COLORADO
Prescription Drug Affordability Board
Division of Insurance

Health & Human ServicesCommittee
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, 2025

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 2024. 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 2024.

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

2024 Activities Summary Report

Table of Contents

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 2024 PDAB Activities Summary Report. Formed in October 2021, the PDAB is a type 1 board[1] which is tasked with protecting Colorado consumers from excessive prescription drug costs pursuant to section 10-16-1403, C.R.S. In its third full calendar year, the Board completed affordability reviews for four drugs and updated its affordability review rule and policy to better guide its future prescription drug affordability work. This is the third report submitted to the Governor and the General Assembly's Health and Human Services 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. The report and recommendations reflect the statements of the Board and do not reflect the opinions 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 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]

[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).
[2] Legislative declaration, SB21-175, Prescription Drug Affordability Review Board (2021).
[3] *Id.*

Prescription Drug Affordability Board Members

The five (5)-member Prescription Drug Affordability Board (the Board) was appointed by Governor Polis on September 27, 2021 and confirmed by the Colorado Senate. All five Board members have been reappointed by the Governor and reconfirmed by the Senate, as noted in Board member descriptions, below.

The Board's duties include collecting and evaluating data to identify drugs that may be subject to an affordability review, performing affordability reviews for drugs selected by the Board, 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 reappointed for a term expiring September 27, 2027. Dr. Diab is the medical lead of the Breast Care Center of Excellence at Intermountain Health. 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, is reappointed for a term expiring September 27, 2026. Dr. Gutierrez is the Chief Pharmacy Officer at John Muir Health, a not-for-profit integrated system of doctors, hospitals and other services. 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 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 is reappointed for a term expiring September 27, 2026. Ms. Harshbarger is an executive healthcare consultant and has worked as a nurse for nearly 40 years. She has experience with retail, hospital, and clinic pharmacies. Representing rural communities, 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 reappointed Board Chair with a term expiring September 27, 2027. Dr. Mizner 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 20,000 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. She is currently serving a 4 year term as the Governor of the Colorado Chapter of the American College of Physicians.
- Dr. James Justin VandenBerg, PharmD, BCPS of Denver, Colorado, is reappointed for a term expiring September 27, 2025. He currently serves as the Pharmacy Business Services Manager at Denver Health. With a background as a clinical pharmacist and formulary management specialist, Dr. VandenBerg brings extensive expertise in revenue cycle, procurement, contracting, financial management, and the 340B program. His broad experience across pharmacy operations enables him to identify cost drivers and implement strategies to reduce drug expenses while ensuring high-quality patient care.

The Board meets approximately every six weeks and met thirteen times in 2024. Board meeting materials can be found here. Typical attendance at Board meetings ranges from 80 to 120 interested parties.

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 stakeholder input to the Board regarding the affordability of prescription drugs.

The Board reappointed three members and appointed four new members to the Advisory Council in 2024. In selecting new Advisory Council members, the Board reviewed twelve (12) applications from Coloradans across the state. 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. Currently, there are two vacant positions in the PDAAC that the Board is working on filling. The thirteen 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
- Robert Mulch, MD representing statewide health care advocacy organizations - appointed in 2024
- Kimberley Jackson, DO (PDAAC Chair) representing consumers with chronic diseases
- Open position representing labor unions
- Nathan Wilkes (PDAAC Vice-Chair), representing employers
- Open position representing carriers
- Marc Reece, representing pharmacy benefit managers - reappointed in 2024
- Richard Miranda, MD, representing health care professionals with prescribing authority - appointed in 2024
- R. Brett McQueen, PhD, representing an organization that researches prescription drugs - reappointed in 2024
- Katelin Lucariello, MPH, representing manufacturers of brand name drugs - reappointed in 2024
- Fayez Azeez, representing manufacturers of generic drugs - appointed in 2024
- Ingrid Pan, PharmD, representing pharmacists - appointed in 2024
- Leah Lindahl, representing wholesalers

The Advisory Council met four (4) times in 2024 and has been instrumental in providing early insights regarding the Board's upper payment limit (UPL) work. In 2024, the Advisory Council identified considerations for the Board in developing the process for its UPL work in 2025. In addition to providing valuable input to the PDAB, the Advisory Council has adopted bylaws that outline expectations to facilitate the full contribution of all Advisory Council members by clarifying the expectations that apply to their service on the Council. The Advisory Council also elected a

vice-chair, Nathan Wilkes, who will assist the Board staff as necessary and manage the Advisory Council meetings when needed. Additionally, the Advisory Council and the Board formed one ad hoc group to discuss policy recommendations to the General Assembly for the 2023 General Assembly Report. Advisory Council meeting materials can be found here.

