25-1641

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

AMGEN INC., IMMUNEX CORPORATION, AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellants

v.

GAIL MIZNER, in her official capacity as Chair of the Colorado Prescription Drug Affordability Review Board, SAMI DIAB, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board, AMARYLIS GUTIERREZ, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board, CATHERINE HARSHBARGER, in her official capacity as a member of the Colorado Prescription Drug Affordability Review Board, JAMES JUSTIN

VANDENBERG, in his official capacity as a member of the Colorado Prescription Drug Affordability Review Board, MICHAEL CONWAY, in his official capacity as Commissioner of the Colorado Division of Insurance, PHILIP WEISER, in his official capacity as Attorney General of the State of Colorado,

Defendants-Appellees.

On Appeal from the United States District Court, District of Colorado
The Honorable Nina Y. Wang, District Judge
District Court Case No. 1:24-cv-00810-NYW-SBP

RESPONSE BRIEF FOR DEFENDANTS-APPELLEES

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for Appellees certifies that the following information is accurate and complete to the best of my knowledge:

1. **Represented Entities:** The full names of all entities represented by undersigned counsel in this case:
    - Gail Mizner
    - Sami Diab
    - Amarylis Gutierrez
    - Catherine Harshbarger
    - James Justin Vandenberg
    - Michael Conway
    - Philip Weiser
2. **Real Party in Interest:** The full names of the real parties in interest for the entities.
    - Not applicable.
3. **Parent Corporations and Stockholders:** The full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities:
    - Not applicable.
4. **Legal Representatives:** All law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4):
    - Heather Flannery
5. **Related Cases:** Other than the originating case(s) for this case, related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a):

- None

6. **Organizational Victims and Bankruptcy Cases:** Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6):
    - None.

Dated: August 22, 2025

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STATEMENT OF RELATED CASES

There are no other appeals in this civil action, nor any proceeding in the U.S. District Court of Colorado regarding this matter. Counsel for Appellees are not aware of any case pending in this or any other tribunal that will directly affect or be directly affected by this Court's decision in this matter.

JURISDICTIONAL STATEMENT

Appellees agree with Appellants' jurisdictional statement except as to this Court's jurisdiction under 28 U.S.C. § 1295(a)(I). While Appellants' Complaint raised one claim under federal patent law, the district court dismissed this case without prejudice for lack of subject matter jurisdiction without reaching the merits of any of Appellants' claims. Accordingly, there is no final judgment on any matter arising under federal patent law in this case; the district court issued a final judgment only as to Appellants' standing at the time the case was filed. Appellees nonetheless consent to this Court's jurisdiction for purposes of this appeal.

STATEMENT OF THE ISSUE

Whether the district court erred in holding that Amgen lacked standing to challenge the constitutionality of Colorado's law concerning the Colorado Prescription Drug Affordability Board.

INTRODUCTION

The prescription drug supply chain is rife with counter-intuitive behavior, irrational incentives, and dramatic asymmetries in bargaining power, with manufacturers and middlemen raising costs that consumers must pay to receive life-changing and life-saving medicine. The complexity and opacity of the supply chain leave Colorado consumers with little recourse against these continually rising costs.

To protect the health and welfare of its residents, in 2021, Colorado acted to address the urgent struggle facing its residents: the inability to afford necessary medicine. It created the Prescription Drug Affordability Board ("PDAB" or the "Board"). The Board is authorized to study eligible drugs—generic and patented alike—by conducting "affordability reviews" of particular drugs. If the Board finds a drug unaffordable, it may establish an upper payment limit ("UPL") on what certain consumers, providers, pharmacies, and insurance companies may pay for

those drugs dispensed in Colorado. The Board leverages these two tools—affordability reviews and UPLs (collectively, "the Affordability Program")—to provide much needed transparency and cost relief in Colorado.

Under this statutory authority, the Board reviewed the affordability of Enbrel, a prescription drug manufactured by Appellants (collectively, "Amgen"). Enbrel is a critical medication for the Coloradans who use it and have little choice but to absorb the drug's rising costs.

Arguing that the Affordability Program is preempted by federal law and violates the Due Process and dormant Commerce Clauses of the Constitution, Amgen sought to halt the Board's work. Through this suit, Amgen seeks to enjoin the Affordability Program so it can be free from *indirect* regulation that *could* make its business less profitable. This is not a result compelled by the Constitution.

Moreover, Amgen's legal challenge fails to meet the basic requirements to be heard. The Board's work is about protecting Colorado consumers, not punishing manufacturers. At the district court, Amgen could not show that the Board's work relating to Enbrel would result in any injury to Amgen as the drug's manufacturer, particularly when, at

the time the suit was brought, whether the Board would even set a UPL for Enbrel and the amount of that UPL were wholly uncertain. In the face of these uncertainties, the district court properly held that Amgen failed to establish the standing necessary to maintain its suit.

STATEMENT OF THE CASE

The Prescription Drug Supply Chain

In a basic sense, the prescription drug supply chain operates by: a manufacturer selling its drug to a wholesaler; the wholesaler selling the drug to a pharmacy or provider; and the pharmacy or provider dispensing the drug to a patient. *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.,* 44 F.4th 959, 965 (10th Cir. 2022); Appx1291. However, the financial transactions in the supply chain tell a different, complex story marked by opacity and counterintuitive pricing behaviors. *See* PhRMA, *Follow the Dollar* at 1 (2017), available at https://cdn.aglty.io/phrma/global/resources/import/pdfs/Follow-the-Dollar-Report.pdf[1]; Appx0005, Appx0016, Appx1292. "*[T]here is no one price for a medicine*, as prices paid by wholesalers, pharmacies, PBMs,

[1] Appellees cite PhRMA's 2017 *Follow the Dollar* report below, Appx1292-95, but the link in the District Court briefing no longer works. An updated link is provided here.

and health plan sponsors all vary and are determined by negotiations between stakeholders, each with varying degrees of negotiating power." PhRMA, *Follow the Dollar* at 1 (2017); Appx1292-95. (emphasis added). Each supply chain step is characterized by different monetary incentives and pressures. Supply chain actors include not only the manufacturers, wholesalers, providers and pharmacies, but two additional actors: (1) health plans or "payers," who offer prescription drug benefits to patients, and (2) pharmacy benefit managers or "PBMs," whom payers hire to formulate and oversee their plan benefits. *See Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023); Fed. Trade Comm'n, *Pharmacy Benefit Managers* at 9-10 (2024), available at https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf (hereinafter, "FTC PBM Report"); Appx1293.

Manufacturers, like Amgen, use two practices to obscure drug prices as they pass through the supply chain: rebates and chargebacks. Rebates are contractual payments between manufacturers and PBMs based on how much of the manufacturer's drug the PBM approves for distribution to patients on behalf of a payer; the more the manufacturer's drug is distributed, the higher the rebate for the PBM. *See* PhRMA,

Follow the Dollar at 1 (2017); Appx1293-94. Rebates incentivize PBMs to sell that manufacturer's drug over other brand-name drugs, biosimilars[2], or generics through more favorable placement on a payer's formulary. *See Mulready*, 78 F.4th at 1188; FTC PBM Report at 1, 9-11, 66; Appx1293-94. Formularies are the list of drugs covered by a payer and determine how much of an insurance benefit is given for each drug. *See Mulready*, 78 F.4th at 1188; Appx1293.

"According to Amgen's CEO, '[c]ompanies in virtually every other industry compete by offering the lowest price. Unfortunately, the current rebate system in the U.S., created with good intent, now often leads to a situation in which not getting kicked off formulary requires matching a competitor's higher price.'" Unsustainable Drug Prices: Testimony from the CEOs (Part II): Hearing Before the H. Comm. on Oversight and Reform, 116th Cong., 2nd Sess. at 5 (2020) (Statement of Robert Bradway, CEO, Amgen) available at https://tinyurl.com/mtj35txr (hereinafter "Bradway Testimony"); Appx1294. Amgen states it often

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[2] A biosimilar is 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)." § 10-16-1401(6), C.R.S. Biosimilars are considered to be "interchangeable" with a specific prescription drug. *See* 42 U.S.C. § 262(k)(3)(A)(ii).

must "pay higher and higher rebates to remain on formulary" and "increases in list prices generally have limited impact on net prices but significantly increase total rebates paid to the PBMs." Testimony of Robert A. Bradway, Chairman and Chief Executive Officer Amgen Inc., Before the U.S. H. Comm. on Oversight and Reform at 7 (2020) (hereinafter, "Bradway Written Statement"), available at https://tinyurl.com/mufwzev3; Appx1302. So, "Amgen has increased list prices over the years in response to competitor list price increases to remain available as a choice on PBM formularies." *Id*. As acknowledged by Amgen, the net effect of this "counterintuitive pricing behavior" is that PBMs receive lower prices, but "consumers instead see prices go up and see little relief at the pharmacy counter since these savings from the PBMs are often not passed on." Bradway Written Statement at 8; Appx1302-03.

Chargebacks are contractual obligations between manufacturers and wholesalers based on the amount the wholesaler sold the manufacturer's drug for. Chargebacks make up the difference to wholesalers between what they paid the manufacturer for a drug and what the pharmacy or other provider paid the wholesaler for the drug.

Op. Br. at 14. Chargebacks prevent wholesalers from selling a drug at a loss, thereby incentivizing them to keep selling that manufacturer's drug. *Id.*

Amgen's Manufactured Drug, Enbrel

Amgen is the sole manufacturer of Enbrel. Op. Br. at 12-13. Enbrel is covered by several United States patents, including two patents that limit market competition until at least 2029. Op. Br. at 13. Between its launch in 1998 through January 2024, Enbrel's list price has increased 1,582.24%, significantly outpacing inflation for the same period. Appx0601. In 2021 and 2022, Amgen earned more than $4 billion annually from Enbrel sales. Appx0585, Appx0601, Appx1114.

