UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

States may not interfere with the incentive structure of the federal patent system by regulating the price of patented drugs. *Biotech. Indus. Org. v. District of Columbia* (*BIO I*), 496 F.3d 1362 (Fed. Cir. 2007). And where price regulation is permitted, a price-control scheme must include ascertainable standards to limit regulators' discretion. As Amgen's motion demonstrated, Colorado flouted these rules when it capped the price of Amgen's patented drug Enbrel at a level that is 72% below Amgen's current price.

In response, Defendants claim to have found a loophole. They say a state can regulate Amgen's prices "indirectly," Opp. 24, by imposing whatever price it wants on "downstream" sales of Enbrel—even if doing so will limit what Amgen can charge just as surely as if the price cap applied directly to Amgen's own sales. That is wrong. A state "cannot do indirectly what [it] is barred from doing directly." *Nat'l Rifle Ass'n v. Vullo* (*NRA*), 602 U.S. 175, 190 (2024). Each preliminary-injunction factor favors granting relief.

First, Amgen has standing and will suffer irreparable harm from the price cap. Defendants condemn Amgen for seeking "to earn the highest possible profits" from Enbrel, Opp. 36, then turn around and claim the UPL will not affect Amgen's profits. But the discovery Defendants insisted on confirmed what was always clear from common sense and basic economics: Wholesalers will not buy Enbrel for more than they can lawfully sell it for. So the UPL will cost Amgen more than [redacted] per

year in lost revenue from sales to wholesalers, as well as force it to incur [redacted] compliance costs ahead of the UPL's effective date. Defendants respond by claiming the UPL is similar to prices Amgen charges in other contexts, which is both factually incorrect and irrelevant.

Second, Amgen is likely to succeed on its patent-preemption and due-process claims. As to patent preemption, Defendants argue that despite binding precedent prohibiting states from limiting the price of patented drugs "directly," states are free to drastically limit those prices so long as they do so "indirectly." Opp. 24, 27. "The Constitution does not tolerate such ready evasion." *Trump v. Mazars USA, LLP*, 591 U.S. 848, 868 (2020). Accepting Defendants' argument would nullify the Federal Circuit's *BIO I* decision and upend the system Congress created to encourage and reward innovation. As to due process, the Supreme Court has long recognized that price-control schemes impair manufacturers' property rights, and Defendants do not identify any statutory standards that meaningfully constrained the Board's decisionmaking or ensured a fair return on investment.

Third, Defendants have no response to binding precedent establishing that the equities and the public interest favor enjoining unconstitutional laws. The Court should therefore grant Amgen's motion and enjoin enforcement of the UPL.

ARGUMENT

I. Amgen's injuries from the UPL demonstrate both standing and irreparable harm.

Defendants make the extraordinary claim that a price cap on Amgen's patented drug that is 72% below Amgen's current price will somehow not injure Amgen. The harm to Amgen is obvious as a matter of common sense and basic economics, and discovery conclusively confirmed it.

A. Defendants do not dispute that the UPL will function as a cap on Amgen's prices.

Defendants do not dispute that Amgen is an "object" of the UPL, which is aimed squarely and exclusively at Amgen's patented drug. That leaves "little question" that Amgen has standing. *Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 112, 114–16 (2025) ("[W]hen a regulation targets the provider of a product … by limiting another entity's use of that product," the provider is likely "an object of the … regulation[.]"); *accord Mirabelli v. Bonta*, 146 S. Ct. 797, 803 (2026) (parents "very likely" had standing to challenge regulation not directly applicable to them because they were "objects" of the regulation); Mot. 18–19.

Even if the Court does not treat Amgen as a formal object of the regulation, Defendants do not dispute that the Enbrel UPL will operate as a cap on what Amgen can charge for Enbrel, because Amgen cannot sell Enbrel to wholesalers for more than the wholesalers can sell the drug for downstream. As Amgen explained, Mot. 19–24, this is obvious as a matter of "commonsense economic inferences" that

courts are encouraged to draw. *Diamond*, 606 U.S. at 120; *accord First Choice Women's Res. Ctrs., Inc. v. Davenport*, 2026 WL 1153029, at *8 (U.S. Apr. 29, 2026) ("[C]ourts may make 'commonsense inferences' … about 'third party behavior.'"). Amgen also submitted with its motion declarations from Amgen and its three largest wholesalers establishing that if wholesalers must sell Enbrel at the UPL, they will not buy it from Amgen for more than the UPL unless Amgen provides a chargeback to make up the difference. ECFs 19–22.

Defendants demanded discovery to test these obvious points, and discovery confirmed them. Amgen's contracts show that whenever a wholesaler is required to sell Enbrel to a downstream customer for less than WAC, including due to a statutory price cap, Amgen must provide a chargeback to reimburse the wholesaler for the difference between WAC and the downstream price. Ex. 3 §§ 1.15, 7.2 & Ex. A; Ex. 15 §§ 1.15, 6.2 & Ex. A; Ex. 16 §§ 1.17, 6.2 & Ex. A; Ex. 29 ("Amgen Dep.") at 50:21–53:22. Defendants also deposed a wholesaler, McKesson, which confirmed that if the UPL applies downstream, McKesson will not buy Enbrel from Amgen at WAC unless Amgen provides a chargeback. Ex. 30 at 44:4–9, 54:5–9, 54:22–55:13. [redacted] Ex. 57 ("Mizner Dep.") at 85:16–22.

In their opposition, Defendants do not deny that the UPL will function as a cap on Amgen's prices. On the contrary, they concede that when wholesalers must "sell

to downstream customers for less than WAC," the wholesalers "typically receive 'chargeback' payments" from the manufacturer to "make up the difference between what the wholesaler paid the manufacturer … and what the downstream customer paid the wholesaler." Opp. 2. And they do not argue that Amgen can sell Enbrel to wholesalers at WAC if the wholesalers must sell to downstream customers at the UPL. Nor do Defendants deny that this is exactly how the UPL was intended to operate. When it enacted the UPL legislation, Colorado well understood that if wholesalers were required to sell a drug at the UPL, they would need to "be made whole … by the pharmaceutical manufacturer." S.B. 21-175 Hr'g at 7:22:00–7:23:30 (statement of Rep. Kennedy).

B. The UPL will cause Amgen severe financial harm when it takes effect on January 1, 2027.

Given these now-undisputed economic realities, it is clear the UPL will cause Amgen serious financial harm. Amgen estimates the UPL will cost it more than [redacted] per year in increased chargeback payments to wholesalers. Amgen Dep. 164:3–15. These fiscal injuries are more than sufficient to establish standing and irreparable harm. *Cf. Chamber of Com. v. Edmondson*, 594 F.3d 742, 756, 771 (10th Cir. 2010) (unrecoverable costs of "more than a thousand dollars per business per year" established standing and irreparable harm).

Defendants devote only two paragraphs to this harm, Opp. 17–18, advancing two arguments that both lack merit. These arguments have nothing to do with the UPL's "downstream" application; Defendants could make the same arguments even

if the UPL applied directly to Amgen's sales.

1. Defendants first compare the UPL to Enbrel's "average net unit price," its "best price," and the federal MFP for Enbrel to contend that Amgen "overstate[s]" its harms from being forced to sell Enbrel to wholesalers for 72% below WAC (either as an initial price or as a net price after chargebacks). Opp. 17. These comparisons are highly misleading.

"Average net unit price" is not a standard pricing metric, but a figure invented by CMS "[f]or the sole purpose of data collection under" the Inflation Reduction Act. Ex. 27 at 196. As Defendants acknowledge (at 4), this figure reflects not what Amgen charges for Enbrel but what it retains *after* providing patient assistance and paying numerous contractual fees, rebates, and discounts. *Id.*; Amgen Dep. 115:12–116:6. These fees, rebates, and discounts are business expenses that Amgen has contracted to pay because it receives value in return, and if the UPL is implemented, Amgen will have to either continue paying them or risk losing the value they provide. These expenses include, among other things: fees and discounts Amgen provides to wholesalers as compensation for their distribution services and to encourage prompt payment, Amgen Dep. 26:14–27:9, 31:16–32:9; discounts Amgen provides to certain large customers "in exchange for preferred placement in their organizations" and other services, *id.* at 40:21–41:5; and fees and rebates Amgen provides to PBMs in exchange for access to and preferred placement on the PBMs' formularies and other services, *id.* at 34:15–36:1, 170:23–171:10, 176:6–177:9. Thus, Amgen's realized "net

unit price" for affected sales under the UPL will not be $600; it will be $600 minus the expenses Amgen must continue to pay.

To the extent Defendants contend that Amgen could theoretically mitigate its UPL-related losses by terminating its patient-assistance programs, modifying its existing contracts, and reducing the fees, rebates, and discounts it pays to promote sales of Enbrel, that argument is not relevant to standing or irreparable harm. Defendants' argument is akin to claiming that a business is not injured by a revenue-reducing regulation so long as it can make up the losses by canceling its advertising or eliminating its sales force. Defendants cite no case suggesting that irreparable harm requires auditing a plaintiff's business to determine whether it can offset the harm by cutting costs elsewhere. When the Tenth Circuit held in *Edmondson* that regulatory compliance costs of "more than a thousand dollars" established irreparable harm, 594 F.3d at 756, it did not ask whether the plaintiffs could recover that money by reducing other expenses. Nor did the Federal Circuit conduct any such inquiry in *BIO I*.

In any event, Defendants make no argument and cite no evidence suggesting Amgen can reduce these expenses without adverse consequences. The IRA, which authorized the federal government to cap drug prices for sales covered by Medicare, addressed one aspect of this problem by requiring health plans to cover a price-limited drug even if manufacturers stop paying rebates. 42 U.S.C. § 1395w-104(b)(3)(I). But Colorado's law does not provide any similar coverage guarantee, and Defendants have

no theory as to why PBMs would provide the same coverage benefits for free if Amgen stopped paying for them. Nor do Defendants contend that the UPL will allow Amgen to stop paying for other services, such as distribution services provided by wholesalers. And Defendants expect Amgen to continue funding patient-assistance programs, acknowledging that patients will "have to continue to rely on" those programs to access Enbrel notwithstanding the UPL. ECF 1-9 at 74:22–76:7; *see* ECF 1-8 at 63:7–64:15; Ex. 54 at 1–2.

Moreover, Defendants make a basic mathematical error. As Defendants recognize, the figure they cite is an average, meaning some sales are above it and some are below. Opp. 17. The UPL, by contrast, is a price ceiling (but not a floor) that applies to every individual sale within its reach. So even if it were appropriate to compare the UPL to the "net unit price"—which it is not—the UPL would eliminate all sales at above-average prices without affecting sales at below-average prices, bringing down the average dramatically. The Court should disregard Defendants' misguided analogy between the UPL and the "average net unit price."

Defendants' attempts to minimize Amgen's injuries by comparing the UPL to Amgen's "best price" and the federal MFP, Opp. 17, are equally illogical. The "best price" can be set by a single sale and is therefore not a valid point of comparison for a market-wide price cap. Amgen Dep. 117:4–23; 42 U.S.C. § 1396r-8(c)(1)(C). And there is no question the MFP has caused Amgen financial harm. Amgen Dep. 167:4–168:9; Ex. 14 at 12, 31, 62. Contrary to Defendants' characterization, Amgen did not

"voluntarily agree[]" to the MFP, Opp. 17, and has supported PhRMA's lawsuit challenging the MFP as coercive and unlawful. Mot. 15 n.6. Regardless, whether Amgen agreed to the MFP for Medicare sales has no bearing on whether Amgen is harmed by a price cap on non-Medicare sales.

2. Defendants contend that Amgen overestimates its losses from the UPL because the UPL does not automatically apply to self-funded health plans regulated by ERISA. Opp. 8, 18. This is wrong for several reasons.

As Defendants recognize, ERISA plans can "opt in" to be covered by the UPL. Opp. 8; *see* Colo. Rev. Stat. §§ 10-16-1407(8), -1413 (ERISA plans can "elect[] to subject [their] purchases of … prescription drugs in Colorado to the requirements of" the UPL). The Court can assume ERISA plan sponsors will be "guided by basic economic rationality," *Nat'l Infusion Ctr. Ass'n v. Becerra*, 116 F.4th 488, 500 (5th Cir. 2024), and will thus opt in to the UPL if doing so would result in the plan paying less for Enbrel.

In any event, whether an ERISA plan formally opts in will make little practical difference. Either way, the UPL will apply to a pharmacy's purchase of Enbrel from a wholesaler, which will require Amgen to pay the wholesaler a chargeback. If the pharmacy subsequently provides Enbrel to an ERISA plan member, the pharmacy will presumably bill the plan only for the amount the pharmacy itself paid for the drug. *See* Ex. 102 at 35 ("Because providers and suppliers buy and bill at no more than the UPL, ERISA plans … will be billed at the UPL, like all other insurers/payers

in the State."). And if the pharmacy bills the plan at a higher price, that might represent a windfall for the pharmacy, but it would do nothing to mitigate Amgen's losses.