2024 PDAB Accomplishments

In the last year, the Board has continued to strengthen and implement its program and be a leader in the nation for addressing the unaffordability of prescription drugs. In 2024, the Board:

- Completed and adopted affordability reviews for four (4) drugs: Enbrel, Genvoya, Stelara, and Cosentyx,
- Updated its affordability review rule and began updating its affordability review policy, and
- Provided several opportunities for stakeholders to participate in the Board's work via a rulemaking guide, office hours, listserv, and stakeholder meetings.

Rule and Policy Development

The Board updated one (1) rule in 2024:

- The passage of House Bill (HB) 2023-1225 required the Board to update its adopted rules (3 CCR 702-9) to align with changes in statute. The passage of Senate Bill (SB) 24-203 required the Board to consider an approved orphan drug designation for a drug and consider input from consumers and the Colorado Rare Disease Advisory Council (RDAC). The Board adopted Amendments to Parts 1 and 3 of 3 CCR 702-9 to align with the statutory changes from HB 23-1225 and SB 24-203 and held rulemaking proceedings in accordance with requirements outlined in the Colorado Administrative Procedures Act.

The Board began updating one (1) policy in 2024:

- Policy 04: Affordability Review Policy and Procedure - This policy further establishes methodologies and processes for the Board to identify and select drugs eligible for affordability review, and conduct affordability reviews. Changes were proposed to this policy to align with the rule.

Affordability Reviews

The Board's third year focused on conducting the nation's first affordability reviews on eligible prescription drugs.

After the completion of its first affordability review for Trikafta at the end of 2023, the Board continued to conduct affordability reviews for Enbrel, Genvoya, Stelara, and Cosentyx in 2024. The Board determined that Genvoya is not unaffordable for Colorado consumers, while Enbrel, Stelara and Cosentyx were deemed unaffordable for Colorado consumers.

The Board heard from 386 patients and caregivers and 51 individuals with scientific and medical training during the affordability review processes for all five selected prescription drugs.

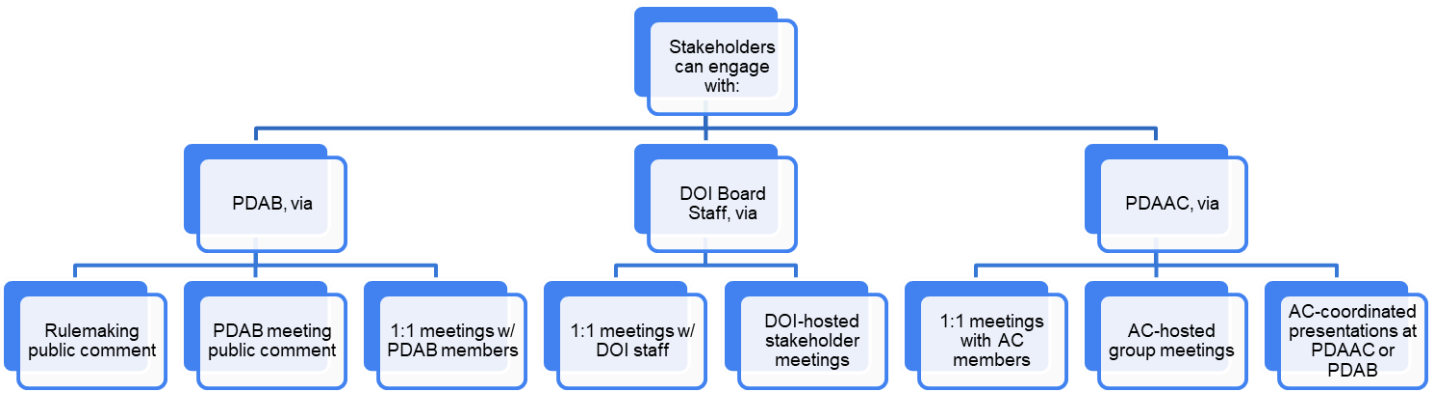
Each Affordability Review Report consists of a Summary Report and sixteen appendices, each addressing the required statutory and regulatory components the Board considers during a drug's affordability review. Each Summary Report is divided into three profiles: a therapeutic and utilization profile; a cost and price profile; and an access to care profile. The therapeutic and utilization profile includes information about the drug's clinical efficacy and its users. It also includes information on the health equity impact of the drug and its therapeutic alternatives. The price and cost profile includes information on prices charged and paid by the different entities for the drug. It also contains information on the financial effects on health, medical, and social service costs. The access

to care profile details any potential access to care concerns related to the drug and any evidence that the causes of access to care concerns may be related to the drug's price or cost. All three profiles contain information from the fifteen statutory and regulatory components the Board must consider as a part of an affordability review. All four reports incorporated robust feedback from the drug's manufacturer, patients, caregivers, and providers.

