#) discussed equity implications and shared patients' concerns with prescription drug affordability and access. Researchers from the [Skaggs School of Pharmacy](#) at the University of Colorado discussed methods to measure patient preference.
- [Overview of the Pharmaceutical Supply Chain](#) - Members of the Prescription Drug Affordability Advisory Council (PDAAC) spoke to their role and perspective as representatives of drug manufacturers, carriers, wholesalers, PBMs, and providers.
- [Comparative Effectiveness and Affordability of Prescription Drugs](#) - Experts from PORTAL and Skaggs School of Pharmacy discussed the relationship between cost effectiveness and affordability.
- [Prescription Drug Affordability Efforts in Colorado and Other States](#) - Colorado's [Canadian Drug Importation Program](#), [Maryland](#) and [Oregon](#) PDABs, [Massachusetts' Healthcare Cost Review Commission](#) discussed how their prescription drug affordability programs could inform the Board's work.

Rule Promulgation

The Board's first year focused on adopting and promulgating five (5) rules to implement statutory requirements. In addition to holding rulemaking proceedings in accordance with the



minimum requirements outlined in the Colorado Administrative Procedures Act, in many cases the Board chose to hold additional rulemaking hearings and hosted four additional stakeholder meetings. The Board received, evaluated, and in some cases incorporated suggested changes from [32 written comments](#) on rules.

The Board's adopted rules, found in [3 CCR 702-9](#), include:

- [Rule Part 1 - General Provisions](#), which contains information on definitions for the program, as well as details on severability and declaratory orders.
- [Rule Part 2 - Appeals](#), which outlines how an aggrieved person may appeal an initial decision by the Board to establish an upper payment limit.
- [Rule Part 3 - Affordability Reviews](#), which sets forth the procedures and factors for identifying prescription drugs for affordability reviews, selecting prescription drugs for affordability reviews, conducting affordability reviews, and determining whether a prescription drug is unaffordable for Colorado consumers.
- [Rule Part 4 - Upper Payment Limits](#) which contains details regarding how the Board will consider the statutory factors, such as prescription drug costs, drug shortage lists, and impacts to older adults and persons with disabilities, when establishing an upper payment limit for a particular prescription drug.
- [Rule Part 5 - Carrier Use of Savings](#) which outlines how carriers must report information to ensure that any savings from an upper payment limit are being utilized to reduce consumer costs, prioritizing the reduction of out-of-pocket costs.

Rule Part 2 - Appeals was promulgated by the Board by the statutory deadline of March 31, 2022 (Section 10-16-1408(2), C.R.S.) and Rule Part 5 - Carrier Use of Savings was promulgated by the statutory deadline of November 1, 2022 (Section 10-16-1410(3), C.R.S.).

Policy Development

The Board also developed and adopted five (5) policies to guide the program:

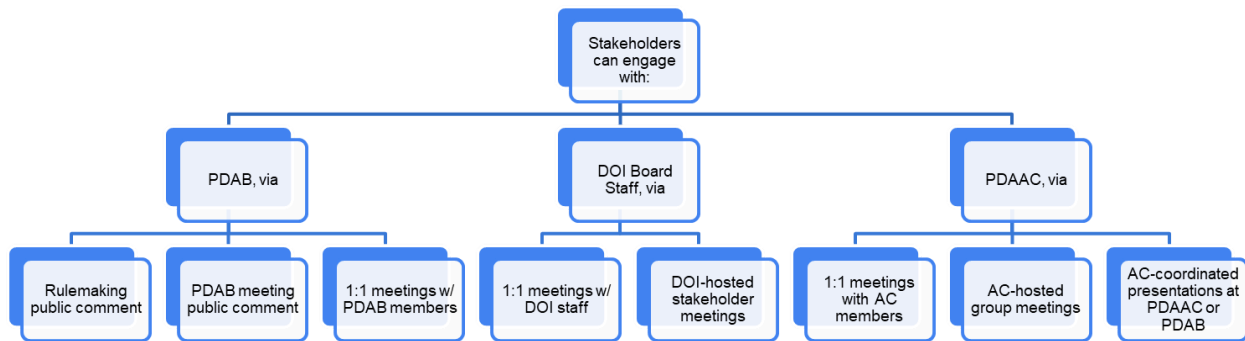
- [Policy 01](#): Delegation Policy and Procedure - This policy clarifies when Board staff, employed by the Division of Insurance, may perform work on behalf of the Board and provides guidance to Board members regarding their duties and responsibilities with respect to Board staff.
- [Policy 02](#): General Policies and Procedures - This policy outlines the general policies and procedures that guide the work of the Board, including: term length and vacancies; conflict of interest; responsibilities of the chair of the Board; open records and open meetings; meetings; meeting agendas, materials, and notes; quorum, decisions, and voting; executive session; meeting attendance, absences, and participation; member resignation and replacement; Board members as public representatives; coordinating with other entities; interaction with media and lobbyists; Board staff; Advisory Council; and annual review.
- [Policy 03](#): Conflicts of Interest Policy - This policy ensures the Board conducts business for the benefit of the public and in the absence of personal, financial, or otherwise improper interests and provides guidance to individual Board members on how to identify and manage conflicts of interest in relation to their statutory obligations as Board members.
- [Policy 04](#): Affordability Review Policy - This policy provides more detail regarding how the Board will consider the information outlined in the Board's Rule Part 3 - Affordability Reviews. This policy provides more detail on identifying prescription drugs for affordability reviews; the selection of eligible prescription drugs for affordability reviews; conducting affordability reviews, including assembling and presenting required

information to the Board, compiling supporting evidence and information for required factors, compiling supporting evidence and information for permissive factors, and notices of submissions of information; and maintaining confidential information.