What is more, even if no ERISA plans opted in to the UPL *and* their decision not to opt in somehow alleviated Amgen's UPL-related losses for those sales, Amgen would still face substantial, irreparable harm from the nearly half of the commercial insurance market that is not self-funded ERISA plans. *See* U.S. Census Bureau, Health Insurance Coverage in the United States: 2024, at 2–3 (Sept. 2025), *available at* https://www.census.gov/library/publications/2025/demo/p60-288.html (about 80% of private health insurance is employer-sponsored); Kaiser Fam. Found., 2025 Employer Health Benefits Survey 11 (Oct. 2025), *available at* https://www.kff.org/health-costs/2025-employer-health-benefits-survey/ (about two-thirds of employer-sponsored plans are self-funded).

C. Amgen will also be harmed before the UPL's effective date.

Discovery also confirmed that the UPL will impose significant costs on Amgen well before its effective date.

Amgen will have to spend [redacted] to modify its payment systems to account for the UPL. Mot. 35–36; Ex. 25 at 12; Amgen Dep. 138:1–146:23. Defendants do not dispute that Amgen will need to incur these costs over the next six months; they note only that the costs have not been incurred yet. Opp. 18. But the point of seeking a preliminary injunction is to avoid future harm, "not to remedy past harm."

Schrier v. Univ. of Colo., 427 F.3d 1253, 1267 (10th Cir. 2005). Amgen is reasonably trying to delay the most expensive and disruptive system changes for as long as possible while its motion is pending, but it cannot do so indefinitely.

Amgen will also have to spend [redacted] strategizing and negotiating with its contracting partners to address the UPL. Mot. 36–37; Ex. 25 at 8–9; Amgen Dep. 202:12–204:22. Defendants dismiss this harm because Amgen routinely negotiates with these entities about other issues. Opp. 19–20. [redacted] Amgen Dep. 130:21–22, 148:22–149:3. These negotiations will be anything but routine: They will concern a novel issue—how to implement the first-ever state UPL for a prescription drug—with major implications for the future of Amgen's business. Defendants provide no reason to doubt that Amgen will have to expend significant resources dealing with this important issue.

The UPL will also damage Amgen's goodwill and business relationships, including by encouraging customers outside Colorado to demand similar discounts. Mot. 37; Amgen Dep. 126:6–129:3. Defendants concede that [redacted] Opp. 20. Although they claim the UPL will not cause "additional harm or disruption," *id.*, there is every reason to expect that it will. Whereas the MFP applies only to Medicare sales, the UPL applies to private-market sales. It will therefore disrupt private-market business relationships and negotiations in a way that the price

demanded by Medicare does not.

D. Amgen's harm is irreparable.

The monetary injuries Amgen will suffer absent injunctive relief are irreparable because they "cannot later be recovered" in the form of damages due to "sovereign immunity." *Edmondson*, 594 F.3d at 770–71; *accord Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1251 (10th Cir. 2001). Amgen does not assert that there is a "presumption of irreparable harm" whenever a state official is sued. Opp. 21. Defendants' immunity from damages "does not, in itself, establish harm"—but when harm is demonstrated, as it is here, sovereign immunity does establish "irreparability" of that harm. *Kan. Health Care Ass'n v. Kan. Dep't of Soc. & Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994).

Defendants also assert that Amgen's harm is not irreparable because "[i]f Amgen believes it is entitled to compensation for a regulatory taking, it can attempt to seek those costs in Colorado state court." Opp. 21. That is a non sequitur. Amgen has never claimed it is entitled to compensation for a regulatory taking—a claim with distinct elements that Amgen has not pled and which Defendants do not contend would be viable here. Defendants' allusion to an entirely different claim not present in this case cannot defeat Amgen's showing of irreparable harm.

II. Amgen is likely to succeed on the merits of its claims.

A. Colorado's price cap is preempted.

1. Defendants do not dispute that under binding precedent, federal patent

law preempts state laws that "restrain" the price of patented drugs and thus "diminish[] the reward to patentees" by "limiting the full exercise of the exclusionary power that derives from a patent." *BIO I*, 496 F.3d at 1374. Instead, Defendants claim to have found a way around that precedent: Simply declare that a price cap applies only to "downstream" sales, and ignore the economic reality that the price cap will inevitably limit what the manufacturer can charge for its patented drug.

The Constitution "does not tolerate such ready evasion; it deals with substance, not shadows." *Mazars*, 591 U.S. at 868 (quotation marks omitted) (holding that constitutional concerns raised by Congress subpoenaing information about the President "are no less palpable here simply because the subpoenas were issued to third parties"). It has thus been "settled" for centuries that "a State cannot do that indirectly which she is forbidden by the Constitution to do directly." *Passenger Cases*, 48 U.S. 283, 458–59 (1849); *see NRA*, 602 U.S. at 190.

This principle applies with full force in the preemption context. Consider *Kansas ex rel. Todd v. United States*, 995 F.2d 1505 (10th Cir. 1993). Kansas, which was preempted from directly regulating federal crop insurance, sought to avoid preemption by regulating contracts "between a private insurance company and [an] agricultural producer" that were "reinsured by the [federal government] in another contract." *Id.* at 1510. The court rejected the state's attempt to regulate federal crop insurance "by the back door," explaining that "[w]hat Kansas cannot do directly, it is, in essence, trying to do indirectly." *Id.*

Here, similarly, Colorado's "downstream" UPL is "an indirect attempt to accomplish what the Constitution prohibits [it] from accomplishing directly." *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995). And as such attempts go, this one is remarkably unsubtle. Common sense and record evidence leave no doubt that the UPL was intended to and will function as a cap on Amgen's prices. It makes no difference whether the state achieves that result directly by regulating Amgen's sales or indirectly by regulating downstream sales; either way, the price control is both field- and conflict-preempted because it "diminish[es] the reward to patentees." *BIO I*, 496 F.3d at 1374.

2. Defendants' attempts to distinguish *BIO I* are unpersuasive. Defendants first assert that D.C.'s price-control law regulated manufacturers' prices "directly," whereas Colorado's law does so indirectly. Opp. 27. Even setting aside that states cannot evade preemption in this way, Colorado is mistaken: D.C.'s law applied only if the drug was ultimately "'sold in the District for an excessive price,'" and the Federal Circuit held that the law was preempted even though it "d[id] not directly regulate manufacturers' wholesale prices." 496 F.3d at 1371.

Defendants next assert that unlike the law in *BIO I*, the statute here "applies to branded and generic drugs alike" and "is not targeted at anyone's patent right." Opp. 27. But Amgen is not challenging the state's ability to set price caps for generic drugs; it is challenging the Enbrel UPL, which applies to one specific patented drug. In any event, Defendants do not respond to the extensive evidence that the Board

brazenly targeted patented drugs. Mot. 11–13, 28–29. Discovery made the targeting even clearer: [redacted] Mizner Dep. 127:12–132:2, 153:20–154:2; Ex. 106 at 1; Ex. 58 at PDAB1589.

Defendants can find no support in cases holding that patented products are subject to generally applicable state taxes and health-and-safety regulations. Opp. 24–25. Those general laws bear no resemblance to a price cap imposed on a specific patented drug because the state believes the prices enabled by the patent are too high. As *BIO I*'s author explained, "that states have broad leeway to regulate patented products does not mean that they have unlimited ability to do so in situations in which the regulation significantly and directly impedes Congress's purpose in providing the federal patent right." *Biotech. Indus. Org. v. District of Columbia (BIO II)*, 505 F.3d 1343, 1346 n.1 (Fed. Cir. 2007) (Gajarsa, J., concurring in denial of rehearing en banc).[1]

[1] Defendants fail to support their claim that states "routinely" regulate patented drug prices. Opp. 26 & n.11. Several of the cited laws merely require insurance plans to provide coverage or limit co-pays, which allocates financial responsibility between insurer and insured but does not impose a price cap. Defendants do not claim that Colorado's novel "affordability programs" for insulin and epinephrine have been or could lawfully be applied to patented products. And the law in *Rutledge v. Pharmaceutical Care Management Ass'n*, 592 U.S. 80 (2020), was the opposite of a price cap—it "require[d] PBMs to reimburse Arkansas pharmacies at a price equal to or higher than that which the pharmacy paid to buy the drug from a wholesaler." *Id.* at 84.

3. The patent-exhaustion doctrine does not entitle Colorado to cap the price of patented drugs indirectly when it cannot do so directly. Patent exhaustion means only that "[w]hen a patentee sells one of its products," it "can no longer control that item through the patent laws." *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 581 U.S. 360, 366 (2017). Amgen does not seek to "set or control" the price of Enbrel in downstream transactions, Opp. 24; it objects to the *state* dictating downstream prices and thus restricting Amgen's prices "by the back door." *Todd*, 995 F.2d at 1510. This case is not about Amgen using patent law to police downstream resale after receiving its reward; it is about the state-law interference with Amgen's first-sale reward caused by Colorado's regulation.

Impression Products confirms that Defendants' patent-exhaustion argument is a red herring. That case had nothing to do with preemption or state price controls. The Court held only that exhaustion principles prevented Lexmark from threatening a "patent infringement suit" to prevent other companies from refurbishing and reselling Lexmark's patented printer cartridges. 581 U.S. at 374. The Court did not suggest that exhaustion is a defense to preemption of state laws that undercut the rewards flowing to the patent owner.

Defendants seize on the Court's statement that "the Patent Act does not guarantee a particular price." Opp. 23, 28 (quoting 581 U.S. at 380). True enough—as the Federal Circuit has explained, "the dictates of the marketplace" ultimately determine what a manufacturer can charge for a patented drug. *BIO I*, 496 F.3d at

1372 (quotation marks omitted). But that does not mean states have free rein to force a below-market price. While the patent laws may not guarantee a particular price, together with the Supremacy Clause, they do ensure that the "determination about the proper balance between innovators' profit and consumer access to medication" is "exclusively one for Congress," not individual states. *Id.* at 1374.

B. Colorado's regime violates due process.

1. It is "'well-settled'" that Amgen's right "'to fix the price at which [it] will sell'" Enbrel is "'within the protection of' due process." Mot. 30–31 (quoting *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936)). Defendants' claim that manufacturers "do not have a protected property interest in selling their products at any particular price," Opp. 31, cannot be squared with decades of precedent applying due process to price-control schemes. Defendants' cases hold only that a manufacturer has no due-process interest in "what the government is willing to pay" for a drug under Medicare. *AstraZeneca Pharms. LP v. Sec'y HHS*, 137 F.4th 116, 126 (3d Cir. 2025). Those cases do not suggest a state can enforce a price cap for *private* sales without implicating due process.

Defendants insist they can circumvent Amgen's due-process rights by applying the UPL "downstream" from Amgen's own sales. Opp. 31. But it strains credulity to argue that a price cap on *Amgen's* drug does not implicate *Amgen's* rights. The right recognized by *Old Dearborn* and other cases would be hollow if a state could strip it without due process simply by moving price controls one step down the supply chain

and thus "do indirectly what [it] is barred from doing directly." *NRA*, 602 U.S. at 190. Due process applies where governmental action "lower[s] the market value of" property by reducing what buyers will pay for it, which a price cap on downstream sales surely does. *Pater v. City of Casper*, 646 F.3d 1290, 1295–96 (10th Cir. 2011).

Defendants' cases do not suggest otherwise. One case held nursing-home residents did not have a property interest in "the home's authority to provide them with nursing care at government expense," *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773, 775 (1980), and another held a victim did not "have a property interest in police enforcement of [a] restraining order," *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 768 (2005). Neither involved anything resembling the core property right at issue here, and neither held that property rights are never implicated unless a party is directly regulated. The other cases Defendants cite did not involve due process at all. *See Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC*, 156 F.4th 68 (2d Cir. 2025); *United States v. Univis Lens Co.*, 316 U.S. 241 (1942).

2. Defendants cannot show that Amgen received adequate process. Defendants' focus on the Board's public meetings and receipt of comments misunderstands Amgen's claim. Amgen was denied "a *meaningful* opportunity to be heard," *In re C.W. Mining Co.*, 625 F.3d 1240, 1244–45 (10th Cir. 2010) (emphasis added), because the law set no "ascertainable limit[s]" on the Board's discretion, *Hobbs ex rel. Hobbs v. Zenderman*, 579 F.3d 1171, 1185–86 (10th Cir. 2009). Holding hearings and receiving comments is insufficient without comprehensible standards

to guide those proceedings. Amgen's comments flagged this problem repeatedly, and the Board never responded. *E.g.*, Ex. 49 at 2–3; Ex. 52 at 2–3. Similarly, the length of the affordability report is not a substitute for constitutionally adequate standards.

Defendants identify nothing in the statute that meaningfully limited the Board's "unfettered discretion" to deem Enbrel unaffordable and cap its price. *White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976). While they point to various factors the Board had to "consider," Colo. Rev. Stat. § 10-16-1406(4), they do not dispute that the statute provided zero guidance regarding "how to assess or weigh those factors," Mot. 32. And Defendants acknowledge (at 34) that the Board ultimately swept those factors aside and based Enbrel's UPL on the federal MFP, [redacted] Mizner Dep. 184:11–14, 186:14–187:14.

Nor do Defendants identify anything in the statute that "ensure[d] a fair and reasonable rate of return on [Amgen's] investment." *Mich. Bell Tel. Co. v. Engler*, 257 F.3d 587, 594 (6th Cir. 2001). They instead contend Amgen had already received a sufficient return "before the UPL was set." Opp. 35. Amgen disagrees with Defendants' simplistic attempt to calculate Amgen's return on investment, which ignores (among other things) that the profits from a successful drug must support not only development and production of that particular drug, but also vast amounts of research that do not result in any marketable products. Amgen Dep. 155:10–156:8.