At a high level, Amgen operates consistently with the basic drug supply chain described above, with Amgen selling Enbrel to wholesalers, who then sell Enbrel to pharmacies and providers for the purpose of distributing to patients. Op. Br. at 13; Appx1292. In addition to distribution fees, Amgen uses chargebacks to reimburse its wholesalers—a practice it labels as "standard practice in the pharmaceutical industry." Op. Br. at 14; PhRMA, *Follow the Dollar* at 3 (2017); Appx1444. Instead of a wholesaler buying for less, Amgen's

chargebacks provide an unusual safety net that allows its wholesalers to lean on the manufacturer for future reimbursement, paradoxically keeping the wholesale acquisition cost—the list price the manufacturer sets—for Enbrel artificially high. There is no requirement that Amgen negotiate chargebacks. It is instead a specific feature Amgen and other drug manufacturers impose on the pharmaceutical industry that results in obscured prices.

Amgen also provides generous rebates to PBMs to ensure Enbrel is distributed to consumers. *See* Appx1024 ("Because of the way PBMs structure relationships with pharmacies and patient-enrollees, increases in list prices generally have a limited impact on net prices, while significantly increasing total rebates paid to the PBMs."), Appx1082-83 ("In 2021, 14 of 25 carriers indicated that Enbrel was in the top 15 drugs for which the carrier received the largest rebate."). These rebate amounts remain undisclosed. They were not publicly released as part of the Enbrel Affordability Review Report, are not discussed in Amgen's Opening Brief with this Court, nor appear in any filings with the lower court.[3] *See*

[3] Notably, even Colorado's Prescription Drug Affordability Board was prohibited from publicly disclosing any Enbrel rebate data it reviewed as part of its affordability review. Appx0585, Appx0604-05.

generally Op. Br., Appx1069-84, Appx1169-1218. Rebates are recognized as a significant driver of higher drug costs. *See* FTC PBM Report at 66; PhRMA, *Follow the Dollar* at 1; Bradway Testimony at 5; Amgen, *Inside the Drug Pricing Loop*, available at https://tinyurl.com/37d6p5tk; Appx1293-95.

Against this backdrop of finger-pointing, private reimbursement agreements, hidden prices, and counterintuitive incentives to keep prices high, Amgen nevertheless characterizes the drug supply chain as abiding by "common sense" and "basic economics." *See, e.g.,* Op. Br. at 19.

The Colorado Prescription Drug Affordability Board

Created by the Colorado legislature in 2021, the Colorado PDAB was designed to "protect Colorado consumers from excessive prescription drug costs." Colo. Rev. Stat. § 10-16-1403(1) (2025); S.B. 21-175, 73rd Gen. Assemb., 1st Reg. Sess. (Colo. 2021) (hereinafter, "SB21-175").

The Board's primary tool in lowering drug costs for Coloradans is setting a UPL on a selected drug it has deemed unaffordable. Colo. Rev. Stat. § 10-16-1403(1)(c) (2025) Whether to set a UPL and, if so, at what level, however, is the culmination of a lengthy process. Before even considering setting a UPL, the Board engages in three steps—

identification, selection, and affordability review—to determine if a drug is unaffordable for Colorado consumers. Colo. Rev. Stat. § 10-16-1406(3) (2025). Each stage requires the Board to consider specific statutory factors. *See* Colo. Rev. Stat. § 10-16-1406(1), (2), (4), (6)-(7) (2025). The identification stage analyzes drugs based on the wholesale acquisition cost ("WAC") set by the manufacturer, which is solely a first step in considering a drug's affordability. Colo. Rev. Stat. § 10-16-1406(1) (2025). The selection stage analyzes five criteria focused on drug availability and patient cost. *See* Colo. Rev. Stat. § 10-16-1406(2) (2025). The affordability review stage analyzes ten required metrics and two optional metrics, the majority of which are focused on patient-centered factors like cost and access. *See* Colo. Rev. Stat. § 10-16-1406(4), (6), (7) (2025).

The goal of the Board's affordability review is not to determine the appropriateness of a manufacturer's price. Rather, the Board considers and weighs robust, contextual factors to determine whether use of a drug, taken consistent with standard medical practice or the FDA label, is unaffordable for Colorado consumers. Colo. Rev. Stat. § 10-16-1406(3) (2025). The result of an affordability review is a comprehensive report that details the Board's analysis of the required factors, supporting

documents, and a determination of whether use of the drug is unaffordable for Colorado consumers.

The Colorado legislature made clear in creating the Affordability Program that the affordability reviews serve standalone purposes of transparency and accountability and may be an end unto themselves. *See* Colo. Rev. Stat. § 10-16-1407(1), (9) (2025). The Board's unaffordability determination is not a final agency action, cannot be challenged as such, and may conclude its review of a prescription drug. *See* Colo. Rev. Stat. § 10-16-1408(1)(c) (2025).

If the Board finds a drug is unaffordable for Colorado consumers as the result of an affordability review, it "*may* establish" a UPL for that drug but, it is not required to do so. Colo. Rev. Stat. § 10-16-1407 (1)(a) (2025) (emphasis added).[4] The Board establishes UPLs through public rulemaking, a proceeding which can be terminated at any time. Colo. Rev. Stat. §§ 10-16-1408(2), 24-4-103(4)(d) (2025); 3 Colo. Code Regs. § 702-9:4.1(D)(1) (2025). The Board sets UPLs consistent with its

[4] The Board does not have to set a UPL for a drug it has deemed unaffordable and the two processes—affordability reviews and UPLs—are not only distinct but explicitly severable. Colo. Rev. Stat. § 10-16-1407(1), (9) (2025); *see also* Colo. Rev. Stat. § 2-4-204 (2025).

methodology laid out in rule, which considers specified drug cost factors paid by actors along the supply chain, including average sales price, out-of-pocket amounts, and retail discount amounts. Colo. Rev. Stat. § 10-16-1407(2) (2025); 3 Colo. Code Regs. § 702-9.4.1(C)(2) (2025). A UPL does not go into effect until at least six months after the Board's adoption of any rule. Colo. Rev. Stat. § 10-16-1407(5) (2025).

The Colorado Attorney General is exclusively authorized to "enforce [Colo. Rev. Stat. §§ 10-16-1401—10-16-1416 (2025)] on behalf of any state entity or any consumer of prescription drugs." Colo. Rev. Stat. § 10-16-1411(3) (2025). The Attorney General has expressly stated that if it is necessary to bring an enforcement action, he will enforce a UPL set by the Board according to the applicability of UPLs as established by the Board. Appx1341-42. Manufacturers are not the target of any UPL enforcement.

The Downstream Application of an Upper Payment Limit

Colorado statutes and the Board's rule dictate that a UPL is a payment restriction on entirely downstream actors for actual sales and reimbursements of a drug dispensed to Colorado consumers. A UPL is defined as:

> [T]he 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.

Colo. Rev. Stat. § 10-16-1401(23) (2025). (emphasis added). Simply put, a UPL regulates the downstream prescription drug transactions that take place in Colorado for a drug also dispensed or distributed in the state.

The Board's rule, adopted March 17, 2023 (over a year before Amgen initiated this suit), solidifies this interpretation of the statute, stating a UPL "applies to a consumer's purchase from a pharmacy [ ] or provider of a prescription drug that is dispensed or administered *to the Colorado consumer*", as well as "any pharmacy or provider's purchase of a prescription drug that is dispensed or administered *to a Colorado consumer*." 3 Colo. Code Regs. § 702-9.4.2(C)(1)-(2) (2025) (emphasis added).

The legislature intended UPLs to specifically apply to entities such as state and local governments, contractors and vendors, commercial health plans, providers, and pharmacies. SB21-175 at 3; Appx1299. The statute also directs the Board to consider the costs of "administering," "dispensing," and "distributing" the prescription drug in Colorado in

establishing a UPL, focusing the Board on the costs incurred by the entities the UPL was designed to apply to: providers, pharmacies, and wholesalers, respectively. Colo. Rev. Stat. § 10-16-1407(2) (2025). A UPL is a payment restriction on entirely downstream actors for actual sales and reimbursements of a drug dispensed to Colorado consumers. The statute should not be read to apply to a wholesaler's purchase from a manufacturer.

The legislative history underscores the specific intent that a UPL not apply to a wholesaler's purchase from a manufacturer. *See Prescription Drug Affordability Review Board: Hearing on SB 21-175 Before the House Comm. On Health & Insurance, 73rd Sess. (2021) (statement of Rep. Chris Kennedy)* ("The way we anticipate this working is that the current relationship between pharmaceutical manufacturers and wholesalers will largely remain unchanged. … [Wholesalers] will purchase drugs at the wholesale acquisition cost. They will sell it to pharmacies or hospitals at the UPL or whatever negotiated price is lower than that – which may be the case. Our hope is that negotiations continue and there will be lower prices that are below the UPL."); Appx1299. A UPL is not a regulation on the manufacturer but rather a limit on what

someone can pay—in particular, what in-state actors and actors doing business in Colorado can pay—for a drug that is dispensed or administered in Colorado.

The Board's Enbrel Proceedings and the District Court Action

In 2023, the Board conducted its affordability review for Enbrel over a period of six months, with Amgen participating in the process at every step. *See* Appx1303 (describing Amgen's participation in all three public Board meetings for Enbrel's affordability review, including providing verbal comment and written submissions, and participating in Board Staff's communication with external stakeholders). The Board deliberated on the 534-page draft affordability report for Enbrel and determined that use of Enbrel was unaffordable for Colorado consumers at its February 16, 2024, meeting.

Four pages out of the 534-page report mention Enbrel's patent protections. *See* Appx0608, Appx642-44. During the February 16 meeting, for less than 15 minutes over the span of an almost two-hour deliberation, the Board discussed Enbrel's status as a patented drug and how that lack of competition from biosimilars might impact Colorado consumers' affordability and access. *See* Appx1191, Appx1230-31. The

remaining substance of the Board's report and the deliberation reflects the overwhelming and true focus of the Board: unaffordability for Colorado consumers. The summary report presents the Board's most salient considerations in reaching its unaffordability determination, including Enbrel's higher out-of-pocket costs compared to therapeutic alternatives and self-reported affordability concerns from Colorado consumers. Appx585-86.

The Board approved the final affordability review report for Enbrel on February 23, 2024. The Board then voted to initiate rulemaking regarding a UPL for Enbrel.