- Enbrel's affordability review was adopted by the Board on February 23, 2024. The Board deliberated whether the data concerning out-of-pocket costs and patients and caregiver experience purchasing the drug provided evidence of Enbrel's unaffordability for patients in Colorado. After deliberations and public comment, the Board ultimately determined that the use of Enbrel is unaffordable for Colorado consumers and that the drug is eligible for a UPL.
- Genvoya's affordability review was adopted by the Board on February 23, 2024. The Board noted that availability of federal and state patient cost assistance programs, patient out-of-pocket costs, and downward utilization trend provided evidence that Genvoya is not unaffordable to patients in Colorado at this time. After deliberations and public comment, the Board ultimately determined that the use of Genvoya is not unaffordable for Colorado consumers.
- Stelara's affordability review was adopted by the Board on June 7, 2024. The Board discussed whether the high out-of-pocket costs of Stelara provided evidence of the drug's unaffordability to Colorado consumers. After deliberation and public comment, the Board ultimately determined that the use of Stelara is unaffordable for Colorado consumers and is eligible for a UPL.
- Cosentyx's affordability review was adopted by the Board on June 14, 2024. The Board deliberated on how the high out-of-pocket cost for Cosentyx, the rapid increase in wholesale acquisition cost (WAC), and the unreliability of patient assistance programs provide evidence of the drug's unaffordability to Colorado consumers. After deliberation and public comment, the Board ultimately determined that the use of Cosentyx is unaffordable for Colorado consumers and is eligible for a UPL.

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 Board's work via a number of paths:



The Board has provided the following guidance for stakeholders who wish to be involved in the Board's work:

- Rulemaking Guide - This document outlines the ways in which stakeholders may get involved in the rulemaking process and details how to provide testimony to be included in the rulemaking record. The Rulemaking Guide is updated regularly as staff receive further guidance from the Board.
- **Office Hours** - Board staff held six (6) one-hour open meetings in 2024 for stakeholders to ask any process questions about the Affordability Review rulemaking and UPL rulemaking processes.
- **PDAB Listserv** - The Board sends out regular updates via the PDAB listserv. There are currently 3,786 individuals subscribed to the listserv.
- **Surveys** - While most of the surveys for the four drugs under affordability reviews were conducted in 2023, the Board requested more information from patients and individuals with scientific training. Thus, the Board members voted to reopen the surveys for Enbrel and Genvoya from December 15, 2023 to January 21, 2024 and voted to reopen the surveys for Cosentyx and Stelara from April 1 to April 30, 2024.
- **Stakeholder meetings** - In 2024, Board staff conducted three (3) 1:1 meetings with individuals with scientific or medical training to gather input on Enbrel and Genvoya. The Board staff also facilitated one (1) stakeholder meeting to discuss suggestions for changes from stakeholders on the Affordability Review rule and policy.

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

2024 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:
    - In 2023, total prescription drug spending for commercial payers was $2.1 billion compared to the rebate amount of $458 million, resulting in a rebate percentage of 22% of total spending.
    - Rebates for Medicaid for all drug types decreased from 56.9% in 2022 to 53.2% in 2023 for all drug types.
    - For commercial payers, from 2021-2023, rebates as a percent of total spending increased from 29% to 33% for brand drugs, and increased from 17% to 19% for specialty drugs.
- 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 2024, 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.
- Prescription Drug Spending, Pricing Trends, and Premiums in Private Health Insurance Plans (report by Assistant Secretary for Planning and Evaluation). This report provides background on the prescription drug market, discusses the need for RxDC (prescription drug data collection), and summarizes the findings from the initial two years of RxDC.

Prescription Drugs Subject to Affordability Review

This section covers the statutory requirement to include the number of prescription drugs that were subjected to an affordability review by the Board (section 10-16-1414(1)(b), C.R.S.).

In 2024, the Board completed four (4) affordability reviews for Enbrel, Genvoya, Cosentyx, and Stelara. The Board ultimately determined that the use of Enbrel, Cosentyx, and Stelara is unaffordable for Colorado consumers and that the use of Genvoya is not unaffordable for Colorado consumers.