But that is beside the point. Due process requires an *ex ante* statutory "mechanism" to "guarantee" a fair return. *Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990). The constitutional problem is not just that the Board set the UPL too low; it is that Colorado supplied no mechanism requiring the Board even to consider whether the UPL would provide a fair return for Amgen.[2]

III. The equities and the public interest strongly favor Amgen.

The last two preliminary-injunction factors are foregone conclusions given that Amgen faces irreparable harm and will likely prevail on the merits. Defendants have no response to precedent holding that a state "does not have an interest in enforcing a law that is likely constitutionally infirm" and "the public interest will perforce be served by enjoining" such a law. *Edmondson*, 594 F.3d at 750, 771 (cleaned up); *accord Ortega v. Grisham*, 148 F.4th 1134, 1154 n.13 (10th Cir. 2025); *Free the Nipple–Fort Collins v. City of Fort Collins*, 916 F.3d 792, 806–07 (10th Cir. 2019). Defendants' contention that the equities do not favor Amgen because Amgen will not be harmed, Opp. 36–37, repackages meritless arguments addressed above. Defendants also claim the UPL will benefit consumers, but a state may not seek to benefit consumers through an unconstitutional law. In any event, Defendants cite no

[2] Defendants falsely claim that "[d]uring rulemaking, the Board specifically asked Amgen to provide additional testimony and submit specific information on Amgen's costs, average and net prices, and chargebacks, but Amgen refused." Opp. 33. Defendants' sole citation for this broadside is one Board member's passing comment that "it would be great to hear from" Amgen regarding whether the UPL would "impact[] patient assistance programs." ECF 1-8 at 73:6–74:2.

evidence that consumers will benefit from the UPL, and any such benefit is dubious. Mot. 38; Amgen Dep. 45:1–50:15; Ex. 47 at J29–J30; Ex. 54 at 1–2.

IV. The Court can resolve this case on the merits.

"Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2). The Court may wish to invoke that rule here, just as the district court did in the challenge to D.C.'s similar price-control scheme. *Pharm. Rsch. & Mfrs. of Am. v. District of Columbia*, No. 1:05-cv-2015 (D.D.C. Nov. 17, 2005) (text order). The parties here agreed that Amgen's claims "raise[] legal questions that may be properly resolved … without the need for discovery or trial." Joint Mot. 2, *Amgen Inc. v. Mizner*, No. 1:24-cv-810 (D. Colo. May 16, 2024), ECF 18. And while the magistrate judge ordered discovery—which is now complete—on irreparable harm, he too recognized that "the ultimate resolution of this case is going to be a pure legal question." ECF 44 at 25. Where state law is preempted and "the only material issue of fact concern[s] irreparable injury," "consolidation of the preliminary injunction application with a trial on the merits … is appropriate." *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1171–72 (D. Colo. 2001).

CONCLUSION

The Court should grant Amgen's motion.

Dated: May 19, 2026

Respectfully submitted,

/s/ Paul Alessio Mezzina

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Counsel for Plaintiffs

I hereby certify that the foregoing paper complies with the length limitation set forth in the Court's December 1, 2025, Order. *See* ECF 33.

CERTIFICATE OF SERVICE

I hereby certify that on May 19, 2026, I electronically filed the foregoing redacted Reply in Support of Motion for Preliminary Injunction with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all attorneys of record.

/s/ Paul Alessio Mezzina
Paul Alessio Mezzina

Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

EXHIBIT 3 – REDACTED

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

EXHIBIT 15 – REDACTED

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

EXHIBIT 16 – REDACTED

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: June 30, 2023

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026

This memorandum provides interested parties with the revised Medicare Drug Price Negotiation Program guidance for initial price applicability year 2026. It includes four sections:

A. An introduction, which begins on page 1.
B. A summary of changes and clarifications to the initial memorandum released on March 15, 2023, which begins on page 2.
C. A summary of the public comments received in response to the initial memorandum, and the Centers for Medicare & Medicaid Services' (CMS') responses, which begins on page 8.
D. Revised guidance that establishes final policies on the topics discussed for initial price applicability year 2026, which begins on page 92 and for which a table of contents appears on page 94.

CMS may supplement this guidance with further program instruction to explain how these policies will be implemented during initial price applicability year 2026 (e.g., technical instructions for data submissions).

A. Introduction

Sections 11001(c) and 11002(c) of the Inflation Reduction Act (IRA) direct the Secretary to implement the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, on March 15, 2023, CMS issued an initial memorandum for implementation of the Negotiation Program for initial price applicability year 2026. CMS also voluntarily solicited comments on a number of key aspects of the initial memorandum. The 30-day comment period for the initial memorandum began March 15, 2023 and concluded April 14, 2023. CMS received more than 7,500 comment letters in response to the initial memorandum, representing a wide range of views from academic experts and thought leaders, consumer and patient organizations, data vendors/software technology entities, health plans, health care providers, health systems, individuals, labor unions, pharmaceutical and biotechnology

Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data

For the purposes of describing the data at sections 1194(e)(1), 1194(e)(2), and 1193(a)(4)(A) of the Act to be collected for use in the Negotiation Program, as described in sections 40.2, 50.1, and 50.2 of this revised guidance and the Negotiation Data Elements Information Collection Request (ICR), CMS adopts the following definitions and standards.

General

- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment. If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount should be used.

Non-FAMP

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.[81] For initial price applicability year 2026, these are the quarters of 2021. When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) for a given NDC-11 of such drug, the non-FAMP reported by the manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2023 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585. Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP unit: Non-FAMP unit is the package unit as described in 38 U.S.C. § 8126(h)(6).
- Non-FAMP dosage form unit: The non-FAMP dosage form unit is the dosage form of the NDC that is reported in the "Dose form" field of the Excel workbook used by the Office of Pharmacy Benefits Management Services at the VA to collect non-FAMP information.

Research and Development (R&D) Costs

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the five categories below, and excluding (a) prior Federal financial support, (b) costs associated with applying for and receiving foreign approvals,

[81] The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. § 8126(h)(5).

and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Acquisition Costs
2. R&D: Basic Pre-Clinical Research Costs
3. R&D: Post-Investigational New Drug (IND) Application Costs
4. R&D: Abandoned and Failed Drug Costs
5. R&D: All Other R&D Direct Costs

CMS is calculating recoupment of R&D costs using both the global and U.S. total lifetime net revenue for the selected drug:

6. Recoupment: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Definitions for 1. R&D: Acquisition Costs

- For the sole purpose of data collection under section 1194(e)(1)(A) of the Act, acquisition costs are defined as costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug.

Definitions for 2. R&D: Basic Pre-Clinical Research Costs

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that indication of the selected drug went into effect.[82, 83] The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.[84]

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[82] CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers should use their best estimate.

[83] For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug, use the earliest date of acquisition for any NDA / BLA of the selected drug.

[84] CMS believes that 52 months represents a solid average across studies. For example, one study reported that the pre-clinical phase takes 52 months on average. See DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, https://fds.duke.edu/db?attachment-

- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative costs are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[85, 86] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs should be allocated proportionally, thus for the selected drug they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Definitions for 3. R&D: Post-Investigational New Drug (IND) Application Costs

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, post-marketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, post-marketing trials that were not completed.
- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, post-marketing trial.

25--1301-view-168. Another study estimated that the pre-clinical phase can take 31 months on average. See DiMasi, J, Grabowski, H, Hansen, R. Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, 2016, as cited by the Congressional Budget Office (CBO) in Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126. Other estimates have found that the pre-clinical phase ranges from three to six years. See PhRMA, "Biopharmaceutical Research & Development: The Process Behind New Medicines," 2015, http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

[85] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA.* 2020;323(9):844–853. doi:10.1001/jama.2020.1166

[86] Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html.

- The post-IND period begins on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug.

Definitions for 4. R&D: Abandoned and Failed Drug Costs

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- Failed or abandoned product costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
    - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
    - Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned product costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
    - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
    - Direct post-IND costs include IRB review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Definitions for 5. R&D: All Other R&D Direct Costs

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1-4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required post-marketing trials that were not completed. No additional definitions adopted.

Definitions for 6. Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.

Definitions for 6a. Global, including U.S., Total Lifetime Net Revenue for the Selected Drug

- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

- Global, total lifetime net revenue period is defined as the date the drug or biologic was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Definitions for 6b. U.S. Lifetime Net Revenue for the Selected Drug

- U.S. lifetime net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- U.S. lifetime net revenue period is defined as the date the drug or biologic was first sold in the U.S. through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If U.S. lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.

Current Unit Costs of Production and Distribution

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)[87]: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-11s of the selected drug. Selections of EA, ML or GM must be made as follows:
    - "EA" is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of "EA" is also used to address exceptions where "GM" and "ML" are not applicable. Examples of products defined as "EA" include, but are not limited to:
        - Tablets;
        - Capsules;
        - Suppositories;
        - Transdermal patches;
        - Non-filled syringes;
        - Tapes;
        - Devices/Digital Therapies;

[87] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

        - Blister packs;
        - Oral powder packets;
        - Powder filled vials for injection;
        - Kits;[88] and
        - Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram should be billed as "one each," for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 ML.
    - "ML" is used when a product is measured by its liquid volume. Examples of products defined as "ML" include, but are not limited to:
        - Liquid non-injectable products of 1 ML or greater;
        - Liquid injectable products in vials/ampules/syringes;
        - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
        - Inhalers (when labeled as milliliters on the product).
    - "GM" is used when a product is measured by its weight. Examples of products defined as "GM" include, but are not limited to:
        - Creams (of 1 GM or greater);
        - Ointments (of 1 GM or greater); and
        - Inhalers (when labeled as GM on the product).[89]
- Costs of <u>production</u> are defined as all (direct and allocation of indirect) costs related to:
    - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
    - Formulation and preparation of the finished drug product;
    - Quality control and testing of the drug; and
    - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of <u>distribution</u> are defined as all (direct and allocation of indirect) costs related to:
    - Packaging and packaging materials;
    - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
    - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
    - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:

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[88] Kits are defined as products that contain one of the following: (1) at least two distinct items with different billing units; (2) one product packaged with medicated or unmedicated swabs, wipes and/or cotton swabs/balls; or (3) meters packaged with test strips.

[89] See: https://standards.ncpdp.org/Standards/media/pdf/BUS_fact_sheet.pdf. *Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.*

  - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
  - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
  - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
  - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
  - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
  - R&D costs; and
  - Marketing costs.
- "Marketing costs" are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion.

Prior Federal Financial Support

For the purposes of describing prior federal financial support for novel therapeutic discovery and development to be collected for use in the Negotiation Program with respect to the selected drug, as described in section 1194(e)(1) of the Act and section 50.1 of this revised guidance, CMS adopts the definitions described in this subsection.

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- "*Prior* Federal financial support" refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for the selected drug.

Patents, Exclusivities, and Approvals

- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
  - All patents issued by the United States Patent and Trademark Office (USPTO), as of September 1, 2023, both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected

drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
    - Patents and patent applications related to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book[90]; utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[91]
    - New Chemical Entity Exclusivity (NCE);[92]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[93]
    - New Clinical Investigation Exclusivity (NCI);[94]
    - Pediatric Exclusivity (PED);[95] and
    - Reference Product Exclusivity for Biological Products.[96]
- Active and pending FDA applications and approvals includes all applications for approval under section 505(c) of the FD&C Act or sections 351(a) of the PHS Act, including those not yet decided.

Market Data and Revenue and Sales Volume Data

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.

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[90] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[91] Section 527 of the Federal Food, Drug and Cosmetic (FD&C) Act.
[92] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[93] Section 505E(a) of the FD&C Act.
[94] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[95] Section 505A(b) & (c) of the FD&C Act.
[96] Section 351(k)(7) of the PHS Act.

- National Council of Prescription Drug Programs (NCPDP) Billing Unit Standards: The three NCPDP Billing Unit Standards (BUS)[97] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505(a). The Medicaid best price is reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration.[98] The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price is reported at the NDC-11 level.
- U.S. commercial average net unit price— without patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of manufacturer-run patient assistance programs that provide financial assistance such as coupons and co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price— without patient assistance program is reported at the NDC-11 level.
- U.S. commercial average net unit price— best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any

[97] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.
[98] See: https://www.fss.va.gov/index.asp.

Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price— best is reported at the NDC-11 level.

Evidence About Alternative Treatments

- Therapeutic Alternative: A therapeutic alternative must be a pharmaceutical product that is clinically comparable to the selected drug. CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS will begin by identifying therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on the subset of therapeutic alternatives that are most clinically comparable to the selected drug.
- Outcomes: Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients, and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered, including patient-centered outcomes when available, to the extent that these outcomes correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternative.
- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.[99]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries including those that may experience disparities in access to care, health outcomes, or other factors when taking the selected drug that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[100]
- Unmet medical need: A drug or biological product may be considered to meet an unmet medical need if the drug or biological product treats a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the

[99] Source: ISPOR Plenary, Patrick (2013) via FDA's "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders" (June 2020). See: https://www.fda.gov/media/139088/download.
[100] See: https://www.cms.gov/pillar/health-equity.

disease or condition.[101] Unmet medical need is determined at the time of submission of this information.

[101] CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014) when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program.