Amgen filed its complaint in the United States District Court for the District of Colorado on March 22, 2024, challenging the constitutionality of the Affordability Program and specifically, the authority of the Board to set UPLs on unaffordable drugs. Appx0035-72. Notably, this challenge came in the middle of the Board's review of Enbrel and before the Board began considering a UPL for Enbrel.[5]

[5] Amgen filed its complaint the day after the Board published the final version of its Enbrel Affordability Review Report. The Board did not start UPL rulemaking for Enbrel until May 2025 and continues to hold UPL rulemaking hearings for Enbrel as of the date of this filing.

The parties filed cross motions for summary judgment. Amgen argued PDAB's upper payment limits violate federal patent law, are preempted by the federal healthcare program, and violate the dormant Commerce Clause, and that the Affordability Program on the whole violates due process. *See generally* Appx1169-1218. As the Board had not (and still has not) set a UPL for Enbrel, each of Amgen's arguments were based on a hypothetical UPL, in an unknown amount.

Appellees cross-moved for summary judgment, arguing against Amgen's premature challenge to a UPL based on lack of standing and subject matter jurisdiction. Appx1279-1344. Specifically, Appellees challenged Amgen's assumption that effects from a downstream UPL would flow upstream to Amgen and argued that Amgen could not claim a concrete injury based solely on that assumption. *Id.* Appellees also responded in opposition to each of Amgen's merits arguments, including patent preemption, arguing that the Affordability Program is constitutional. *Id*. The court heard oral argument on the parties' summary judgment motions on October 22, 2024.

During its subsequent meetings in 2024 and while this case was pending at the district court, the Board conducted affordability reviews

for two other selected drugs and discussed and solicited feedback from stakeholders and Board members on the upcoming UPL process. On May 23, 2025, and July 11, 2025, the Board held UPL rulemaking hearings for Enbrel. During these hearings, the Board analyzed the UPL data benchmarks outlined in statute and rule and took stakeholder testimony. *See* Colo. Rev. Stat. § 10-16-1407(2) (2025); 3 Colo. Code Regs. § 702-9:4.1(C)(2) (2025).

As of the filing of this brief, no UPL has been set for Enbrel. The Board conducted an Enbrel UPL rulemaking hearing at its Board meeting today, August 22, and continued future Enbrel UPL rulemaking to its next meeting on October 3.[6] The Board may terminate these rulemaking proceedings at any time without setting a UPL. 3 Colo. Code Regs. § 702-9:4.1(D)(1) (2025).

Even if set, any UPL would be subject to judicial review under Colorado's Administrative Procedure Act. But Amgen sought instead to prematurely invalidate Colorado's entire Affordability Program. Without

[6] Appellee's discussion of the Enbrel UPL rulemaking hearings is meant to provide context to this Court regarding the status of an Enbrel UPL. It does not indicate consent by Appellees to inclusion of any information in the appellate record that was not available to the district court.

a UPL, Amgen cannot demonstrate that its costs or prices will be affected—one of the key reasons the lower court denied standing.[7]

The District Court's Ruling Against Amgen

On March 28, 2025, the district court found Amgen failed to establish standing to bring its complaint. Appx0001-19. The district court explicitly declined to reach the merits of the complaint, dismissing Amgen's motion for summary judgment without prejudice, and granting Appellees' cross-motion for summary judgment. Appx0019. The district court relied on two key findings in its Order: (1) Amgen was not subject to direct regulation, and (2) Amgen failed to meet its burden to demonstrate injury as an unregulated party. Appx0012.

First, the district court found a UPL only applies to downstream supply chain transactions and actors, rather than upstream at a drug manufacturer's point of sale. Appx0012-14. Specifically, the district court interpreted use of "the" in Colo. Rev. Stat. § 10-16-1401(23) (2025), to limit the scope of UPL applicability only to financial transactions in

[7] Appellees do not concede that if a UPL is set for Enbrel, any future challenge by Amgen would be timely or that Amgen would have standing. It is, however, clear that Amgen's instant challenge is overtly hypothetical and premature given that no UPL has been set.

which "the" prescription drug is "dispensed or distributed in Colorado." Appx0013. Further, the district court understood the words "administering", "dispensing" and "distributing" as used in statute to be associated with costs for providers, pharmacies, and wholesalers, rather than manufacturers. Appx0013-14. Even further, the district court pointed to the legislative history of the UPL as being targeted to payers, providers, and pharmacies. Appx0014. For these reasons, UPLs were consistently interpreted to apply only downstream to the actual sales and reimbursements of the drug dispensed to Colorado consumers. Appx0012.

Second, the district court found Amgen did not meet its burden as an unregulated party to show it would be injured by any UPL. Appx0014-19. At the outset, the district court rejected Amgen's arguments of "basic economics and common sense" as the basis for injury, questioning if this concept should even apply to the pharmaceutical industry given the "counterintuitive pricing behavior" recognized by Amgen's own CEO. Appx0016. The district court stated Amgen failed to recognize the complexities of the drug supply chain and the importance of "whether, when, or what UPL may be set." *Id.*

The district court further rejected the statements in the declaration made by Amgen employee Partick Costello and submitted by Amgen, finding it failed to "articulate[] a specific and concrete injury." *Id.* Specifically, the district court found the declaration contained "two unfulfilled conditions precedent": (1) if a UPL is set, that wholesalers will not absorb the cost; and (2) if wholesalers must sell a drug for less than WAC, that Amgen will be required to reimburse any monetary loss to wholesalers. Appx0016. For these reasons, the district court characterized Amgen's assertion that an Enbrel UPL will necessarily impact Amgen as "conclusory in nature." Appx0017. The district court emphasized the speculative nature of Amgen's standing arguments as "premised on 'the predictable effect' of a *hypothetical* UPL on the decisions of wholesalers." *Id.* (emphasis in original). The district court thereby declined to "assume or predict one of several possible outcomes to find Article III standing at this time." Appx0018.

SUMMARY OF THE ARGUMENT

Through this appeal, Amgen seeks to disturb the constitutional balance struck by Article III standing and prematurely avail itself of federal court jurisdiction before a case or controversy exists. "Under

Article III, federal courts do not adjudicate hypothetical or abstract disputes. … Federal courts do not exercise general legal oversight … [a]nd [] do not issue advisory opinions." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423-24 (2021). Amgen's challenge to the constitutionality of the Affordability Program presents this type of hypothetical dispute. The Board has not set a UPL on Enbrel, and, even if it had, Amgen cannot use such a UPL to argue for standing retroactively on appeal. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 68, n.22 (1997). Moreover, Amgen is not subject to the Board's regulation and cannot show it will be injured by downstream transactions in the drug supply chain. This Court should uphold the district court's dismissal for lack of standing.

Amgen cannot argue it is injured by an upper payment limit that does not exist. And the Board is not required to set a UPL. *See* 3 Colo. Code Regs. § 702-9.4.1(D)(1) (2025). Appellees do not dispute that the Board is currently holding Enbrel UPL rulemaking hearings. However, without the Board's adoption of a specific UPL rule, including that UPL's scope, amount, and effective date, Amgen is left with nothing more than speculation as to a UPL's existence and potential effect.

Amgen's reliance on the May and July 2025 Enbrel UPL rulemaking hearings—which occurred after the district court's dismissal in this case—to now shore up its standing similarly fails. In discussing Enbrel UPL proceedings that occurred more than a year after it filed its complaint in district court, Amgen insists it has standing because the rulemaking hearings demonstrate the Board "has been deliberately and methodically marching toward imposing an upper payment limit on Enbrel." Op. Br. at 42. However, Amgen lacked standing when it filed its complaint and cannot seek to use recent Board proceedings to prove so now.

Even if the Board were to set a UPL on Enbrel, Amgen cannot show it will be injured. Amgen is not directly regulated by a UPL and cannot show that a UPL that would apply to downstream actors would be the cause of any alleged injury. Amgen must be able to show the predictable or intended effects of a UPL are that it, as a manufacturer unregulated by the Board, would be injured. In the absence of a UPL and any corroborating statements about how a UPL would be implemented in the complex pharmaceutical supply chain, Amgen proffers only speculation and fails to meet its burden.

Amgen's attempts to address substantive issues of patent law are outside the scope of this appeal. Because Amgen lacked standing, the district court declined to reach the merits of the case. Appx0018. Amgen cannot appeal a final judgment that was never made and one over which this Court lacks subject matter jurisdiction to reach. *See Earth Island Inst. v. Albright*, 147 F.3d 1352, 1355-56 (Fed. Cir. 1998) (citing *United States v. Corrick,* 298 U.S. 435, 440 (1936)).

Amgen's arguments fail at every turn: there is no UPL for it to challenge; it is not injured by a UPL even if there was one; and its patent law arguments are not subject to this appeal. The district court's decision should be upheld.

ARGUMENT

I. Standard of Review and Choice of Law

This Court reviews the district court's dismissal for lack of subject matter jurisdiction de novo. *Uniloc USA, Inc. v. Motorola Mobility LLC*, 52 F.4th 1340, 1345 (Fed. Cir. 2022). Factual findings relevant to a lack of standing determination are reviewed for clear error. *Advanced Video Techs. LLC v. HTC Corp.,* 879 F.3d 1314, 1317 (Fed. Cir. 2018).

Because standing is the only issue subject to this appeal, and this appeal does not involve questions unique to patent law, this Court should apply Tenth Circuit, rather than Federal Circuit, law to review Amgen's standing. *See Univ. of S. Fla. Rsch. Found., Inc. v. Fujifilm Med. Sys. U.S.A., Inc.*, 19 F.4th 1315, 1323 (Fed. Cir. 2021) ("We apply regional circuit law to our review of a dismissal of a complaint for lack of standing unless the issue is unique to patent law and therefore exclusively assigned to the Federal Circuit.").[8]

II. The district court properly dismissed Amgen's Complaint for lack of subject matter jurisdiction because it lacks standing.

To prove standing, a plaintiff must show they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo v. Robins*, 578 U.S. 330, 338 (2016). Because causation and redressability are often "flip sides of the same coin," *Sprint*

[8] Appellees recognize that the question of standing relies primarily on Supreme Court case law and that it is unlikely that this case turns on applicability of Tenth Circuit rather than Federal Circuit case law. However, to the extent that this Court looks to other federal circuit courts for guidance on the issue of standing, Appellees believe reliance on Tenth Circuit case law is appropriate.