Conflict of Interest Disclosures

This section covers the statutory requirement to report a description of each conflict of interest that was disclosed to the Board during the preceding year (section 10-16-1414(f), C.R.S.).

Per section 10-16-1402, C.R.S., the Board members, Council, staff members, and contractors of the Board are required to disclose any conflict of interest to the Board.

- Board members - Pursuant to section 10-16-1402(3)(d), C.R.S., Dr. Sami Diab disclosed conflicts of interest relating to multiple manufacturers and prescription drugs, the full list of which is available on the Division's website. Due to conflicts, Dr. Diab recused himself from the affordability reviews for Enbrel, Genvoya, and Cosentyx.
- Advisory Council members - Pursuant to sections 10-16-1409(5)(b) and 10-16-1402(3)(d), C.R.S., the Advisory Council disclosed the following conflicts of interest to the Board in the linked document.
- Staff and contractors - Pursuant to section 10-16-1402(3)(c)(II)-(III), (d), C.R.S., a conflict of interest disclosed to the Board by a staff member or by a contractor of the Division, which disclosure pertains to a personal association, must remain confidential. Staff members and contractors did not disclose any public conflicts of interest to the Board.

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 developed the following policy recommendations:

- **Strengthen Consumer Input**: The Board recognizes the importance of hearing directly from patients who face challenges affording prescription drugs. Though the Board values the patient voice and has outlined avenues for feedback, the Board also recognizes that consumer anxieties persist regarding how the Board receives input. Currently, the Board may seek patient and caregiver input once a prescription drug has been selected for an affordability review. The Board recommends that patient input should be included earlier in the affordability review process as part of the identification criteria, and that patients may identify a drug to be considered for selection by the Board. The Board recommends the General Assembly consider revising section 10-16-1406(1), C.R.S. to allow for consumers to identify prescription drugs for consideration for affordability reviews, recognizing that some parameters regarding this process could and should be established, either in law or in regulation. Furthermore, the Board also recommends the General Assembly consider the pros and cons of adding a consumer representative to the Board, along with defining the expertise and educational qualifications the representative must have to be appointed to the Board.
- **Change Eligibility Thresholds**: The Board recognizes that drugs treating more common conditions may often fall below the current $30,000/yr threshold required for eligibility but may still pose affordability challenges to patients. The Board recommends reducing the threshold for identified brand name drugs below the current $30,000/yr threshold, though further research and discussion may be warranted to determine the specific, lower threshold. The Board is also interested in identifying high volume drugs that impact the largest number of patients based on indication.

Other topics discussed by the Board, that may result in policy recommendations in future reports to the General Assembly, include:

- Affordability reporting at the point-of-sale transactions or failed transactions, including ascertaining a deeper understanding of when and how manufacturer and other patient assistance programs are utilized.
- Potentially identifying, selecting, and conducting affordability reviews differently for

different types of prescription drugs (e.g., gene therapy prescription drugs) to understand if there are distinct affordability challenges consumers face with different types of prescription drugs.

- Conflict of interest disclosure for stakeholders, including patients and individuals with scientific or medical training.
    - Board members discussed requiring stakeholders to disclose conflicts. However, initial research suggests they cannot be required to disclose conflicts but could be encouraged to do so. In 2024, the Board began the process to approve a policy that would allow a workgroup of PDAB, PDAAC, RDAC, and other stakeholders to identify best practices regarding requesting patients and individuals with scientific or medical training to identify conflicts or dualities of interest.

Other 2024 Activities

The Board has not yet set upper payment limits (UPLs), or received appeals or violations, and therefore is not reporting on sections 10-16-1414(1)(c) through 10-16-1414(1)(e), and 10-16-1414(1)(g), C.R.S.

It is important to note that while the Board has not yet set a UPL, the rulemaking hearing to potentially set a UPL for Enbrel began at the end of 2024 and is still underway. The Board also began to outline what information will be considered during the UPL rulemaking process. Board staff drafted a memorandum that highlights what data will be collected for the Board's consideration in potentially establishing a UPL for the three drugs determined to be unaffordable: Enbrel, Stelara, and Cosentyx. Board and PDAAC meetings in 2024 also identified a recommendation that a Data Submission Guide (DSG) be created to assist prescription drug manufacturers, wholesalers, PBMs, commercial carriers, providers and pharmacies, and consumers in submitting relevant data to the Board during the UPL rulemaking process.

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Colorado is one of ten (10) states with a Prescription Drug Affordability Board, with the other nine (9) being Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, 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.