UNITED STATES DISTRICT COURT
DISTRICT OF COLORADO
Denver

AMGEN INC., *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action
No. 1:25-cv-3452-DDD-STV

EXHIBIT 57 – REDACTED

COLORADO
Prescription Drug Affordability Board
Division of Insurance

Prescription Drug Affordability Board DRAFT Meeting Minutes
Friday, August 4, 2023; 10 am - 2 pm - Virtual Meeting
Meeting Recording

Meeting Attendance

Board Members
Dr. Gail Mizner
Dr. Sami Diab
Dr. Justin VandenBerg
Dr. Amy Gutierrez
Ms. Cathy Harshbarger

Board Staff
Lila Cummings
Kate Davidson
Callie Shelton
Moroj Salih
Abby Chestnut
Sara Stultz

Absent
N/A

Agenda

- Call to Order, Roll Call, Member Updates, Minutes Approval
- Public Comment
- Director Update & Board Business
- Break
- Board Business

Call to Order and Roll Call

Gail Mizner called the meeting to order at 10:01 am and all Board members were present. Board staff disclosed meetings with the Cystic Fibrosis Foundation, Vertex, Novartis, and a coalition of consumer advocacy groups.

Approval of June 23 Meeting Minutes

Amy Gutierrez proposed an addition to the minutes to reflect the time she left the last meeting. The Board voted unanimously to approve the minutes as discussed. Sami Diab moved and Cathy Harshbarger seconded to approve the June 23 meeting minutes. The Board voted unanimously to approve the minutes.

DECISION: June 23 meeting minutes approved at 10:05 am.

Public Comment

- Bridget Federico, consumer
- Katelin Lucarello, PhRMA
- Brian Warren, Bio
- Michiel Peters, Global Coalition on Aging
- Hope Stonner, CCHI
- Amy Goodman, CBSA
- Kat Gruschow, on behalf of Claudia Curry Hill, a Coloradan living with MS

Case 1:25-cv-3452-DDD-STV
EXHIBIT 58

COLORADO
Prescription Drug Affordability Board
Division of Insurance

- Elyse Blazevich, CO BioScience Association
- Sabrina Walker, CF advocate
- Patrick Sosnay, Vertex
- Bethany Pray, CCLP

Board members requested to hear all public comments at the beginning of the meeting and omit the second public comment period.

- Lindsey Viscarra, National Organization for Rare Disorders
- Kelly Keena, cystic fibrosis advocate
- Siri Vaeth, Cystic Fibrosis Research Institute
- Michael Eging, Rare Access Action Project
- Stacie Abbott, Incyte
- Joni Inman, CO Womens' Alliance,
- Amber Strickler, cystic fibrosis advocate
- Wyatt Cunningham, student
- Kelly Wiberg, parent of cystic fibrosis adult
- Brian Callanan, Cystic Fibrosis Lifestyle Foundation
- Nina Anderson, small business owner.
- Toni Mulroy, family of adult cystic fibrosis patient
- Scott Sagel, Children's National Colorado
- Laura Bonnell, cystic fibrosis advocate

Public comment concluded at 11:03 am.

Director Updates & Board Business

Sami Diab disclosed conflicts with the following manufacturers due to clinical research activities, speaker/consulting fees, travel/food/beverage/lodging/educational activities:

- Abbvie US, LLC
- Alexion Pharmaceuticals
- BMS Primary Care
- Eli Lilly & Co
- Pharmacyclics
- Amgen Inc
- AstraZeneca Pharmaceuticals
- Celgene Corporation
- Clovis Oncology
- Daiichi Sankyo
- Eisai
- Genentech USA, Inc.
- Gilead Science
- Lexicon Pharmaceutical
- Lilly USA
- Novartis Pharmaceuticals Corporation
- Pfizer Inc

COLORADO
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- Puma Biotechnology, Inc.
- Seagen Inc
- Takeda

Board staff presented PDAAC selection recommendations to the Board, including general principles and specific drugs. Board staff then recommended the Board select 3-5 prescription drugs by utilizing the dashboard and secure spreadsheets to narrow the focus and use additional selection research as contextual or tie-breaking factors.

Staff presented additional research requested by the Board regarding:

- Therapeutic class, equivalents, and indications,
- Patient out-of-pocket cost, and
- Payer mix.

The Board took a brief break from 12:03 - 12:08.

Board Deliberates Whether to Select Specific Drugs

The Board sorted the list of eligible drugs according to the following criteria:

- Sorted patient count from highest to lowest,
- Only included drugs without therapeutic equivalents,
- Excluded drugs with biosimilars,
- Excluded biosimilars, and
- Removed deprioritized drugs.

The Board selected the top 5 drugs appearing on the list after these filters were applied.

After Board discussion, a break was called from 12:36 - 12:56 pm.

Board Votes to Adopt Resolutions Selecting Specific Drugs

Resolution 1: Enbrel

Amy Gutierrez moved, Justin VandenBerg seconded. Sami Diab recused. The remaining four Board members voted to approve the resolution.

DECISION: Resolution 1: Enbrel approved at 1:00 pm.

Resolution 2: Genvoya

Cathy Harshbarger moved, Amy Gutierrez seconded. Sami Diab recused. The remaining four Board members voted to approve the resolution.

DECISION: Resolution 2: Genvoya approved at 1:01 pm.

Resolution 3: Cosentyx

Amy Gutierrez moved, Justin VandenBerg seconded. Sami Diab recused. The remaining four Board members voted to approve the resolution.

DECISION: Resolution 3: Cosentyx approved at 1:03 pm.

Resolution 4: Stelara

COLORADO
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Justin VandenBerg moved, Amy Gutierrez seconded, and the Board voted unanimously to approve the resolution.

DECISION: Resolution 4: Stelara approved at 1:05 pm.

Resolution 5: Trikafta

Cathy Harshbarger moved, Amy Gutierrez seconded, Sami Diab voted nay, all other Board members voted to adopt the resolution.

DECISION: Resolution 5: Trikafta approved at 1:08 pm.

PDAAC Member Appointment

One application was received for the open PDAAC seat representing wholesalers.

Amy Gutierrez moved, Justin VandenBerg seconded, and the Board voted unanimously to appoint Leah Lindahl to the Advisory Council.

DECISION: Leah Lindahl was appointed to the PDAAC at 1:11 pm.

The second public comment period was omitted due to extended public comment at the beginning of the meeting.

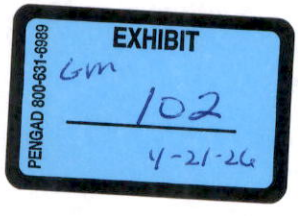
Chair Mizner adjourned the meeting at 1:14 pm.

DRAFT

Oregon Prescription Drug
Affordability Board

Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Draft Board Report

October 2024



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Executive Summary

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Background

The Prescription Drug Affordability board (PDAB or the board) was established in the Department of Consumer and Business Services (DCBS) and is committed to protecting residents of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon, and other constituent groups within the Oregon health care system from the high costs of prescription drugs. The board was established by the legislature in 2021 under Senate Bill (SB) 844, later codified in Oregon Revised Statute (ORS) 646A.693.[1] The board provides policy recommendations and reports to the Oregon Legislature. These materials include a report issued each December with legislative policy recommendations for making prescription drugs more affordable within the state's healthcare system. The board also produces an annual legislative report that address issues relating to generic drugs.

The responsibilities of the board include conducting affordability reviews to identify nine drugs and at least one insulin product that it determines may create affordability challenges for health care systems or through high out-of-pocket costs incurred by Oregonians. Oregon Administrative Rules include the criteria to be used in conducting affordability reviews on prescription drugs and insulin products.[2] Through the authority granted under SB 192 (2023), the PDAB is developing a plan for establishing upper payment limits (UPLs) on drugs sold in the state of Oregon that are subject to affordability reviews under ORS 646A.694.[3,4]

In December 2023, the board, acting through the Department of Consumer and Business Services, Division of Financial Regulation, contracted with Myers and Stauffer (PO-44000-00028053) to provide prescription drug consulting and outreach services related to the board's SB 192 obligations. As part of these services, Myers and Stauffer conducted focus group meetings with constituent groups as identified and approved by board staff, including the Public Employees' Benefits Board (PEBB), Oregon Educators' Benefits Board (OEBB), carriers, consumer organizations, hospitals, retail pharmacies, 340B covered entities, pharmaceutical manufacturers, pharmacy benefit managers, and patient advocacy groups. After each focus group meeting, Myers and Stauffer compiled a summary document and then created a final report identifying any critical discussions, recommendations, or strategies that arose from the constituent group engagement meetings. The board also contracted with Horvath Health Policy to provide consultant services. Their work is referenced throughout this report and included in the appendices.

More information on the board's mission, meetings, decisions and reports may be found on the PDAB website (https://dfr.oregon.gov/pdab/Pages/index.aspx).

Oregon PDAB's Prior Work

The Oregon Legislature created the board in 2021 due to concerns about rising prescription drug costs and their negative effect on patients and the health system in the state. The board met for the first time on June 23, 2022 and convened eight times in 2022, 12 times in 2023, and is set to meet 11 times in

[1] S.B. 844, 81st Leg. Assemb., Reg. Sess. (Or. 2021) https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/SB844.

[2] Or. Admin. R. 925.200.0010 – 925.200.0020 https://dfr.oregon.gov/pdab/Documents/PDAB-1-2023-affordability-review-rule.pdf.

[3] Oregon Prescription Drug Affordability Board website. Frequently Asked Questions. https://dfr.oregon.gov/pdab/Pages/pdab-faqs.aspx, accessed 4/2/2024.

[4] Senate Bill 192 (2023) https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB192/Enrolled, accessed 4/2/2024.

2024. Board members started immediately working on the road map provided in its founding legislation. An early task was to study the entire prescription drug distribution and payment system and the generic drug market. The board presented its first report to the Legislature in December 2022, which contained recommendations for the Oregon Legislature including: (1) implementing a UPL; (2) promoting transparency in supply chain rebate; (3) expanding reporting requirements for patient assistance programs (PAPs); and (4) expanding reporting to more insurers for the Drug Price Transparency (DPT) Program.[5] These recommendations were later proposed as part of SB 404 in the 2023 legislative session. In June 2023, the board presented its second annual generic drug report to the Legislature that reviewed generic spending, drug shortages, price fixing, pay for delay, spread pricing, market disrupters, and cost savings from biosimilars. Also in 2023, the board drafted a legislative report of policy recommendations. The report included three policy recommendations: (1) lower insulin co-pay limit to $35 and/or decouple from inflation index; (2) Change Oregon's statute language regarding substitution requirements for biological products and biosimilars; and (3) expand pharmacy benefit managers (PBMs) reporting requirements for more transparency. In 2024, the board submitted its third annual legislative report on generic drugs. The 2024 generic drug report evaluated the use of generic drugs to lower the cost of medications for consumers and the health care system.

The board approved policies to guide its work when it was first established in June 2022. Each year, the board reviews the policies and amends them if needed. These policies address board administrative requirements including but not limited to board composition, board member terms, quorum, conflict of interest, and public comment. The board may also adopt rules in accordance with applicable provisions under ORS Chapter 183 including authority to adopt criteria for drug affordability reviews and to provide consultation to DCBS in the adoption of annual fees to be paid by manufacturers to meet the cost of program and board administration costs. During the rulemaking process the public is encouraged to submit comments to provide feedback by signing up for and attending board meetings and hearings. In December 2022, the board adopted the Oregon model Rules for Rulemaking and Public Records Requests. This permanent administrative order provided a legal framework for the board to engage in rulemaking as authorized by ORS 646A.964 and SB 192.

Drug Affordability

The pace of retail prescription drug spending in the United States has varied in recent decades. According to the most recent national health expenditures (NHE) accounts compiled by the Centers for Medicare & Medicaid Services (CMS), the United States spent $405.9 billion on prescription drugs in 2022—approximately 9.02 percent of total health consumption expenditures.[6] Of this figure, $43.8 billion was attributed to Medicaid—approximately five percent of total Medicaid expenditures.[7] Additionally, 32 percent of prescription drug spending, or $378 billion, is attributed to Medicare, and 42

[5] OR PRESCRIPTION DRUG AFFORDABILITY BOARD, 2022 REPORT FOR THE OREGON LEGISLATURE (Dec. 19, 2022) https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Report_2022.pdf.

[6] CMS.GOV, NHE FACT SHEET (2024) https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet#:~:text=Historical%20NHE%2C%202020%3A,20%20percent%20of%20total%20NHE.

[7] Elizabeth Williams, et al., *Recent Trends in Medicaid Outpatient Prescription Drug Utilization and Spending*, KFF (2023) https://www.kff.org/medicaid/issue-brief/recent-trends-in-medicaid-outpatient-prescription-drug-utilization-and-spending/#:~:text=Spending%20Trends,-Net%20spending%20(spending&text=Gross%20Medicaid%20spending%20(spending%20before,gross%20spending%20is%20drug%20rebates.

percent is attributed to private health insurance.[8] By 2028, overall prescription drug spending is projected to increase to $560.3 billion, and Medicaid spending on prescription drugs is projected to increase to $57.6 billion.[9] Importantly, this data does not include drugs administered in clinics or hospitals such as gene therapies, which are generally very expensive.