Commc'ns Co. v. APCC Servs., Inc., 554 U.S. 269, 288 (2008), "the two key questions in most standing disputes are injury in fact and causation." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380-81 (2024). As found by the district court, Amgen meets neither requirement. Appx0012, Appx0014. Additionally, with respect to parties not directly regulated by a government action, "the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff." *All. for Hippocratic Medicine*, 602 U.S. at 385. Again, the district court properly found Amgen could not meet this causation standard. Appx0014-0019.

Importantly, this standing inquiry must be conducted when a plaintiff files its complaint; Amgen ignores this requirement and improperly uses recent Board Enbrel UPL proceedings to seek to establish newly found standing. Based on its failure to meet the basic injury and causation requirements for standing, even if the Board sets a UPL for Enbrel, Amgen cannot prove it is directly regulated by a UPL or that it will be injured by the same. Because Amgen continues to fail to

prove standing to bring this suit, this Court should uphold the district court's order.

a. Amgen cannot establish standing.

i. Amgen is not subject to direct regulation by an Enbrel UPL.

Designed to alleviate affordability challenges of Coloradans and downstream actors in the prescription drug supply chain, a UPL does not apply to a wholesaler's purchase of a drug from the manufacturer. *See* Appx1299-1300.

A UPL is "the maximum amount that may be paid or billed for a prescription drug that is dispensed or distributed in Colorado" and applies to a consumer's purchase from a pharmacy or provider, reimbursements by certain insurance payers, and pharmacies' and providers' purchases of the prescription drug. Colo. Rev. Stat. § 10-16-1401(23) (2025); 3 Colo Code Regs. § 702-9:4.2(C) (2025). The statute directs the Board to consider the costs of "administering" the drug (costs incurred by providers); "dispensing" the drug (costs incurred by pharmacies); and "distributing" the prescription drug in Colorado (costs incurred by wholesalers). Colo. Rev. Stat. § 10-16-1407(2) (2025). Put simply, a UPL is a payment restriction on entirely downstream actors for

actual sales and reimbursements of a drug dispensed to Colorado consumers.

The district court agreed that until a drug is "dispensed or distributed in Colorado," the UPL does not apply to financial transactions in the supply chain concerning it. *See* Appx0013-14. The UPL was not intended to apply to purchases or reimbursements in the supply chain when the drug is not destined for Colorado. It is not until the drug is purchased by the pharmacy to be dispensed in Colorado that any UPL attaches. This interpretation, codified by the Board in rule in 2023, adheres to the legislature's intent to protect consumers, as well as "state and local governments, contractors and vendors, commercial health plans, providers, and pharmacies" from excessive costs of prescription drugs. SB21-175; 3 Colo. Code Regs. § 702-9:4.2(C) (2025); *see* Appx1299.

Amgen attempts to make several arguments that the Affordability Program is indeed aimed at manufacturers. Op. Br. at 12, 56-57. Amgen argues that if a UPL is set, the Board is required to inquire with manufacturers if they are "able to make the prescription drug available for sale in the state and request the rationale for the manufacturer's response." Colo. Rev. Stat. § 10-16-1407(10)(a) (2025). But this inquiry

does not equate to a change in manufacturer price. Given the manufacturer's position at the top of the supply chain and originating source of a drug, this inquiry makes sense, as the manufacturer is the party initially supplying the drug into the market. If they do not intend to continue to supply the drug after adoption of a UPL, the manufacturer would be the only party with that knowledge, not downstream actors.

Similarly, the notification and fine provisions for a manufacturer's failure to provide a withdrawal notice follow the same logic. *See* Colo. Rev. Stat. § 10-16-1412(1), (3) (2025). Withdrawal from the Colorado market is a decision for the manufacturer alone—it does not necessitate or imply a manufacturer such as Amgen will bear costs from a UPL.

Further, the Board's conflict of interest statutes cannot be used to show any direct connection between a UPL and manufacturers. While members of the Board are not permitted to be an employee, board member, or consultant of a drug manufacturer or trade association of manufacturers, the same is true of Board member's employment by carriers and their trade associations and PBMs and their trade associations. Colo. Rev. Stat. § 10-16-1402(3)(b) (2025). This statutory provision, aimed only at ensuring Board members remain unbiased,

cannot be read so broadly as to presume costs of a UPL will fall to a drug's manufacturer.

Amgen cannot demonstrate that, under Colorado statutes and Board rules, it is the direct object of regulation such that it has standing.

ii. Amgen's alleged harm from an Enbrel UPL is too speculative to satisfy the injury-in-fact requirement.

The district court properly found Amgen failed to satisfy the injury-in-fact requirement for Article III standing. "To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo,* 578 U.S. at 339 (citation omitted). For an injury to be concrete, "it must actually exist." *Id.* at 340. "A claimed injury that is contingent upon speculation or conjecture is beyond the bounds of a federal court's jurisdiction." *Tandy v. City of Wichita*, 380 F.3d 1277, 1283-84 (10th Cir. 2004). Additionally, "[w]here an injury is threatened rather than actual, '[a]llegations of *possible* future injury are not sufficient' to establish standing." *Tennille v. Western Union Co.,* 809 F.3d 555, 560 (10th Cir. 2015) (citation omitted) (emphasis in original). Amgen's alleged injury from a

hypothetical future UPL is based on conjecture of what effects may flow from a downstream UPL that does not apply to Amgen. This is insufficient to demonstrate standing.

Amgen argues the district court applied the wrong standard in determining Amgen did not have standing. Amgen asserts that, in a pre-enforcement challenge, it need only show "there is a substantial risk that the harm will occur." Op. Br. at 34. But "preenforcement" standing is inapposite when, as here, Amgen does not stand to be subject to an enforcement action under the Affordability Program at all. *See* Appx1341-42; *see, e.g., California v. Texas,* 593 U.S. 659, 670 (2021) ("our cases have consistently spoken of the need to assert an injury that is the result of a statute's actual or threatened enforcement"); *Susan B. Anthony List v. Driehaus,* 573 U.S. 149, 158-59 (2014). Because any UPL applies downstream, any enforcement action—which in itself is purely speculative—would not be against Amgen. Colo. Rev. Stat. § 10-16-1411(3) (2025); *see also* Appx1341-42. Unlike the price cap law at issue in *Biotechnology Indus. Org. v. D.C.*, that held prescription drug manufacturers liable if their drug was sold in Washington D.C. for an "excessive price", manufacturers are not the intended target of UPL

enforcement. *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1370-71 (Fed. Cir. 2007) ("*BIO*"). The slightly relaxed standards for a pre-enforcement challenge are thus inapplicable.

The district court appropriately required Amgen to show any purported injury was based on more than conjecture, not that it was a certainty. The district court found Amgen's declarations in support of its motion for summary judgment regarding anticipated harm from a UPL to be conclusory and based on "unfulfilled conditions precedent":

> Amgen *might* be able to demonstrate harm *if* the Board sets a UPL for Enbrel; *if* that UPL is set lower than the WAC for Enbrel; and *if* wholesalers react by demanding that Amgen absorb any costs associated with the same. Unless and until a UPL is set for Enbrel and at a price lower than WAC, however, Amgen's alleged future injuries are hypothetical at best. In other words, Amgen's theory of standing is premised on "the predictable effect" of a *hypothetical* UPL on the decisions of wholesalers.
>
> Appx0016-17 (emphasis in original).

Finally, to the extent Amgen argues its injury arises from the Board's mere determination that Enbrel is unaffordable, it does not advance a cognizable injury. Allegations of "a bare procedural violation, divorced from any concrete harm" cannot satisfy the injury in fact requirement under Article III. *Spokeo,* 578 U.S. at 341. The "process

itself" is one that Amgen can and has amply participated in and that has procedural safeguards under Colorado's Administrative Procedure Act. Amgen is not harmed simply because a state chooses to review the affordability of a drug for its consumers.

iii. Amgen cannot establish that a UPL will cause its alleged injury.

The district court also properly found Amgen failed to establish that the Board would cause its alleged injury. Standing is "substantially more difficult" to establish when the plaintiff is not the object of the government's action, because the plaintiff must show that the "unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict … have been or will be made in such a manner as to produce causation and permit redressability of injury." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992) (internal citations omitted). Amgen did not make such a showing here. Amgen's alleged injury arises not from the Board's actions, but from the possibility that independent supply chain actors may try to negotiate a lower price from the manufacturer. The district court correctly found that Amgen's

speculation of how a UPL, if set, could harm it was insufficient to carry its burden to show it had standing.

Any UPL set by the Board would apply to downstream actors including consumers, PBMs, insurance carriers, pharmacies, and providers, not Amgen itself. If the Board sets a UPL, it will be the first state to chart this path toward addressing rising prescription drug costs for its consumers with such a tool. Given the complexity of the pharmaceutical supply chain—a fact widely acknowledged even by Amgen itself (Appx0016, Appx1291-95)—how intermediaries in the supply chain will respond to a UPL is a matter of pure speculation. The potential for indirect impact does not transform a UPL into a regulation on the manufacturer and does not show causation necessary to establish standing.

While the Supreme Court recently reinforced that a plaintiff who is not the subject of direct regulation may be able to demonstrate the causation and redressability prongs of the standing test sufficient to challenge the government action, such a showing has not been made here. In *Diamond Alternative Energy*, fuel producers challenged the EPA's approval of California regulations that, to alleviate greenhouse gas

emissions caused by fuel, require auto manufacturers to meet certain vehicle electrification targets. *Diamond Alt. Energy, LLC v. EPA*, 145 S.Ct. 2121 (2025). The Court acknowledged that, on its face, California's regulations applied to auto manufacturers, not the fuel producers themselves, but nevertheless found the fuel producers could establish that they satisfied the causation and redressability requirements of the Article III inquiry because the intended and likely effect of California's regulations was a decreased demand for gasoline as fuel. *Diamond Alt. Energy*, 145 S.Ct. at 2135-37. The Court relied on "commonsense economic realities" of the regulations—realities which were supported by record evidence from every side of the debate: 14 declarations from the fuel producers, statements by the EPA, statements by California itself, and statements by auto manufacturers—that the intent of the regulations were to drive down demand for fuel that contributed to greenhouse gas emissions. *Id* at 2131, 2135, 2137-38.