- [Policy 05](#): Upper Payment Limit Methodology Policy - This policy provides more detail regarding how the Board will consider the information outlined in the Board's Rule Part 4 - Upper Payment Limits. This policy provides more detail on the methodology to establish upper payment limits; the process for establishing an upper payment limit through rulemaking; the process for prescription drug availability inquiries and reporting; and maintaining confidential information.

Stakeholder Engagement

The expertise of Board members and Advisory Council members is paramount to the success of the Board's work, but Board members also recognize that due to the complexity of the prescription drug supply chain and impact to patients, stakeholder input is important at many junctions of the Board's work. The Board has created multiple avenues to receive feedback and has established open lines of communication with a large array of stakeholders, including: consumers, patients, providers, pharmacies, hospitals, wholesalers, insurance companies, pharmacy benefit management firms, and prescription drug manufacturers. Stakeholders can engage in the work via a number of paths:



Additionally, Board staff have established open lines of communication with the staff of the Prescription Drug Affordability Boards in Oregon, Maryland, and Washington.

Obtaining Additional Expert Support

In addition to seeking advice from the PDAAC, the work of the Board is continuously informed by additional experts, specifically:

- The Program on Regulation, Therapeutics, and Law (PORTAL) from Brigham & Women's Hospital at Harvard Medical School - the Board has contracted with PORTAL to support the PDAB through providing data analysis and research; technical assistance in developing methodologies to calculate selection criteria data points for affordability reviews; and recommendations for affordability review processes and upper payment limit methodologies.
- The Colorado Department of Health Care Policy and Financing (HCPF) - HCPF has significant expertise with regards to prescription drug cost and utilization analytics. Recognizing this, Board staff entered into an Inter-Agency Agreement (IAA) with HCPF. The Board has utilized HCPF expertise to identify and assess data sources to fulfill statutory requirements related to affordability reviews and upper payment limits; assist Board staff in establishing processes to implement methodologies to identify drugs using



wholesale acquisition cost (WAC) and claims data, and select drugs using multiple data sources; and analyze claims data and WAC from other data sources to identify drugs outlined in statute, analyze drugs meeting triggers outlined in statute for the purpose of selecting drugs; and accessing drug pricing data and manufacturing data when conducting affordability reviews.

2022 PDAB Activities Summary

Publicly Available Price Trends

This section covers the statutory requirement to include “publicly available data concerning price trends for prescription drugs” (Section 10-16-1414(1)(a), C.R.S.).

Significant attention has been paid to prescription drug price trends at both the national level and in Colorado. Some of the more recent data and reports include:

- [Prescription Drug Rebates in Colorado](#) (report by the Colorado Center for Improving Value in Healthcare). Highlights from this data include:
 - Across all payers, from 2017-2019, total pharmacy spending without rebates grew 14%, but only grew 11% when factoring in drug rebates.
 - Drug rebates as a percent of total pharmacy spending for all payers increased from 25% to 27% from 2017-2019.
 - For commercial payers, from 2017-2019, rebates as a percent of total spending increased from 21% to 24% for brand drugs, and increased from 10% to 13% for specialty drugs. In 2019, rebates represented 18% of total spending for brand and specialty drugs combined.
 - Across all payers, in 2019, specialty drugs represent 39% of pharmacy spending, but only 1% of the total number of prescription drugs filled.
- [Reducing Prescription Drug Costs in Colorado](#) (report by the Colorado Health Care Policy and Financing Department). This report, focused on Colorado’s Medicaid program, highlights cost drivers and strategies to address them.
- [Annual Cost Review Report](#) (report by the Maryland Prescription Drug Affordability Board). This report provides an overview of national price trends from 2021-2022, as well as Maryland state price trends.
- [Prescription Drug Distribution System and Generic Drug Report](#) (report by the Oregon Prescription Drug Affordability Board). This report provides information on several topics, including how patents, shortages, contracts, and biosimilar products affect the availability and cost of generic drugs nationwide.

Legislative and Regulatory Policy Recommendations

This section covers the statutory requirement to include “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” (Section 10-16-1414(1)(h), C.R.S.).

The Board does not have recommendations for legislative and regulatory policy changes at this time. A number of topics have emerged during the Board’s work in 2022 that may warrant further research and discussion. In the event the Board is considering particular recommendations as a result of that further research and discussion, the Board looks forward to working with the Division on possible recommendations at that time.

Other 2022 Activities

The Board anticipates conducting its first affordability review in the last quarter of 2023 and potentially establishing upper payment limits in 2024. In future annual reports, the Board will report on the information required by sections 10-16-1414(1)(b) through 10-16-1414(1)(g), C.R.S.

In 2022, Colorado was one of four states with a Prescription Drug Affordability Board, with the other three being Maryland, Oregon, and Washington. While there are similarities among the states, Colorado’s law has the broadest applicability and the Colorado Board has chosen to develop its program at a faster pace than any other state. Colorado is leading the nation in its efforts to address the unaffordability of prescription drugs.