Opacity surrounding drug pricing and reimbursement practices obscures understanding and accountability for the cost of drugs. This lack of transparency underscores a pressing need for comprehensive reforms to ensure affordability, fairness, and efficiency within the pharmaceutical landscape. States throughout the nation have taken legislative action in an attempt to control drug spending while increasing pricing transparency, including the creation of PDABs to review the affordability of certain drugs and make policy recommendations on how to control state spending.

Transaction Relationships in the Supply Chain

At its highest level, the phrase "drug supply chain" is used to describe the process of delivering prescription medications from the manufacturer to the ultimate end user, the patient. The pharmaceutical supply chain is complex, involving two concurrent streams: the flow of product and the flow of payment. Within these flows exists an intertwined and complex system of participants. This discussion focuses on the delivery of medications in an outpatient setting, specifically those drugs delivered through retail, mail order or specialty pharmacies, and drugs administered on an outpatient basis through a clinic or physician's office. The system is made further complex with the addition of the purchasing streams for inpatient and nursing facility medications. This discussion is not intended to describe in detail the further complex interactions of the individual markets (brand, generic, biologic, and biosimilar drugs). The outpatient focus of this discussion reflects the expected nature of the drugs that would be most likely to be evaluated for action by the PDAB. The groups involved in the supply chain mirror those included in the constituent and consumer group discussions:

- **Manufacturers.** Manufacturers hold the approval from the Food and Drug Administration (FDA) to produce and/or sell the prescription drugs. They also manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, physician offices, and some health plans.[10]
- **Distributors/Wholesalers.** Wholesalers purchase pharmaceutical products from manufacturers and sell them to a variety of customers, including pharmacies (retail, mail-order, and specialty), hospitals, and long-term care and other medical facilities (e.g., community clinics, physician

[8] Juliette Cubanski, et al., *What to Know about Medicare Spending and Financing*, KFF (2023) https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-spending-and-financing/#:~:text=Medicare%20plays%20a%20major%20role,drug%20sales%20(Figure%201). Juliette Cubanski et al., *How does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KFF (2023) https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/#:~:text=Among%20all%20payers%2C%20private%20health,of%20total%20retail%20drug%20spending.

[9] Id.

[10] The Health Strategies Consultancy LLC, *Following the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, The Kaiser Family Foundation, Mar. 2005, https://tinyurl.com/2p9a38p6.

offices, and diagnostic labs).[11] They also resell to smaller, regional distributors for regional or local distribution to retail pharmacies and hospitals.[12]

- **Pharmacy Benefit Managers (PBMs).** PBMs manage prescription drug benefits on behalf of health plans and payers. PBMs design and maintain drug formularies to encourage patients and prescribers to use certain drugs in exchange for post-utilization price concessions. Price concessions from manufacturers are paid to PBMs via rebates, a share of which are passed back to payers, and which ultimately could result in lower premiums or other benefits for insured patients. Generally, PBMs do not buy or sell medicines, although this is starting to change with PBMs establishing their own private label to sell drugs that no longer have federal law protections from market competition. Separately, PBMs maintain networks of pharmacies, including pharmacies owned by the PBM's parent company and/or owned by the PBM directly.[13] PBMs also serve as gatekeepers to patient access/utilization through utilization management policies such as prior authorization.
- **Payers.** Payers are health insurers, large employers, and government programs that offer drug coverage to individuals. Payers include employers offering health plans to their employees, commercial insurers selling health plans to employers and individuals, and government programs such as Medicare, Medicaid, and state and local government employee benefit plans.[14]
- **Pharmacies.** Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products. After purchasing pharmaceuticals, pharmacies assume responsibility for their safe storage and dispensing to patients. Pharmacy operations include maintaining an adequate stock of drug products, providing information to consumers about the safe and effective use of prescription drugs, and facilitating billing and payment for consumers participating in health plans.[15] Pharmacies are often are owned by large vertically-integrated corporations that include PBMs, insurers, and medical provider organizations.
- **Group Purchasing Organizations (GPOs).** GPOs allow independent pharmacies and small pharmacy chains to join together to leverage combined purchasing power to negotiate discounts with manufacturers, wholesalers, and other vendors.[16] GPOs are used extensively in the hospital and health care system markets to negotiate discounts on drugs, and other supplies and services. GPOs do not take physical possession of drug products.[17] These purchasing organizations should not be confused with PBM-owned entities that are also called GPOs; PBM-

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[11] Id.

[12] National Academy for State Health Policy, *A Glossary of All Terms Pharma*, June 15, 2018, https://nashp.org/a-glossary-of-all-terms-pharma/.

[13] *Pharmacy Benefit Managers and Their Role in Drug Spending*, The Commonwealth Fund, (Apr. 22, 2019), https://tinyurl.com/uvdfeynf.

[14] Andrew W. Mulcahy & Vishnupriya Kareddy, *Prescription Drug Supply Chains*, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[15] The Health Strategies Consultancy LLC, *Following the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, KFF, (Mar. 2005), https://tinyurl.com/2p9a38p6.

[16] *The Evolution of Group Purchasing* Organizations, Drug Topics, (Oct. 10, 2016), https://www.drugtopics.com/view/evolution-group-purchasing-organizations.

[17] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

based GPOs function as rebate aggregators and engage directly with manufacturers to negotiate rebate and other contracts.[18]

- **Pharmacy Services Administrative Organizations (PSAOs).** PSAOs represent and provide services for independent or small chain pharmacies. Services offered can include negotiating and entering into PBM contracts on the pharmacy's behalf, providing the pharmacies with communications and information regarding contractual and regulatory requirements, and providing general, claim-specific assistance by means of a help desk or dedicated staff person.[19] PSAOs are often owned by wholesalers or PBMs.[20]
- **Patients.** Patients, may also be referred to as "consumers", "enrollees", or "beneficiaries". Their access to prescription medications and financial responsibility for payment are governed by a variety of factors including health plan formulary placement, plan benefit design, and most importantly, whether or not they have access to a health plan or prescription drug plan. Typically, lower out-of-pocket costs and fewer utilization management requirements are applied to preferred drug lists or PBM alternatives. The type and magnitude of out-of-pocket payments vary depending on benefit design.[21]

Any conversation about the drug supply chain must recognize the influence of manufacturer-paid rebates on the distribution of drugs. The majority of rebate payments occur between manufacturers and PBMs, although there are also on-invoice discounts for purchasers based on volume starting with wholesalers to smaller distributors, then pharmacies, and large purchasers such as hospitals. Manufacturers generally offer discounts to wholesalers based on volume purchases and prompt payment. Wholesalers also offer discounts to buyers based on volume and timely payments. Rebates are paid to PBMs for preferred placement of a drug or bundle of drugs on the formulary or preferred drug list. Rebates are paid after a drug has been dispensed and periodic payments are based on the number of units dispensed. Patient cost sharing is generally based off the list price without regard to any manufacturer price concessions.[22]

The illustration in Figure 1 presents the typical supply chain flow for branded products dispensed through the retail pharmacy market and reimbursed by the PBM as a pharmacy benefit. The flow for distribution of generic drugs and payments is similar, although it lacks the influence of rebates paid by manufacturers. Pharmaceutical manufacturers noted during the focus group sessions that rebates on branded products provide cost savings of approximately 50 percent on branded products and may be as much as 80 percent on highly rebated products.

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[18] U.S. Federal Trade Commission Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies,* (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

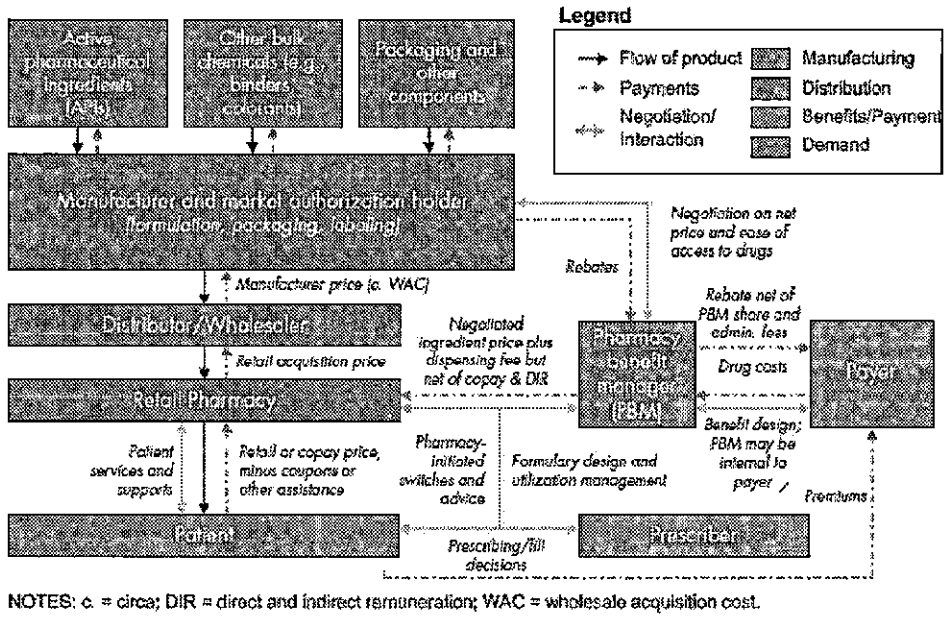
[19] U.S. Gov't Accountability Office, *Prescription Drugs the Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, Government Accountability Office, (Jan. 2013), https://www.gao.gov/assets/gao-13-176.pdf.

[20] National Academy for State Health Policy, *A Glossary of All Terms Pharma*, June 15, 2018, https://nashp.org/a-glossary-of-all-terms-pharma/.

[21] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[22] U.S. Senate Committee on Finance, Minority Staff, A Tangled Web: An Examination of the Drug Supply and Payment Chains (June, 2018), https://www.finance.senate.gov/imo/media/doc/A%20Tangled%20Web.pdf.

Figure 1: Typical Supply Chain for Brand-Name Drugs Dispensed Through Retail Pharmacies[23]



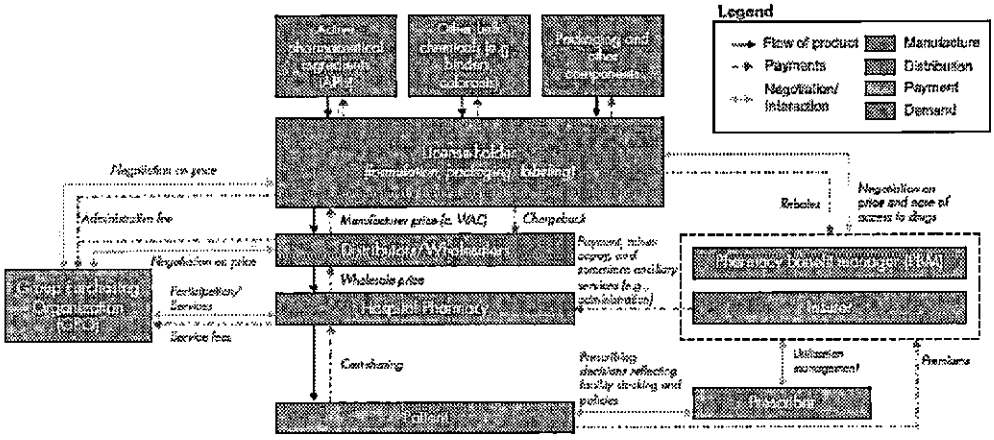
NOTES: c. = circa; DIR = direct and indirect remuneration; WAC = wholesale acquisition cost.

Distribution through hospitals and physician offices carries a similar level of complexity, as illustrated in Figure 2. Generally, prescription drugs distributed through this method are administered in settings such as hospital outpatient departments or physician offices, and often are covered through the medical benefit rather than the pharmacy benefit. White bagging (delivery by a specialty pharmacy to the provider and processed for payment by the PBM) and brown bagging (delivery by a specialty pharmacy to the patient and processed for payment by the PBM) are other mechanisms for dispensing in this setting. A more recent development is the increase in clear bagging, in which the specialty pharmacy is owned by the health system and distributes the drug to the provider for administration; claims payment is generally processed through the PBM.[24]

[23] Andrew W. Mulcahy & Vishnupriya Kareddy, Prescription Drug Supply Chains, Rand Corporation, (2021), https://www.rand.org/pubs/research_reports/RRA328-1.html.

[24] Jason Shafrin, White vs. Brown vs. Clear Bagging, Healthcare Economist (April 25, 2023), https://www.healthcare-economist.com/2023/04/25/white-vs-brown-vs-clear-bagging/.

Figure 2: Typical Supply Chain for Drugs Dispensed in Outpatient Facility Settings[25]



PDAB Landscape

As described above, states leverage a variety of public oversight laws in an attempt to control costs and increase transparency. One such method is through the creation of PDABs. PDABs are government entities charged with assessing which prescription drugs present affordability challenges to a state's health care system and to consumers. Many, but not all, PDABs are designed to identify unaffordable drugs, to help assess the causes of high costs for particular drugs, and to identify appropriate policy solutions.[26] Generally speaking, PDABs gather data regarding the cost of drugs, specifically high-cost drugs. Data is gathered from constituent groups directly, from state agencies, or from outside services and vendors. Using the pricing and cost data collected, PDABs determine whether to conduct an affordability review of the identified drugs and may subsequently set upper payment limits.

Four states, in addition to Oregon, have established PDABs with authorization to conduct affordability reviews, but unlike Oregon, also have authority to set UPLs on certain medications.[27] This authority empowers these states to establish maximum payments for specific drugs, offering a potential mechanism to contain escalating prescription drug costs and ensure affordability for patients and payers alike.