So while third parties may establish standing when they are not the subject of direct regulation, including with reference to "commonsense economic realities" that show how a regulation will cause harm to a third party, the third party must still meet its burden of

demonstrating that this is the predictable or intended effect of the government's action. Unlike *Diamond Alternative Energy*, where the Supreme Court found that the purpose of California's regulations was to reduce demand and use of fuel produced by the plaintiffs, Amgen lacks similar supporting statements from supply chain actors that the purpose of the Board's Affordability Program is to control drug manufacturers' pricing. *Id*. at 2135-37. Here, the district court cited fundamental flaws in Amgen's single substantive declaration from Patrick Costello, whose statements the court found to be speculative and incomplete. Appx0016-17 ("But at this juncture, Colorado has not fulfilled either of these prerequisites. Moreover, Mr. Costello's statement that '[t]here is no scenario in which an upper payment limit for Enbrel would negatively impact Amgen,' necessarily relies on both foregoing conditions and is conclusory in nature."). The district court did not clearly err by discounting Amgen's self-serving declaration in finding these statements were too speculative.

The district court properly held that Amgen failed to establish that the predictable effect of a UPL was an effect on a drug manufacturer's price or cost. The requirement still stands: "to establish causation, the

plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff." *All. for Hippocratic Med.*, 602 U.S. at 385. And, in the case of alleged future injury, the likelihood of that injury is brought into even sharper focus when evaluating standing. *Id.* at 385, n.2. Here, the district court properly found that where there may never be a UPL and the business decisions of independent third parties will determine any impact of a UPL, Amgen has not satisfied this minimum. *See Kane Cnty., Utah v. United States*, 928 F.3d 877, 888 (10th Cir. 2019) (impact of a government's decision "almost inevitably" causing specific harm to plaintiffs sufficient to establish imminent injury); *Maine Lobstermen's Ass'n v. Nat'l Marine Fisheries Serv.*, 70 F.4th 582, 592-93 (D.C. Cir. 2023) (discussing the established behavior of fishermen in response to a governmental action to find potential harm was "fairly traceable" to the agency action).

Amgen must do more than gesture toward "commonsense economics" to demonstrate how a UPL would predictably and assuredly harm it as the manufacturer. While some "upstream economic injuries"

may be sufficient to satisfy this standard, Amgen fails to carry its burden here. *See All. for Hippocratic Med.*, 602 U.S. at 384.

Amgen also failed to provide sufficient evidence to show the actions of wholesalers in response to a UPL are so predictable as to satisfy causation. *See Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019) (burden to demonstrate third parties will react in predictable ways met by introducing evidence at trial of historic responses); *Growth Energy v. EPA,* 5 F.4th 1, 33 (D.C. Cir. 2021) ("In considering the likely reaction of third parties, we may consider a variety of evidence, including the agency's own factfinding; affidavits submitted by the parties; evidence in the administrative record; arguments firmly rooted in the basic laws of economics; and conclusions in other agency orders and rulemakings."). Amgen relies on a single declaration as its only evidence to support its claims of causation—a self-serving statement from Amgen's Associate Vice President that describes its current business operations and how it anticipates a UPL would impact those operations. Appx1442-47. But more is needed to support summary judgment; "[i]t is well settled that 'a conclusory statement on the ultimate issue does not create a *genuine* issue of fact.'" *Applied Cos v. United States*, 144 F.3d 1470, 1475 (Fed.

Cir. 1998) (citation omitted) (emphasis in original). Without a UPL, its amount, and other evidence demonstrating monetary loss, Amgen's statements regarding how it anticipated a UPL operating are grounded in its own speculation. The district court properly treated these statements as conclusory. Amgen did not provide statements from its wholesalers regarding how they might respond to a UPL established by the Board, though any such statements would have suffered from the same problem as Amgen's declaration—they would be too speculative.[9]

And even if Amgen's factual allegations that the wholesalers would utilize the "chargeback" mechanism in existing contracts ultimately proves to be true, this harms, not helps, its causation argument. Amgen makes much of its "unrebutted" evidence that under its existing contractual agreements with wholesalers, it may be required to provide the wholesaler with a chargeback if a UPL is set and if the UPL is for less than WAC. But far from underscoring Amgen's purported injury, this

[9] "[B]iosimilar manufacturers typically sell their products to wholesale distributors pursuant to pre-negotiated, long-term bulk contracts that cover a range of products for resale nationwide." *Ass'n for Accessible Meds v. Ellison*, 704 F. Supp. 3d 947, 952 (D. Minn. 2023). How and whether a wholesaler might react to a UPL on some purchases of one drug in one state with respect to its contracts with manufacturers is unknown.

evidence undermines Amgen's ability to show that the *Board's* action is the cause of Amgen's purported injury. According to Amgen, Amgen and its wholesalers have made a business decision to negotiate for chargebacks. But Amgen's independent business decision does not transform any UPL into a direct regulation on the manufacturer.

Instead, what is borne out by the record is that the Board, in setting a UPL, is concerned first and foremost with alleviating costs of downstream actors: consumers and entities in Colorado suffering from the crippling costs of prescription drugs. How the various actors in the supply chain will adapt to a single state's downstream regulation of some purchases on a single drug is not clear. The district court properly found that Amgen failed to show the predictable effect of a UPL sufficient to establish standing.

b. Amgen cannot use Board activities occurring after the district court's decision to argue it has standing because standing is determined when a party files its complaint.

Standing is a baseline prerequisite that all plaintiffs who file federal court complaints must meet. *See Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) ("While the proof required to establish standing

increases as the suit proceeds, [citation omitted], the standing inquiry remains focused on whether the party invoking jurisdiction had the requisite stake in the outcome *when the suit was filed*." (emphasis added). Standing is the "requisite personal interest that must exist at the commencement of the litigation." *Arizonans for Official English* 520 U.S. at 68, n.22. In this appeal, Amgen presents new facts about the Board's May 23 and July 11, 2025, Enbrel UPL rulemaking hearings to support standing and potential outcome that the Board will set an Enbrel UPL above the manufacturer's list price, none of which was before the district court and so cannot be used to bolster standing on appeal. *Compare* Op. Br. at 1-2, 21-22 *with* Appx0056-60, Appx1188-92.

First, Amgen cites to "ongoing regulatory proceedings" it states as being held "for the express purpose of determining what Enbrel's upper payment limit should be." Op. Br. at 1-2, 22. Here, Amgen disregards the Board's express statutory ability to terminate UPL rulemaking at any time. *See* Colo. Rev. Stat. § 24-4-103(4)(d) (2025); 3 Colo. Code Regs. § 702-9.4.1(D)(1)(b) (2025). Then, pointing to the Board's May 23, 2025, Enbrel UPL rulemaking hearing, Amgen states the Board never discussed the possibility of not establishing a UPL for Enbrel and in fact

discussed a potential UPL amount. Op. Br. at 22. Amgen ignores that the Board is required to examine specific data benchmarks in determining whether to set a UPL —there remains no requirement for one to be set. *See* 3 Colo. Code Regs. § 702-9.4.1(C)(2) (2025).

Amgen further suggests the Board's cost-benefit analysis of an Enbrel UPL says "a UPL [has] significant benefits and only 'minimal' costs." Op. Br. at 21. Amgen fails to mention that this analysis was produced in response to stakeholder requests and does not advocate for setting a UPL. *See* Colo. Rev. Stat. § 24-4-103(2.5)(a) (2025) ("Any person may … request that the department of regulatory agencies require the agency submitting the proposed rule or amendment to prepare a cost-benefit analysis."). Through these arguments, Amgen seeks to paint the Board as having a singletrack for a UPL that cannot be stopped. However, not only is a UPL not a foregone conclusion, but Amgen also cannot use any alleged "progress" toward a UPL to establish standing.

Amgen cannot claim standing based on facts developed over the course of Enbrel UPL rulemaking, including but not limited to, May 23, 2025, and July 11, 2025, Board meetings, considering its complaint was filed with the District of Colorado on March 22, 2024. These subsequent

facts cannot support standing and are ultimately misplaced in the context of the appeal. *See Brown v. Buhman*, 822 F.3d 1151, 1163-65 (10th Cir. 2016) ("Standing concerns whether a plaintiff's action qualifies as a case or controversy when it is filed; mootness ensures it remains one at the time a court renders its decision."). Amgen did not have standing to bring its current suit when it filed its complaint, and it does not have it now.

To the extent subsequent events have bolstered Amgen's standing arguments, it has a readily available remedy: filing a new case. Moreover, even if the Board sets a UPL during the pendency of this appeal, Amgen cannot use support from the currently cited or future Enbrel UPL rulemaking hearings to support its standing arguments before this Court. Because Amgen's attempted additions to the record from recent Enbrel UPL rulemaking hearings cannot be considered as part of standing, this Court should uphold the district court's order.

III. Amgen's arguments concerning patent preemption are outside of the scope of this appeal and, in any event, unavailing.

Whether Colorado's Affordability Program is preempted by federal patent law is a question requiring a determination on the merits of

Amgen's underlying claims—merits that were not reached by the district court and therefore are not and cannot be at issue in this appeal.[10] But even still, Colorado's Affordability Program is not preempted by federal patent law, either under a conflict preemption or field preemption analysis. Colorado has constitutionally exercised its police powers to address an affordability crisis facing its consumers by generally regulating downstream drug purchases using a UPL. A regulation of this type falls outside the ambit of patent law protections.

a. Whether Colorado's law is preempted by federal patent law is a merits issue outside the scope of this appeal.

The district court properly dismissed Amgen's suit for lack of standing and did not have subject matter jurisdiction to rule on whether Colorado's law is preempted by federal patent law. *Univ. of Pittsburgh v. Varian Med. Sys., Inc.*, 569 F.3d 1328, 1332 (Fed. Cir. 2009) ("A dismissal for lack of standing is jurisdictional and is not an adjudication on the merits."). And "[i]f the trial court lacked jurisdiction, then this court has

[10] Even if this Court finds that Amgen did establish standing and the district court erred, remand is appropriate so that the district court can consider the merits and any intervening facts concerning the Board's UPL proceedings in the first instance.