[25] Id.

[26] CO, WA, MN have statewide prescription drug UPL setting authority; MD has UPL setting authority for just state and local governments; ME and NH have unspecified cost control authority for state agencies and programs; OH, NJ only have study authority; and NY and MA have Medicaid pharmacy budget growth caps and remediation authority. OR has authority to assess affordability of certain drugs but no UPL setting authority.

[27] Additionally, thirteen states have proposed legislation to create PDABs: Arizona, Connecticut, Iowa, Kentucky, Michigan, Nebraska, Pennsylvania, South Carolina, Vermont, Virginia, West Virginia, and Wisconsin.

In addition to the states with UPL-setting authority, six states have implemented various drug affordability review initiatives, signaling a growing trend in addressing pharmaceutical pricing and accessibility at the state level.[28]

UPL States

Maryland, Minnesota, Washington, and Colorado have enacted legislation authorizing the boards to set UPLs for certain prescription drugs. While none of these states have set a UPL, the summaries below describe factors these states may consider, or have proposed to consider (i.e., Maryland), when doing so. No state's law limits what factors to consider (other than certain cost effectiveness analysis) or limits the approach to setting a UPL. The boards in three states – Maryland, Washington, and Colorado –are required to consider similar factors, such as:

- The cost of administering the drug,
- The cost of delivering the prescription drug to consumers,
- Whether the drug is included on the FDA Drug Shortage List, and
- Any other relevant administrative costs.

Additional details for each state's UPL authorization are provided below.

Maryland

The Maryland PDAB has the authority to establish payment rate limits (UPLs), but that authority only extends to drugs purchased or covered by state or local government or Medicaid.[29] The Board is required to conduct a study to determine policy options that would establish UPLs.[30] The overall UPL Action Plan has to be approved by the legislature, or the governor and the attorney general. As of this writing, the Board has identified eight prescription drugs that may be eligible for a UPL, and it voted to conduct cost reviews on six of those identified drugs.[31] The Board will then undertake a cost review to determine the affordability of the selected drugs.

At the meeting held on September 10, 2024, the Board proposed a plan of action to implement the process to set UPLs. Per the action plan, methodologies for calculating a UPL may include cost effective analysis; therapeutic class reference; indexed launch price; same molecule reference (i.e., set UPL based on costs of other products with the same active ingredients with the same indication of use);

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[28] NASHP, DRUGS TAKE DIVERSE APPROACHES TO DRUG AFFORDABILITY BOARDS (2021) https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/. In addition to the states with UPL-setting authority, six states have implemented drug affordability initiatives through a variety of alternative methods. While these states are not authorized to establish UPL methodology, they are authorized to explore and implement other cost-saving measures for prescription drugs. In Ohio, the Board is required to issue a report making recommendations on a number of areas, such as how the state can achieve cost transparency and new payment models. In New Hampshire, the Board must establish drug spending targets and recommend strategies for public purchasers to lower costs to meet those targets. In Massachusetts and in New York, the Medicaid programs are authorized to negotiate supplemental rebates with manufacturers. In Maine, the board is authorized to determine and set spending target recommendations. Lastly, in New Jersey, the Board is authorized to identify drugs that present affordability challenges and make legislative or regulatory recommendations that would advance the state's goal of more affordable and accessible prescription drugs.

[29] Md. Laws § 21 – 2C – 13 (2024); H.B. 279, Gen. Assemb., Reg. Sess. (Md. 2023).

[30] Id.

[31] MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD, COST REVIEW STUDY PROCESS (2024).

international reference; budget impact-based; or a blend of multiple methodologies. The draft action plan also notes additional factors to be considered when setting a UPL including any information gathered during the cost review study process or the policy review process; utilization in government-sponsored health plans; the amount of direct government purchases; net prices for government-sponsored health plans; total out-of-pocket costs for government-sponsored health plans; current coverage status of the drug in government-sponsored health plans; the number of prescriptions paid through the State Medicaid program; the number of patients for the drug helped through the State Medicaid program; the total amount paid for the drug through the State Medicaid program; any budget impact analysis; comparisons of health system costs to research and develop cost; life cycle revenue analysis; and any information that can be derived from the manipulation, aggregation, calculation, and comparison of any available information. The Board will vote on whether to adopt the plan at its next meeting.[32]

Colorado

Per statute, the Colorado PDAB may establish up to 12 payment rate limits (UPLs) each calendar year until 2025, at which point they may establish unlimited UPLs.[33] In addition to the factors listed above, the Board must consider the impact to older adults and persons with disabilities when exploring potential UPL methodologies. The Board must not include research or methods that employ dollars per quality-adjusted life year (QALY). With respect to assessing the impact of a UPL on older adults (i.e., individuals over 65), the Board will consider utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by individuals with lived experience or expertise of the drug's impact to older adults. Similarly, when assessing the impact to persons with disabilities, the Board may consider the therapeutic classification of the drug, including its therapeutic purpose and any conditions or diseases the drug may treat, as well as utilization of the drug, cost of the drug, insurance coverage type for individuals utilizing the drug, and qualitative or quantitative analyses and information submitted by individuals with lived experience or expertise of the drug's impact to older persons with disabilities.

Per regulation, costs to be considered include wholesale acquisition cost (WAC), average sales price (ASP), National Average Drug Acquisition Cost (NADAC), out-of-pocket spending, carrier paid amounts, public program fee schedules, net cost estimates, Medicare maximum fair price (MFP), and cost information voluntary provided by supply chain entities. If a drug is on the FDA drug shortage list, the Board may consider availability and estimated shortage duration; shortage reason; therapeutic classification; and other related information.

The Board may set a UPL for any drug for which the Board has performed an affordability review. To determine whether a drug is unaffordable, the Board must consider the availability of therapeutic alternatives; the effect of price on consumer access; the relative financial effects on health, medical, or social services costs; patient copayment or other cost sharing of the drug; the impact on 340B safety net providers if the prescription drug is available through section 340B; input from patients and caregivers affected by the condition or disease that is treated by the prescription drug under review by the Board; and whether the pricing of the prescription drug results in or has contributed to health inequities in

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[32] MARYLAND.GOV, MARYLAND PRESCRIPTION DRUG AFFORDABILITY BOARD PLAN OF ACTION FOR IMPLEMENTING THE PROCESS FOR SETTING UPPER PAYMENT LIMITS (2024) https://pdab.maryland.gov/Documents/comments/Draft%20Outline%20UPL%20Action%20Plan.2024.08.09.1700.pdf.

[33] COLO. REV. STAT. §§ 10-16-1406, 10-16-1407 (2024).

priority populations.[34] After analyzing each of these factors, the Board issues an Affordability Review Summary Report for the drug under review, which also states the Board's determination of affordability. As of the time of this writing, the Colorado PDAB has conducted affordability reviews for five drugs – Trikafta, Enbrel, Genvoya, Stelara, and Cosentyx. The Board has declared Enbrel, Stelara, and Cosentyx to be unaffordable and has voted to establish UPLs for each of the drugs.[35]

At its August meeting, the Board proposed draft revisions to its policies and procedures for conducting affordability reviews. The revisions would expand the affordability assessment to "consumers" broadly, and not just to consumers of the drug under review. Further, the revisions would require the Board to consider additional factors to determine whether a drug is deemed unaffordable. The Board will vote on whether to adopt the proposed revisions.

The Board is currently facing litigation challenging its determination that the arthritis drug, Enbrel, is unaffordable and subject to a UPL. On March 22, 2024, Amgen Inc., along with Immunex Corporation and Amgen Manufacturing, Limited, initiated legal action against Colorado's PDAB, contesting the validity of the board's decision and the regulatory framework surrounding it. The complaint filed by Amgen Inc. et al. outlines several key arguments challenging the actions of Colorado's PDAB[36]:

- **Violation of Supremacy Clause:** The complaint asserts that the Colorado law the Supremacy Clause of the US Constitution because it conflicts with federal patent law. It argues that federal patent law grants pharmaceutical manufacturers a designated period of exclusivity to market and sell their products, thereby establishing a delicate equilibrium between innovation incentives and price competition. Enbrel has had 40 years of patent and other federal market exclusivity protection.
- **Due Process Concerns:** Amgen Inc. et al. contend that Colorado's process for declaring a drug unaffordable does not ensure due process because manufacturers are not afforded a meaningful opportunity to present their case. The suit cites the absence of statutory standards to ensure a "constitutional rate of return" to a manufacturer.
- **Federal Preemption of Colorado Rate Setting Statute:** The complaint posits that Colorado's rate setting statute oversteps its bounds by attempting to dictate prices that federal healthcare programs, such as Medicare, must pay for prescription drugs on behalf of beneficiaries. This argument rests on the assertion that federal law preempts state regulation in this domain.
- **Commerce Clause Challenge:** Amgen Inc. et al. argue that Colorado's law violates the Commerce Clause of the US Constitution by extending its reach beyond state borders. This contention hinges on the allegation that the statute's broad applicability encroaches upon interstate commerce.

As of the time of this writing, no significant developments in the litigation have occurred.

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[34] COLO. REV. STAT. §§ 10-16-1406(4)(a)-(j).

[35] CO PRESCRIPTION DRUG AFFORDABILITY BOARD, 2023 AFFORDABILITY REVIEW SUMMARY REPORT: ENBREL (2023). CO Prescription Drug Affordability Board, Affordability Review Summary Report: Stelara (2024). CO Prescription Drug Affordability Board, Affordability Review Summary Report: Cosentyx (2024).

[36] Complaint, Amgen Inc. et al., v. Colo. Prescription Drug Affordability Board, No. 1:24-cv-00810 (D. Colo. March 22, 2024).

Washington

Per statute, the Washington PDAB has the authority to set payment rates statewide, including for all payers and all purchasers, for certain drugs. The methodology must not include QALY considering a patient's age or severity of illness or disability to identify subpopulations for which a prescription drug would be less cost-effective. For any drug that extends life, the board's analysis of cost-effectiveness may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit. Finally, the UPL must apply to all purchases by any entity and reimbursement for a claim by any carrier/health plan when dispensed or administered in the state by any means, the UPL must be reassessed annually based on current economic factors. However, carrier may disregard UPL and provide coverage if it is determined the drug should be covered based on medical necessity. The board is authorized to conduct up to 24 affordability reviews per year and to set UPLs for up to 12 drugs per year, no earlier than January 1, 2027.

Minnesota

Per statute, the Minnesota PDAB has the authority to establish statewide cost rate setting (UPL) for certain drugs provided its methodology include consideration of extraordinary supply costs, if applicable; the range of prices at which the drug is sold in the United States according to one or more pricing files (e.g., Medi-Span or FirstDatabank, or as otherwise determined by the Board); the range at which pharmacies are reimbursed in Canada; and any other relevant pricing and administrative cost information for the drug.[37] The board may not consider cost-effectiveness analyses that include the cost-per QALY or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability. For any treatment that extends life, if the Board uses cost-effectiveness results, it must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability. Finally, when setting a UPL for a drug subject to the Medicare MFP, the Board will use the MFP as the UPL. The board has begun the process of identifying eligible drugs and selecting drugs for cost review.[38]

Public Engagement Efforts

To support the work of the board and meet the requirements of SB 192 (to develop a plan for establishing upper payment limits on drugs sold in Oregon that are subject to affordability reviews), the board sought feedback from multiple constituent groups in Oregon. To fulfill its mandate to include outreach to constituent groups, the board worked with consultants Lou Savage and Myers and Stauffer LC (Myers and Stauffer) to host 23 community meetings and focus groups in April, May and June 2024. The board chair, vice chair, and consultants met with representatives from hospitals, pharmacies, insurance companies, manufacturers, pharmacy benefit managers, advocacy groups, patients and consumers. The board also hosted question and answer sessions with constituents during the July 24 board meeting.[39] In addition to the consumer and constituent group outreach, the board also offered three additional mechanisms for public engagement. Constituents wishing to provide oral comments or testimony at any scheduled PDAB meeting by submitting a public comment form no later than 24 hours before the PDAB meeting. Written comments could be submitted via a public comment form no less

[37] Publicly available Canadian prescription price/cost data comes from provincial public prescription coverage for people without drug coverage. The provinces post their drug by drug pharmacy reimbursement rates.

[38] MINN. COMMERCE DEP'T., MINNESOTA'S PRESCRIPTION DRUG AFFORDABILITY BOARD (2024).

[39] Upper payment limit study. https://dfr.oregon.gov/pdab/Pages/upper-payment-limit-study.aspx.

than 72 hours before a PDAB meeting. The same mechanisms could be used to submit oral or written comments specific to drugs under review by the board.[40]

Consumer Engagement

As previously described, the board contracted with Lou Savage, a past DCBS director of the Department of Consumer and Business Services and former Oregon insurance commissioner, to conduct in-person and online community forums across Oregon to discuss the high cost of prescription drugs and its effect on Oregonians' lives, health, and budgets. The board held events in five cities, along with two online meetings in April and May. About 156 people attended the sessions held in Portland, Lincoln City, Woodburn, Medford, Bend, and online through Zoom. For the community forums, the board selected locations around the state in venues that were centrally located and easily accessible to the public; the five in-person meetings were supplemented with two virtual meetings. The board also invited people to take a survey about medication names and costs, along with insurance coverage. Fifteen people completed the survey.

Consumers and advocates who shared their stories at the forums about their challenges with the cost of prescription drugs had a wide range of experiences; however, some common themes came through. Consumers are experiencing uncertainty, confusion, and anxiety about being able to afford and have access to the prescription drugs needed to maintain their health.

- Consumers experience uncertainty with the cost of their prescription drugs.
- Uncertainty about the ability to access prescriptions was frequently expressed.
- Consumers expressed confusion about how much they will need to pay for their prescription drugs.
- Consumers expressed anxiety about the future.

The board laid a foundation for future public input when it hosted seven community forums around the state in April and May 2024. The board can build on this foundation by engaging with the consumers throughout the year, inviting them to board meetings and informing them of the board's work. The board can also target its outreach to existing community events with high attendance. The board can plan and publicize future events well in advance and hopefully draw more people to come and share their stories about burdensome high-cost medications. The full consumer forum report can be found at https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Consumer-Report-2024.pdf.

Panel Discussions

The board held seven constituent panels during their July meeting. The panels used a question-and-answer format moderated by the board chair and which served as a follow up to the focus groups and community forums the board held to collect feedback about upper payment limits. The board heard from a consumer representative and representatives from PBMs, insurance companies, manufacturers, advocacy groups, pharmacies, and hospitals/FQHCs/providers. The consumer representative spoke to the board about the personal impact of drug prices, while the remaining constituent groups were queried about topics specific to their expertise. Topics included rebate pass through to consumers, insurance benefit designs, the impact of a UPL on manufacturer pricing strategies, data and data confidentiality, patient and provider protections, reimbursement impacts, and recommendations for strategies to address drug affordability.

[40] Public comment form. https://dfr.oregon.gov/pdab/Pages/public-comment.aspx.

Constituent Group Engagement

As previously described, the board contracted with Myers and Stauffer to conduct constituent outreach on the board's behalf. The purpose of this outreach was to capture the perspectives of constituents throughout the pharmaceutical supply chain regarding a UPL in general, rather than targeting discussions around a particular model or approach. Seven constituent groups were identified for targeted outreach: 340B Covered Entities (CEs), carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, PBMs, and retail pharmacies. Myers and Stauffer then developed and administered an informal survey and facilitated two, one-hour virtual focus group meetings per constituent group, to identify perceptions regarding strengths, weaknesses, opportunities, and threats associated with a UPL methodology. The surveys included a series of questions and multiple response questions, as well as free-text questions to allow recipients to provide more detailed information on approaches, recommendations, or concerns. Focus group questions were organized around topics including the impact of drug affordability impact of a UPL, UPL methodologies, desired state of drug affordability, and recommendations or other strategies. The full report can be found at https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Observations

Responses to the surveys and engagement with the focus groups found that all groups were concerned about drug affordability and the impact of drug affordability on their organizations, patients and/or members. While the constituent group discussions were not intended to assess affordability reviews or the previous work of the board, participants frequently mentioned the definition of affordability and a concern about how it should be defined. Participants also struggled to assess the impact of a UPL, indicating a need to better understand how it would be developed and implemented, and reflecting a lack of experience to draw from in other states.

Key concerns centered on revenue impact, impact to patient access, and system complexity. Regarding revenue impact, pharmacies were extremely concerned that a UPL will negatively impact already thin margins and that the savings from a UPL will come from reductions in reimbursement to providers rather than being borne throughout the supply chain. 340B covered entities, particularly Federally Qualified Health Centers (FQHCs), focused on their use of 340B savings and revenue to provide additional uncompensated services and copayment support to patients, and expressed concern that a UPL would require them to reduce or eliminate services. Patient impact concerns centered on potential manufacturer withdrawal from a market in response to a UPL, an unintended impact if manufacturers chose to reduce or eliminate patient assistance programs, and responses by PBMs or payers to shift utilization into non-UPL drugs through formulary design and benefit design changes that may lead to placing UPL drugs in a non-covered or higher copayment tier. System complexity was cited as a concern, especially related to implementation, contracting and necessary system enhancements. Participants also had questions around how the UPL was intended to be implemented for patients, payers, or providers who live or conduct business in states outside of Oregon, especially bordering states, or for costly therapies that may be administered at regional centers of excellence outside of Oregon.

Recommendations

The most frequently cited recommendations are noted in Table 1. It should be noted that there are additional recommendations that could be considered from the original Constituent Group Engagement Report presented to the board in August, 2024.[41]

[41] Draft Constituent Group Engagement Report. https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Table 1: Constituent Group Recommendations

Recommendation	Constituent Group Recommendations							
	340B CEs	Carriers	Hospitals	Patient Advocacy Groups	Pharmaceutical Manufacturers	PBMs	Retail Pharmacies (Ind./GPO/PSAO)	Retail Pharmacies (Grocery/Chain/ Wholesalers)
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Incorporate lessons learned from other state PDABs into the board's affordability reviews and UPL planning processes		✓		✓			✓	
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	

Plan for Establishing an Oregon-Specific UPL

The board has engaged in an extensive and intensive process, detailed here and in other public documents, to assess the feasibility of establishing an upper payment limit in Oregon as a method for improving drug affordability. Our discussions establish the complexity of the concept, the implementation, and regulatory considerations such an approach would warrant. As has been noted in public meetings, the establishment of a UPL would require flexibility of approach and adequate, likely lengthy, time to develop and test models, assess impacts, and implement through the rulemaking process (including public comment).

Prior to establishing UPLs, the board must first determine if a drug is unaffordable through the affordability review process. The board's enabling legislation requires the board to identify nine drugs and at least one insulin product under ORS 646A.694 that may create affordability challenges for the healthcare system or high out-of-pocket costs for patients in the state.

With UPL authority, if a drug is deemed unaffordable, the board would then consider setting a UPL on the drug or its therapeutic class. There are a variety of approaches that the board may choose to leverage; it may choose one or several of the methodologies for setting a UPL or it my subsequently identify other, unique approaches that were not contemplated at the time of this report. Upon determining a UPL approach or approaches, the board would then move through the rulemaking and public comment process to establish the upper payment limit. While the affordability review process is an important step on the path to setting UPLs, not all drugs reviewed will be considered for a UPL.

UPL Potential Methodologies

There are several approaches states may leverage when setting a UPL. The board considered a number of high-level approaches (general concepts) to setting a UPL, as well as associated methodology and implementation considerations (see Table 2 below). These are intended as a framework to drive discussion about what an Oregon-specific UPL approach might look like. Ultimately, any approach to setting a product-specific UPL could involve one or more approaches, be influenced by the type of drug (e.g., specialty, physician or self-administered, etc.), market factors (e.g., level of rebates or therapeutic competition), and other strategies that have not yet been identified. As such, this should not be considered an exhaustive list of options. Alternatively, the board may determine that a particular option presented below is no longer a viable option for consideration. There is a consensus that no single methodology will work for all drug products considered for a UPL, and that multiple approaches may be considered. The board will select the best option(s) for each drug or therapeutic class.

In addition to the potential specific approach(es) to developing a UPL, there are multiple models for implementing a UPL. A rebate model implemented at the state level would offer an opportunity for the State to leverage its buying power by consolidating utilization at the state level, including utilization for uninsured and underinsured patients that are not typically included in negotiations. This model offers the advantage of increased negotiating power, but is often hampered by opacity in the process and lack of transparency in the use of savings. Additionally, leveraging a rebate model similar to that used in the Medicare Fair Price (MFP) may not be a viable approach because it would likely place administrative burdens on providers and result in payment delays that could further threaten providers' financial viability, especially for retail pharmacies. An up-front, net cost approach would likely offer the benefits of a transparent upper cost limit throughout the supply chain and reduced administrative burden,

especially on downstream members of the supply chain such as carriers and providers. It may also provide an added benefit of visibility to patients, especially those who are uninsured or who have high coinsurance obligations. These operational level details will be determined through the rulemaking and public comment process.

Table 2: UPL Approaches (General Concepts)

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
Net Cost	Establish UPL at or near the existing average net price of the drug after any rebates or discounts negotiated between the drug manufacturer and PBM. UPL then becomes the benchmark from which patient out-of-pocket costs are calculated by payers. This is particularly useful for highly rebated drugs which are generally placed on high formulary cost share tier. Consider leveraging publicly available average sales price (ASP) data for provider administered drugs to ensure that patient out-of-pocket costs are based on reimbursement rates that reflect net price.	• Option could include use of rebates negotiated at a state-wide level • Highest potential for drugs with significant rebate opportunities • Concerns include administrative complexity and concerns around a lack of transparency • Desire to ensure distribution throughout the supply chain • Requires assurances that providers are kept whole
Reference Pricing to Existing Benchmarks	Establish UPL based on prices already negotiated or set by other entities. Reduces the administrative burden of conducting independent UPL analyses, provided that the external prices are useful comparators. Most common external references include the price of drugs negotiated by other countries, Medicare MFP, and/or price negotiated by the Department of Veterans Affairs. NASHP has published a model bill leveraging MFP as the ceiling for all purchases of a referenced drug and reimbursements for a claim for a referenced drug when the drug is dispensed, delivered, or administered to a person in the state.[43]	• Use of drug prices negotiated in other countries is an option, but is controversial and would be challenging to evaluate and implement • International reference pricing carries the risk of limiting manufacturer participation in the process • Using a U.S. published reference pricing file, such as VA federal supply schedule pricing offers the benefit of being publicly available and easily accessible and could serve as a benchmark for state-level negotiations with manufacturers • Must ensure that using VA pricing as a benchmark does not create Medicaid best price implications

[42] Program on Regulation, Therapeutics, And Law (PORTAL), Determining Upper Payment Limits: Considerations for State Prescription Drug Affordability Boards (PDABs) (2024), *available at* https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf.

[43] NATIONAL ACADEMY FOR STATE HEALTH POLICY, AN ACT TO REDUCE PRESCRIPTION DRUG COSTS USING REFERENCE-BASED PRICING (2022), *available at* https://nashp.org/an-act-to-reduce-prescription-drug-costs-using-reference-based-pricing/.

UPL Approaches (General Concepts)[12]		
Concept/Source	**Description**	**Considerations**
Reference Pricing to Therapeutic Alternatives	Establish UPL based on the price of drugs that can be used in place of the selected drug. For drugs with multiple approved indications, the therapeutic alternatives may differ for each indication. In these instances, it may be necessary to only include alternatives that are approved for all of the same indications as the selected drug; or to set separate prices based on reference groups for each of the drug's indications. Where multiple alternatives exist, health plans and PBMs often select one or two "preferred" drugs within a class, which often have lower out-of-pocket costs for patients than non-preferred alternatives. Consider setting same UPL for all therapeutic alternatives, based on the lowest-priced drug of the group.	• Setting a UPL at a therapeutic class level increases the complexity of the analysis needed • This option could avoid some of the challenges noted by constituent groups that an unintended consequence of a UPL could be that an agent is moved to a non-preferred status to avoid the UPL • Long contracting runways with PBMs and carriers could be a barrier to implementation
Launch Price Indexing	Establish a UPL that uses the product launch price and indexes that price to the yearly or consolidated average CPI.	• Indexing the UPL to a launch price plus an appropriate annual CPI provides a straightforward option that may have reduced complexity at implementation • Concerns that increased or higher launch prices could be an unintended consequence of this approach • Changes to Medicare (new financial penalties for drug prices that increase faster than inflation) and Medicaid (price inflation penalties are uncapped and can exceed the WAC of a drug) make this option most applicable to drugs that have been on the market a long time with price increases before the change to Medicare and Medicaid rebates.
Percentage off of WAC	Establish a UPL that is a fixed percentage off of WAC. For brand drugs, the federal minimum Medicaid rebate is 23% of the AMP, which is confidential but, given the formula, is likely to be close to WAC. If a board is uncertain about the level of discounting in the market for first-in-class or other type of sole source products, but the drug is causing clear affordability challenges (e.g., clearly resultant premium increases, very high patient cost sharing, minimal manufacturer	• Offers a straightforward approach • Could leverage information available through a data call to determine a reasonable discounted WAC • Information is often hard to obtain • Inaccuracies in the data or inability to obtain the data could result in setting a WAC that is too low or too high

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
	patient assistance), this approach may be sufficient to induce payers to improve patient access.	
Payer Return on Investment (ROI)	For a drug that has been subject to valid pharmacoeconomic research on value/cost savings, establish an initial UPL with a minimal lower cost and assess health plan savings over a given period (e.g., 5 years). Limiting the period in which medical benefits and savings start to accrue is important, as multimillion dollar drugs that produce savings over a lifetime may not be affordable to the healthcare system for many years.	• Allows the board to assess the potential savings from a UPL along with a drug's positive impact on overall cost of therapy • A long period for assessment may limit the utility of the approach
Budget Impact-Based	Establish a UPL such that spending on the drug does not exceed a certain percentage of a given budget or have a disproportionate impact on a given budget. Could be accomplished by limiting the drug's contribution to increases in health insurance premiums (i.e., premium growth thresholds) or by leveraging a modified budget impact analysis to establish cost savings targets (i.e., assessment of costs only, rather than costs and health outcomes, as is done in cost-effectiveness analyses).	• Complex concept that requires more exploration • Assessment of the unintended consequences of the approach such as high launch prices
340B Program-Specific	Establish a UPL reimbursement adjustment for some or all 340B entities. The cost of drugs for 340B entities is approximately equal to the net cost after Medicaid rebate for the drug, although unlike Medicaid, it may not go below a penny. The 340B supply chain will continue to be discrete with much lower costs than even a UPL for a variety of programmatic reasons.[44] Regardless, profit on UPL drugs will be less than in the absence of a UPL.	• Requires an assessment of the cost to the 340B market • Recognition that the margins are important to Oregon covered entities since there is no state funding for non-grantee programs • Concern that this option doesn't fulfill the desire to ensure that all Oregonians benefit from a UPL

[44] For brand drugs, the Medicaid rebate and corresponding discounts available through the 340B program are based on 23 percent of the Average Manufacturer Price (AMP), which is roughly equivalent to federal WAC or, if greater, AMP minus the Best Price in the market to almost any entity *and* an inflation penalty rebate. A Consumer Price Index (CPI) penalty is added if/when the AMP of the drug in a given quarter exceeds CPI growth. In general, it is the CPI penalty that produces very low costs and very high rebates, and affects drugs that have been on the market many years. Best Price does *not* include the CPI penalty. Best Price may be much higher than the total 340B cost (i.e., federal rebate + CPI penalty). Under current law, a Board should avoid creating a UPL that creates a new Best Price, as it would likely automatically be extended to every state Medicaid program.