'jurisdiction on appeal, not of the merits but merely for the purpose of correcting the error of the lower court.'" *Earth Island Inst.* 147 F.3d 1t 155-56, (*citing United States v. Corrick,* 298 U.S. 435, 440 (1936)). Accordingly, this Court should not consider whether federal patent law preempts Colorado's law unless and until the district court makes a final judgment on the merits of Amgen's claims.

b. Nevertheless, Colorado's law is not preempted by federal patent law.

Even if this Court were to consider whether Colorado's law is preempted by federal patent law, precedent from the Supreme Court and this Court establishes that it is not. As discussed above, any UPL established by the Board does not apply to a manufacturer's sale of a prescription drug. And because the patentee's sale is the *only* sale that implicates federal patent rights, Colorado's law does not stand in conflict with federal patent law at all. The doctrine of patent exhaustion forecloses Amgen's preemption argument.

In this case, Amgen asserted that Colorado's law is preempted because it conflicts with its right to exclude under the Patent Act, and therefore stands as an obstacle to Congress's objectives. *See* Appx0046-47, Appx0060-63, Appx1194-95. The ultimate touchstone in every

preemption case, and especially conflict preemption cases, is Congress's purpose. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). And the presumption against preemption applies. *See, e.g.*, *Wyeth*, 555 U.S. at 565; *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1326 (Fed. Cir. 2017).

Patent law has three main objectives: (1) to foster and reward innovation; (2) to promote the disclosure of inventions; and (3) to assure that ideas in the public domain remain there for use by the public. *See Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979); 35 U.S.C. § 154(a)(1). To promote these objectives patent law gives patentees the right to exclude. *Id.*

But the right to exclude is a negative right. *See Leatherman Tool Grp. Inc. v. Cooper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997) ("federal patent laws do not create any affirmative right to make, use, or sell anything."). And it has clear limits. For over 160 years, the doctrine of patent exhaustion has served as one "uniform and automatic" limit on patent rights. *See Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 370, 377 (2017).

Under the patent exhaustion doctrine, when "a patentee chooses to sell an item, that product is no longer within the limits of the monopoly"

granted by a patent. *Id.* at 370. (quotations omitted). That is because "the purpose of the patent law is fulfilled when the patentee has received his reward for the use of his invention." *Id.* at 371 (alterations omitted). Therefore, a "patentee is free to set the price and negotiate contracts with purchasers, but may not, *by virtue of his patent*, control the use or disposition of the product after ownership passes to the purchaser." *Id.* at 370 (quotations omitted) (emphasis in original). "The sale terminates all patent rights to that item." *Id.* (quotations omitted). Patent law does not give patentees the right to set or control prices of the product after the first authorized sale. *See, e.g., United States v. Univis Lens Co.*, 316 U.S. 241, 252 (1942) (rejecting patentee's attempt to rely on its patent in antitrust suit brought by government); *Impression Prods.*, 581 U.S. at 372-73 (discussing *Univis* and other cases).

Patent law does not give patent holders, like Amgen, the unfettered right to reap maximum profits. This principle is illustrated in *Impression Products v. Lexmark*, the most recent Supreme Court case on the purpose and the scope of the right to exclude. In *Impression Products*, the Supreme Court considered, among other things, whether patent exhaustion applied to foreign transactions. 581 U.S. at 366, 370. This

Court held that foreign sales did not exhaust patent rights because patentees were entitled to a particular "reward from sales in American markets." *Lexmark Int'l, Inc. v. Impression Prods., Inc.*, 816 F.3d 721, 761 (Fed. Cir. 2016). Lexmark argued that foreign exhaustion should not apply since "a patentee selling in a foreign market may not be able to sell its product for the same price that it could in the United States, and therefore is not sure to receive 'the reward guaranteed by U.S. patent law.'" *Impression Prods.*, 581 U.S. at 379. PhRMA argued that foreign exhaustion would result in "downward pricing pressures on pharmaceutical sales in the United States" which "would hinder pharmaceutical companies from using the patent exclusivity period to recover their research and development costs." Br. for PhRMA as Amicus Curiae in Support of Respondent, *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360 (2017) (No. 15-1189) 2017 WL 894890, at *12. PhRMA also argued that, because some foreign governments impose price controls on patented drugs, a foreign exhaustion rule would "effectively usurp Congress' policy judgment about the proper balance between innovation and access to medication" and would "permit foreign price controls or patent policy to encroach on the U.S. market." *Id.* at 14.

The Supreme Court rejected all of these arguments. The Court explained that "the Patent Act does not guarantee a particular price, much less the price from selling to American consumers." *Impression Prods.*, 581 U.S. at 380. "Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive." *Id.* at 382. All that the right to exclude ensures is that a patentee receives "one reward" for every item that is sold. *Id.* at 380. Once a patentee decides to sell, it receives that one reward and the sale automatically exhausts the patentee's patent rights domestically and internationally. *See id.* at 377, 382.

The Patent Act also does not give Amgen an unfettered right to prevent any state regulation that might have an indirect effect on its profits. As the Supreme Court explained over 140 years ago, "Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace, and general welfare of the community are promoted. Whatever rights are secured to inventors must be enjoyed in subordination to this general authority of the State over all property within its limits." *Webber v. Virginia*, 103 U.S. 344, 347-48 (1880). It is

well-established that states can regulate patented products in their borders. *See, e.g.*, *Patterson v. Kentucky*, 97 U.S. 501, 503-05 (1878) (regulation prohibiting sale of patented illumination oil); *Webber*, 103 U.S. at 347 (tax on patented products).

It is also well-established that states can regulate the practice of pharmacy and the sale of drugs. *See Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 84-85 (2020); *Moore v. Dist. Ct.*, 518 P.2d 948, 952 (Colo. 1974); *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143-44 (8th Cir. 2024). States pass regulations that impact the costs of doing business all the time. States pass safety regulations and registration and licensing schemes. States require fees for companies doing business. States tax. If every state regulation that incidentally impacted profit margins conflicted with federal patent law, state police powers would be eviscerated.

Here, there is no patent preemption because the UPL would regulate downstream transactions after Amgen's patent rights have been exhausted. Amgen does not dispute that it sells Enbrel to wholesalers, that those wholesalers sell Enbrel to pharmacies, and pharmacies in turn sell Enbrel to Colorado consumers. Amgen can sell Enbrel to a wholesaler

if it believes it will receive "satisfactory compensation" in the transaction. *See Impression Products*, 581 U.S. at 363, 380. As *Impression Products* makes clear, the moment Amgen chooses to sell its product to its wholesalers for the price wholesalers are willing to pay, the purposes of federal patent law have been fully achieved and Amgen has "no exclusionary right left to enforce." 581 U.S. at 375. Colorado's law would regulate transactions at the pharmacy level, after Amgen's patentee's rights have exhausted, after the Patent Act's objectives have been achieved, and after Enbrel has traveled through several links in the chain of commerce. Amgen cannot sell Enbrel to wholesalers and then claim the Patent Act prohibits state regulation of the pharmacy's subsequent purchase because that regulation may indirectly interfere with Amgen's business model. There is simply no conflict between patent law and Colorado's law because the law is an exercise of the state's police power in an area where Amgen's patent rights do not apply.

Amgen relies on *BIO*, 496 F.3d 1362, for the argument that Colorado seeks to regulate a manufacturer's sale and so Colorado's law is preempted. But Colorado's law is distinguishable from the D.C. law struck down in *BIO* in two key ways.

First, and most importantly, the D.C. law in *BIO* directly prohibited a manufacturer from charging an excessive price. *Id.* at 1365. This Court found this direct prohibition significantly and directly interfered with the manufacturer's rights to secure above-market profits on its products and so was preempted. But a UPL is a *downstream* regulation that does not apply to a wholesaler's purchase from a manufacturer. Because Amgen's patent rights are exhausted before the UPL would apply, *BIO*'s reasoning is inapposite.

Second, *BIO* stated that critical to its analysis was that the D.C. law was not general, but rather exclusively regulated patented products. 496 F.3d at 1373-74. But the Board's work applies to patented and generic drugs alike. Colo. Rev. Stat. § 10-16-1406(1) (2025).

Regardless, *BIO* is also not unlimited in application. Reading *BIO* and *Impression Products* together, courts have left open the door for a law just like Colorado's that could incidentally impact a patentee's profits: a law enacted under the state's police powers to regulate downstream purchases after a manufacturer's rights have been exhausted. *Biotechnology Indus. Org. v. D.C.*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Gajarsa, J., concurring in denial of reh'g en banc) ("Whether

future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day."). Colorado's law is not aimed at upending patent rights but at protecting consumers by rebalancing bargaining power downstream, after a patentee's rights have been exhausted. It is exactly the type of law that does not significantly or directly interfere with the ability to make a profit and so does not stand as an obstacle to federal patent law.[11]

c. Amgen waived its field preemption argument, and, in any event, field preemption is inapplicable here.

In the district court, Amgen asserted that Colorado's law was preempted under the doctrine of conflict preemption. Appx1192-96, Appx1411-12. But Amgen now tries to argue, for the first time on appeal, that state efforts to regulate downstream costs of patented drugs are preempted by federal patent law under not only conflict preemption, but also the doctrine of field preemption. Despite every opportunity to assert

[11] And states have leveraged their police powers to pass laws in this space for decades. Healthcare regulations do not stand in conflict with federal patent law. *See supra Section III.c.*

field preemption at the district court, Amgen did not raise this argument below and so it is waived. *Stauffer v. Brooks Bros. Grp.,* 758 F.3d 1314, 1322 (Fed. Cir. 2014) ("Issues not properly raised before the district court are waived on appeal.").

Field preemption also does not apply here. Amgen asserts that Colorado's law "invades the preempted field of federal patent policy" and that state efforts to regulate the price of patented drugs implicate this field preemption. Op. Br. at 24, 28. But Amgen cannot circumvent the requirements of field preemption by simply narrowly defining the "field" at issue. Colorado does not dispute that federal law controls certain questions relating to patented prescription drugs. But federal laws concerning patented prescription drugs and transactions by the patent holder do not displace decades of state police power regulation to protect the health and welfare of their consumers.

There is a presumption against federal preemption of state statutes designed to foster public health. *Pharm. Rsch. and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003). And under field preemption, the "framework of regulation [must be] 'so pervasive ... that Congress left no room for the States to supplement it'" or where there is a "federal interest ... so

dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citations omitted).

But states have long been the default regulator of healthcare and, in the case of insurance, Congress has expressly *protected* state regulation through the McCarran-Ferguson Act. 15 U.S.C. § 1012(b) ("No Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance … unless such Act specifically relates to the business of insurance"); *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) (finding a federal law was silent as to intent to regulate the practice of medicine generally given "the structure and limitations of federalism, which allow the States "'great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.'") (citations omitted).

States have used their authority to attempt to rein in prescription drug costs for their residents for decades. *See Rutledge*, 592 U.S. at 84-85 (upholding state law regulating reimbursement rates between pharmacies and pharmacy benefit managers as applied to ERISA plans);

Walsh, 538 U.S. at 661-66 (upholding a state prescription drug rebate and prior authorization program as not preempted by federal Medicaid laws); *c.f. Mulready*, 78 F.4th at 1209 (holding that Oklahoma's regulations of pharmacy benefit managers was preempted as applied to ERISA and Medicare Part D plans, but leaving in place application to PBMs acting pursuant to state-regulated insurance plans). These state laws are not crowded out by federal patent law, nor do they stand in conflict with it. "It is universally recognized that the state has authority under the police power for the protection of the public health and welfare to regulate the practice of pharmacy and the sale of drugs." *Moore*, 518 P.2d at 952; *see also McClain*, 95 F.4th at 1143-44. Consistent with this authority, states, like Colorado, routinely regulate the prices that pharmacies and payers can charge consumers for prescription drugs.[12]

[12] *See, e.g.*, Colo. Rev. Stat. §§ 10-16-151 and 12-280-139 (2025) (payment and cost-sharing caps on insulin); Colo. Rev. Stat. §§ 10-16-160 (2025) (payment and cost-sharing caps on epinephrine auto-injectors); Colo. Rev. Stat. § 10-16-104(18.1) (2025) (requiring insurance plans/payers to provide coverage for total cost of contraception); Colo. Rev. Stat. § 10-16-104(18) (2025) (requiring insurance plans/payers to provide coverage for total cost of preventative health services, including certain vaccinations and HIV prevention drugs).

The Affordability Program is a straightforward exercise of these police powers.

Colorado's Affordability Program is not preempted under conflict or field preemption. The Affordability Program is designed to protect the health, safety, and welfare of Coloradans by reducing excessive prescription drug costs for Coloradans. *See* SB21-175. Excessive drug costs are a life-or-death issue that extract a real human and economic toll. Enshrined nowhere in federal patent law is a principle that a state may not regulate downstream transactions for the health and welfare of its citizens after a patent holder has sold its product. In fact, the opposite is clear: once Amgen sells its patented product, its rights and benefits under the federal patent law system are exhausted.

CONCLUSION

At the time Amgen filed its complaint, Amgen's purported injury from a UPL was speculative and indirect. Even if the Board were to set a UPL on Enbrel, the district court's order makes clear that Amgen is not a downstream actor, cannot rely on "basic economics and common sense" to explain its role in the supply chain, and cannot use wholesalers' hypothetical business decisions to manifest its own injury. No facts or

arguments raised by Amgen in this appeal alter these findings. Amgen remains an unregulated party uninjured by a downstream UPL, whether or not one is set. This Court should affirm the lower court's decision and uphold the dismissal of Amgen's complaint without prejudice.

Dated: August 22, 2025

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32 and Federal Circuit Rule 32, I certify that this brief:

(i) complies with the type-volume limitation of Federal Circuit Rule 32(b)(1) because it contains 11,565 words, including footnotes and excluding the parts of the brief exempted by Federal Circuit Rule 32(b)(2) and Federal Rule of Appellate Procedure 32(f); and

(ii) complies with the typeface and style requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6) because this document has been prepared using Microsoft Office Word and is set in 14-point Century Schoolbook font.

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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 MARKETED 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 HEATH 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) "WHOLESALER" 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 RENDERS 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 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 9:36 am
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

West's Colorado Revised Statutes Annotated
Title 10. Insurance
Health-Care Coverage
Article 16. Health-Care Coverage (Refs & Annos)
Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1401

§ 10-16-1401. Definitions

Currentness

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.

(7.5) “Board activity” means:

(a) Selecting prescription drugs for an affordability review pursuant to section 10-16-1406(2);

(b) Determining whether a prescription drug is unaffordable pursuant to section 10-16-1406(3);

(c) Selecting prescription drugs for which the board establishes an upper payment limit pursuant to section 10-16-1407; and

(d) Establishing an upper payment limit for a prescription drug pursuant to section 10-16-1407.

(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 marketed 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.

<Text of (15)(a) effective until January 1, 2026>

(15)(a) “Large employer” means any person, firm, corporation, partnership, or association that:

<Text of (15)(a) effective January 1, 2026>

(15)(a) “Large employer” means any person that:

(I) Is actively engaged in business;

<Text of (15)(a)(II) effective until January 1, 2026>

(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

<Text of (15)(a)(II) effective January 1, 2026>

(II) Employed an average of more than fifty 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 heath 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) “Wholesaler” has the meaning set forth in section 12-280-103(55).

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021. Amended by Laws 2023, Ch. 162 (H.B. 23-1225), § 1, eff. Aug. 7, 2023; Laws 2024, Ch. 146 (S.B. 24-073), § 4, eff. Jan. 1, 2026.

C. R. S. A. § 10-16-1401, CO ST § 10-16-1401

Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

End of Document

C.R.S.A. § 10-16-1402

§ 10-16-1402. Colorado prescription drug affordability review board--created--membership--terms--conflicts of interest

Currentness

(1) The Colorado prescription drug affordability review board is created in the division. The board is a **type 1** entity, as defined in section 24-1-105. The board exercises its powers and performs its duties and functions under the department of regulatory agencies and is allocated to the division of insurance. 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 renders 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)(I) Board members shall recuse themselves from any board activity or vote in any case in which they have a conflict of interest.

(II) Staff members and contractors of the division, on behalf of the board, shall disclose any conflict of interest related to a prescription drug for which the board is conducting an affordability review or establishing an upper payment limit.

(III) Notwithstanding subsection (3)(d) of this section and the reporting requirements set forth in section 10-16-1414(1)(f), a conflict of interest disclosed by a staff member or by a contractor of the division, which disclosure pertains to a personal association, must remain confidential. The board, upon review of such a disclosure, may direct the staff member or contractor to recuse themselves based on the 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.

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021. Amended by Laws 2022, Ch. 469 (S.B. 22-162), § 102, eff. Aug. 10, 2022; Laws 2023, Ch. 162 (H.B. 23-1225), § 2, eff. Aug. 7, 2023.

C. R. S. A. § 10-16-1402, CO ST § 10-16-1402

Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

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West's Colorado Revised Statutes Annotated
Title 10. Insurance
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Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1403

§ 10-16-1403. Colorado prescription drug affordability review board--powers and duties--rules

Currentness

(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.

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021.

C. R. S. A. § 10-16-1403, CO ST § 10-16-1403

Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

End of Document

C.R.S.A. § 10-16-1406

§ 10-16-1406. Colorado prescription drug affordability review board--affordability reviews of prescription drugs--repeal

Currentness

(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:

(a) Any prescription drug that has:

(I) A wholesale acquisition cost of three thousand dollars or more;

(I.5) An increase of three hundred dollars or more above the wholesale acquisition cost for the prescription drug in the preceding twelve months;

(II) An increase of two hundred percent or more above the wholesale acquisition cost for the prescription drug in the preceding twelve months; or

(III) A current wholesale acquisition cost for an average course of treatment per person per year of thirty thousand dollars or more; and

(b) Any biosimilar drug that has an initial wholesale acquisition cost that is not at least fifteen percent lower than the wholesale acquisition cost of the corresponding biological product.

(c) Repealed by Laws 2023, Ch. 162 (H.B. 23-1225), § 4, eff. Jan. 1, 2025.

(1.1) Subsection (1)(c) and this subsection (1.1) are repealed, effective January 1, 2025.

(2) After identifying prescription drugs as described in subsection (1) of this section, the board shall determine whether to conduct an affordability review for an 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;

(d) Considering the average patient's out-of-pocket cost for the prescription drug; and

(e) Considering whether the drug has an approved orphan drug designation for one or more rare diseases and no other indications and, if so, considering input from consumers and the Colorado rare disease advisory council created in section 25-1-1503.

(3) If the board conducts an affordability review of a prescription drug, the affordability review must determine whether use of the prescription drug 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;

(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; and

(III) The Colorado rare disease advisory council created in section 25-1-1503;

(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.

(8) The board shall issue a report summarizing, to the extent permitted by section 10-16-1404(3), the data that the board considered in making the board's determination as to whether a prescription drug is unaffordable. The board shall make the report available on its public web page.

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021. Amended by Laws 2023, Ch. 162 (H.B. 23-1225), § 4, eff. Jan. 1, 2025; Laws 2024, Ch. 454 (S.B. 24-203), § 1, eff. Aug. 7, 2024.

C. R. S. A. § 10-16-1406, CO ST § 10-16-1406

Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

End of Document

West's Colorado Revised Statutes Annotated
Title 10. Insurance
Health-Care Coverage
Article 16. Health-Care Coverage (Refs & Annos)
Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1407

§ 10-16-1407. Colorado prescription drug affordability review board--upper payment limits for certain prescription drugs--rules--severability

Currentness

(1)(a) 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:

(I) 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, unless the board determines that there is a need to establish upper payment limits for more than twelve prescription drugs, in which case the board may establish an upper payment limit for up to eighteen prescription drugs so long as the board has sufficient staff support to do so; and

(II) For each prescription drug for which the board establishes an upper payment limit, the board may include multiple national drug codes, as described in 21 CFR 207.33, that are indicated for the prescription drug.

(b) 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 a 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 upper payment limits and 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.

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021. Amended by Laws 2023, Ch. 162 (H.B. 23-1225), § 5, eff. Aug. 7, 2023.

C. R. S. A. § 10-16-1407, CO ST § 10-16-1407

Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

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West's Colorado Revised Statutes Annotated
Title 10. Insurance
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Article 16. Health-Care Coverage (Refs & Annos)
Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1408

§ 10-16-1408. Colorado prescription drug affordability review board--judicial review

Currentness

(1) The following board functions are not final agency actions subject to judicial review under the "State Administrative Procedure Act", article 4 of title 24:

(a) Identification of eligible prescription drugs pursuant to section 10-16-1406(1);

(b) Selection of a prescription drug pursuant to section 10-16-1406(2); and

(c) Determination that a prescription drug is unaffordable pursuant to section 10-16-1406(3).

(2) A rule of the board establishing an upper payment limit is a final agency action subject to judicial review under the "State Administrative Procedure Act", article 4 of title 24. A party seeking judicial review of a rule establishing an upper payment limit may seek review of whether the prescription drug satisfies the necessary criteria in section 10-16-1406 to be eligible for an upper payment limit.

(3) Repealed by Laws 2023, Ch. 162 (H.B. 23-1225), § 6, eff. Aug. 7, 2023.

(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.

Credits

Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021. Amended by Laws 2023, Ch. 162 (H.B. 23-1225), § 6, eff. Aug. 7, 2023.

C. R. S. A. § 10-16-1408, CO ST § 10-16-1408
Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

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West's Colorado Revised Statutes Annotated
Title 10. Insurance
Health-Care Coverage
Article 16. Health-Care Coverage (Refs & Annos)
Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1411

§ 10-16-1411. Unlawful acts--enforcement--penalties

Currentness

(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.

Credits
Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021.

C. R. S. A. § 10-16-1411, CO ST § 10-16-1411
Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

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Title 10. Insurance
Health-Care Coverage
Article 16. Health-Care Coverage (Refs & Annos)
Part 14. Colorado Prescription Drug Affordability Review Board

C.R.S.A. § 10-16-1412

§ 10-16-1412. Notice of withdrawal of prescription drugs with upper payment limits required--rules--penalty

Currentness

(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.

Credits
Added by Laws 2021, Ch. 240 (S.B. 21-175), § 2, eff. June 16, 2021.

C. R. S. A. § 10-16-1412, CO ST § 10-16-1412
Current through legislation effective August 6, 2025 of the First Regular Session, 75th General Assembly (2025). Some statute sections may be more current. See credits for details.

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West's Colorado Administrative Code
Title 700. Department of Regulatory Agencies
702. Division of Insurance
3 CCR 702-9. Prescription Drug Affordability Board
Part 4. Upper Payment Limits

3 CCR 702-9:4.1
Alternatively cited as 3 CO ADC 702-9

702-9:4.1. Upper Payment Limit Methodology

Currentness

A. Authority

The statutory authority for this part 4.1 is sections 10-16-1407, 10-16-1412(2), and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 4.1 is to establish the methodology required pursuant to section 10-16-1407, C.R.S., for the Board to establish upper payment limits for prescription drugs it has determined to be unaffordable pursuant to section 10-16-1406, C.R.S., and part 3 of these rules.

C. Methodology to Establish Upper Payment Limits

1. Number of Upper Payment Limits on Prescription Drugs: 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, C.R.S., and part 3 of the Board's rules and determined that the use of the prescription drug is unaffordable for Colorado consumers.

a. The Board may not establish more than twelve upper payment limits each calendar year from 2022 through 2024. If the Board finds a need to establish upper payment limits for more than twelve prescription drugs in the 2023 and 2024 calendar years, the Board may establish an additional six upper payment limits during that calendar year.

b. Beginning in 2025, the Board may establish any number of upper payment limits.

2. Upper Payment Limit Methodology: In establishing an upper payment limit, the Board shall review the following factors to determine an upper payment limit for a prescription drug, in accordance with section 10-16-1407(2)-(4), C.R.S.

a. Prescription Drug Costs: To approximate prescription drug costs, the Board may consider one or more price and cost metrics as an estimation of the cost of administering or dispensing the prescription drug, the cost of distributing the prescription drug, and other relevant costs. Price and cost metrics include but are not limited to:

i. Wholesale Acquisition Cost,

ii. Average Sales Price,

iii. National Average Drug Acquisition Cost as reported by the Center for Medicare and Medicaid Services,

iv. Out-of-pocket amounts,

v. Carrier paid amounts,

vi. Retail discount amounts,

vii. Public health care program fee schedules,

viii. Estimates of manufacturer net-cost and net-sales amounts,

ix. Medicare's Maximum Fair Price, and

x. Cost information voluntarily provided by a wholesaler, pharmacist, or provider.

b. Drug Shortage List: The Board will consider the status of the prescription drug on the Drug Shortage List published by the Drug Shortage Program within the Food and Drug Administration and the American Society of Health System Pharmacists. The Board's consideration may include:

i. Whether the prescription drug is listed on the Drug Shortage List on the day the Board adopts an upper payment limit for the prescription drug, as well as whether the prescription drug is subject to a resolved or discontinued shortage.

ii. If the prescription drug is listed on the Drug Shortage List, the Board may consider:

(1) Availability and estimated shortage duration,

(2) Shortage reason,

(3) Therapeutic classification, and

(4) Other related information.

c. Impact to Older Adults and Persons with Disabilities: The upper payment limit methodology must consider 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.

i. Impact to Older Adults - the Board will consider the following metrics for individuals 65 years and older: to the extent such information is readily available in the APCD:

(1) 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

(2) 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.

ii. Impact to Persons with Disabilities: The Board will consider the following metrics for persons with disabilities:

(1) Therapeutic classification of the prescription drug, including the prescription drug's therapeutic purpose and any conditions or diseases the prescription drug may treat,

(2) To the extent it is known that any conditions or diseases the prescription drug may treat are considered disabilities, or to the extent it is known the drug treats a condition or disease causes 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

(3) 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.

d. Reasonable Pharmacy Fees: 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.

e. Research and Methods that Employ a Dollars-Per-Quality Adjusted Life Year (QALY): 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.

f. 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.

D. Process for Establishing Upper Payment Limits

1. Process: The Board will establish upper payment limits through rulemaking, as required by section 10-16-1406(1)(a)(II), C.R.S., and in compliance with section 24-4-103, C.R.S. The Board will select drugs for which to establish an upper payment limit and initiate a rulemaking for a rule establishing an upper payment limit for the prescription drug. An upper payment limit may apply to multiple NDCs that are indicated for the prescription drug.

a. If the Board has determined a prescription drug to be unaffordable pursuant to section 10-16-1406, C.R.S, the Board may choose to establish an upper payment limit for that prescription drug. The Board will select drugs for which to establish an upper payment limit and initiate a rulemaking for a rule establishing an upper payment limit for the prescription drug.

b. The Board may terminate a rulemaking to establish a specific upper payment limit for a prescription drug.

2. Consumer Notice: The Board's initiation of a public rulemaking pursuant to section 24-4-103, C.R.S., shall constitute notification to consumers of the Board's decision to establish an upper payment limit as required by section 10-16-1407(6), C.R.S.

3. Effective Date: rules establishing upper payment limits promulgated by the Board will identify an effective date for the upper payment limit as required by section 10-16-1407(5), C.R.S.

4. Unit: The Board will identify the unit to which the upper payment limit applies for the prescription drug.

E. 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:

(1) Whether the manufacturer is able to make the prescription drug available for sale in the State of Colorado, and

(2) 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.

F. Confidentiality

A person submitting information for the Board's consideration pursuant to this part 4 shall clearly designate the specific information it deems to be confidential, trade secret or proprietary. The Board may also determine that information submitted to it is confidential, trade secret, or proprietary. The Board will not disclose confidential, trade-secret, or proprietary information in an open meeting or its public meeting materials. The Board may seek additional information regarding whether the information is confidential, trade-secret, or proprietary from the person submitting the information or, to the extent the Board is able to determine who created the document or information, the person who created the document or information. To the extent the information submitted to the Board contains confidential information, the Board will consider such information in executive session and will not disclose the information publicly pursuant to sections 10-16-1404(3), and 10-16-1407(7), C.R.S.

Credits
Adopted March 17, 2023. Amended Nov. 14, 2023.

Current through CR, Vol. 48, No. 12, June 25, 2025. Some sections may be more current, see credits for details.

3 CCR 702-9:4.1, 3 CO ADC 702-9:4.1

West's Colorado Administrative Code
Title 700. Department of Regulatory Agencies
702. Division of Insurance
3 CCR 702-9. Prescription Drug Affordability Board
Part 4. Upper Payment Limits

3 CCR 702-9:4.2
Alternatively cited as 3 CO ADC 702-9

702-9:4.2. Upper Payment Limit Methodology

Currentness

A. Authority

The statutory authority for this part 4.2 is sections 10-16-1407 and 10-16-1403(5), C.R.S.

B. Scope and Purpose

The purpose of this part 4.2 is to establish the applicability of all upper payment limits for prescription drugs set by the Board pursuant to section 10-16-1407, C.R.S. and part 4.1 of these rules.

C. Applicability of Upper Payment Limits

1. An upper payment limit established by the Board, plus any reasonable fees charged by the pharmacy or pharmacist for dispensing or delivering a prescription drug, applies to a consumer's purchase from 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. If the Colorado consumer is insured, the consumer's portion of the payment together with the reimbursement to the pharmacy 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.

2. An upper payment limit established by the Board also applies to any pharmacy (as defined by section 12-280-103(43), C.R.S.) or provider's purchase of a prescription drug that is dispensed or administered to a Colorado consumer in person, by mail, or by other means.

Credits
Adopted March 17, 2023.

Current through CR, Vol. 48, No. 12, June 25, 2025. Some sections may be more current, see credits for details.

3 CCR 702-9:4.2, 3 CO ADC 702-9:4.2

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