Analysis of Resources Needed by the PDAB to Implement UPL

Additional resources may be necessary to implement a UPL plan. The board must identify if the UPL shall be placed within the supply chain, as a pricing benchmark similar to WAC, rebate mechanisms, or another mechanism altogether that may be identified at a later time. Resources will be needed to support the development of a UPL, any costs or savings analysis that must be performed, and implementation support that may be required to support the board's ongoing work. Initial considerations are identified below and subsequent reports will likely result in additional recommendations. Resource requirements will be driven by the many options that are still under development not only for the UPL, but also by the stated desire to improve access to data, improve affordability review processes, and expand constituent group engagement.

- The board may need to utilize the services and expertise of the Office of Pharmacy Policy, Purchasing and Programs within OHA. This would be in lieu of creating a new government function or enlarging the PDAB to manage implementation. If needed, the Office could contract with wholesalers dedicated to supply UPL products into Oregon and work with manufacturers to prevent diversion.[45]
- The board may need to contract with the OHSU Center for Evidence-Based Policy to support the board's work. The Center provides assistance in areas such as strategic planning, training, and clinical and process consultation.
- Commercial products exist that can assist with determining the estimated impact and availability of rebates in the non-Medicaid space; if the board wishes to explore these options, separate funding will be required.
- If there is a desire to establish an advisory committee or council that includes representatives of the constituent community, including patients, providers, caregivers and other, the board may need additional staff to support the activities of this council. The number and type of staff would be determined after an assessment of current staff availability and workload.
- The Oregon Health Authority and plans administered by the Public Employees' Benefit Board and the Oregon Educators Benefit Board will be impacted by a statewide UPL.

Analysis of How UPL Would be Enforced[46]

A statewide UPL is generally intended to be self-enforcing. For example, suppliers, pharmacies, and hospitals have no incentive to buy a UPL product at a cost higher than the UPL given subsequent purchasers will not pay more than the UPL. Further, public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State, and consumers will be aware of what they should be charged when paying for a drug.

One potential enforcement challenge could be diversion. This has the potential to occur when a supplier buys a quantity of products subject to a UPL and then sells the product at market price into another state. In 2013, Congress passed the Drug Supply Chain Security Act (DSCSA), which establishes a track and trace system for prescription drugs to reduce diversion and counterfeiting of drugs.[47] Once the DSCSA is fully implemented, diversion will become less likely. A state may want to contract with a wholesaler dedicated to distribution of UPL products. The wholesaler can work with manufacturers on

[45] Horvath Health Policy, *Upper Payment Limit Operational Features*, March 2024.
[46] Horvath Health Policy, *Upper Payment Limits*, March 2024.
[47] U.S. Food and Drug Admin., Drug Supply Chain and Security Act (DSCSA) https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

avoiding diversion. State offices that operate the federal (free) Vaccine for Children Program may also have experience to share thwarting diversion laws.[48]

Authorities Necessary for Enforcement of UPL

Leveraging UPL authority as a mechanism could improve prescription drug affordability for Oregonians; however, it also recognizes that a lengthy implementation will be required, given the effects on contractual relationships, potential procurement implications on the supply side, and a desire to ensure that implementation addresses concerns expressed by constituents. Moreover, implementation and enforcement of a UPL will require the board to conduct rulemaking through the authority granted under ORS 646A.693. The proposed list of authorities below are not considered exhaustive, and will likely require further evaluation as the board pursues its work.

- The board will require statutory authority to establish UPLs and conduct rulemaking, inclusive of a transparent public notice and comment period.
- Regulatory authority is likely required to establish an advisory council to support the board's work.
- Using a supply side or buy side approach that establishes a UPL for all transactions in the State could require regulatory authority to establish the UPL as the maximum amount to be paid throughout the supply chain.
- Regulatory authority may be required to establish a UPL at the class level, and reduce the unintended consequence of moving coverage away from a specific drug (as appropriate) in an approach that result in a situation that functions similarly to a protected class in the Medicare program.
- Regulatory authority may be required to establish an acceptable time period for implementing a UPL within systems and contracts, or to automatically apply the UPL to existing contracts without re-negotiation.
- Regulatory authority necessary to establish wholesaler relationships as needed to support the program.
- Board discussions have identified a need for improved claims data. Evaluation of recent PBM data may identify areas of improvement that will require a new or updated regulatory authority. Similarly, carrier data improvements could require updated regulatory authority to strengthen reporting requirements.
- Pharmaceutical manufacturers have indicated a willingness provide more data. Expand confidentiality protections and improve regulatory authority as needed to support these initiatives.
- Regulatory authority to establish a reporting mechanism and associated staffing to provide individuals at any level (consumers, supply chain members, etc.) with a mechanism to report noncompliance with the use of the UPL for pharmacy transactions in the state of Oregon.

Analysis of how UPLs Could be Implemented

This section will discuss the considerations for implementation for constituent groups including PEBB, OEBB, state administered health benefits, health benefit plans, and other forms of health insurance. The board's work, as described in the 2024 Annual Report, is "to consider prescription drugs that may create

[48] Horvath Health Policy, *Upper Payment Limits*, March 2024.

affordability challenges for Oregonians and the state's health care system."[49] The board work plan published on August 3, 2022, expresses an intent to study the "entire prescription drug distribution and payment system in Oregon". The discussion, which includes upper payment limits along with other options, frames the UPL as applying to "all financial transactions in this state involving a drug" and specifies that it should not "undermine the viability" of any part of the drug supply chain.[50] Throughout its deliberations, the board has consistently reiterated that an upper payment limit must not be determined to be harmful to the overall supply chain or damage an already fragile system, especially for disadvantaged populations.[51]

As described in this and other reports, the board undertook significant activities to engage constituent groups and solicit feedback on the use of a UPL, potential consequences of implementing a UPL, and alternative solutions for either developing a UPL or developing alternative or complementary strategies to improve drug affordability for all Oregonians. The board engaged consumers, pharmacy providers, PBMs, wholesalers, PSAOs and GPOs, pharmaceutical manufacturers, hospital providers, 340B covered entities, and insurance carriers licensed in the state in public comment forums. The board has also engaged with other state agencies, such as the Oregon Health Authority, to assess the impact on the state Medicaid program and on the Oregon Educators and Public Employees Benefit Boards. Each option ultimately put forth by the PDAB will be evaluated against various metrics. All metrics may not be applicable to all potential options. Generally, the approaches taken by the board will assess:

- The operational impact to constituent groups in the supply chain, including an assessment of reasonable allowances for implementation (systems, contracts and other impacts) and necessary legislative changes to ameliorate negative impacts to the greatest extent possible.
- The rulemaking necessary to ensure transparency in UPL implementation and provide financial protections for providers and consumers within the pharmaceutical supply system and ensure that providers, consumers, payers, insurance carriers, and state health authorities receive the benefit of savings generated through a UPL or other mechanisms.
- The rulemaking necessary to address the major concerns described by constituents during the forum discussions, especially:
    - Protections for the confidential and trade secret information from manufacturers, PBMs, carriers and others that is necessary to conduct affordability reviews and assess system savings and impact
    - The intersection of the use of an acquisition cost model and appropriate dispensing fee and the appropriateness of leveraging existing information from other state agencies, such as cost modeling by OEBB or PEBB or clinical reviews by the Medicaid agency, to develop Oregon-specific reimbursement models. Legislative and regulatory support will be required to appropriately gain access to the data needed to fully evaluate the impact on supply chain; for example, the impact of changes in provider reimbursement methodologies.
    - The potential to reinvest savings into the supply chain, for example, supporting changes to reimbursement models to community pharmacies or preserving access to services

[49] 2024 Report for the Oregon Legislature: Generic Drug Report Pursuant to Senate Bill 844 (2021), Oregon PDAB, https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Generic-Drug-Report-2024.pdf.
[50] Oregon PDAB Agenda, Proposed Work Plan, August 3, 2022, https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf.
[51] Oregon PDAB Minutes, November 16, 2022 https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-approved-minutes.pdf.

provided by 340B covered entities, such as federally qualified health centers, who do not otherwise receive state funding.

As the approach to the upper payment limit is defined, the board will engage the resources needed to assess the impact of any proposed upper limit on the supply chain, including gathering input from constituent groups regarding potential areas of impact. While not an exhaustive list, this could include an estimated impact on patient copayments based upon claims provided by the carriers, an impact assessment by Medicaid to ensure there is not an unanticipated impact on best price, or impact of the UPL on net costs and copayments for the benefits provided to state employees and Oregon educators.

Current Analysis of Potential Costs and Savings

The board initially aimed to analyze and model costs associated with implementing a UPL and the resulting savings across various points within the pharmaceutical supply chain. The implementation of a UPL could potentially yield savings for the State, insurers, hospitals, pharmacies, and consumers. Myers and Stauffer elected to use a net price strategy to establish a "proxy" for determining the impact of a UPL. This approach links a UPL to the net price of a drug after accounting for rebates and discounts. Many of the products selected for initial affordability were found to be highly rebateable. Since patient copayments are generally based on the total cost of a product, reducing this cost could potentially lower patients' out of pocket expenses. The complexity of the pharmaceutical supply chain, along with the intricacies of drug reimbursement, has made this analysis challenging.

Board staff provided Myers and Stauffer with data which included insurance carrier list price concessions for specific prescriptions medications, which varied by carrier and market type. The quality and completeness of this data was higher for medications that are typically dispensed by outpatient pharmacies and self-administered by the patient. Conversely, the quality and completeness of list price concession data was more limited for medications that are typically administered to the patient by a health care provider. Using the available list price concession data, it is possible to express these concessions as a percentage of the list price. For each medication, three distinct price concession percentages were selected, either based on the data received or, in cases where data was limited, based solely on historical experience. These percentages were then applied to the current list price (WAC) of each medication, resulting in three potential UPLs for each medication. These theoretical UPLs were subsequently provided to Oregon PDAB staff for use in their modeling. The PDAB staff has tasked PEBB, OEBB, and Oregon Medicaid with modeling the costs and savings associated with these theoretical UPLs using utilization data from their plans. An overview of findings are reported below; full reports are included in the appendices.

Potential savings and costs are indeterminate at this time; savings and costs will be impacted by the drugs selected for UPL and the methodologies chosen to establish the UPL.

PEBB/OEBB Analysis

On behalf of the Oregon Health Authority (OHA), Mercer Health & Benefits LLC analyzed prescription and medical drug costs, utilization, and enrollment data for PEBB and OEBB for the period of April 1, 2023, to March 31, 2024. They calculated the impact of the proposed UPL scenarios for eight selected drugs. It was expected that the reduction in in the point of sale drug prices due to UPLs would result in lowered or eliminated rebate payments. Because this was a novel proposal, the rebates retained with UPLs in place were uncertain. To account for this uncertainty, the three different UPL scenarios were modeled with no rebates (0 percent) as well as 25 percent and 50 percent of the current rebate retained, with the most conservative estimate being that rebates for the affected drugs are eliminated upon implementation. The analysis never allowed the rebate to exceed the ingredient cost for a drug/scenario combination.

Under a scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a cost savings of $18.7 million (price reduction exceeds existing rebates) to a combined increase of $12.1 million in plan spend (where the modest price reduction is less than existing rebates). The UPL scenario prices for drugs commonly used in the medical benefit represent less of a discount from WAC than the UPL scenarios provided for drugs typically dispensed through the pharmacy benefit. As a result, there is more opportunity for savings in the pharmacy benefit than the medical benefit.

Board staff observed that the projected outcomes leading to increased program costs were based on assumptions of a modest UPL reduction from WAC and the complete elimination of all rebates. However, total loss of rebates may not be a realistic assumption. Conversely, setting a UPL close to the current net price after rebates while assuming retention of 25 to 50 percent of rebates is also unlikely. In general, if implementation a UPL results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings. Board staff expect analysis of commercial plan data would have similar findings. Given the complexity of the drug supply chain, it is important to consider a range of scenarios and account for potential market shifts that could continue to offer price concessions where feasible.

Medicaid Analysis

In order to model impacts to the Oregon Medicaid program, board staff tasked OHA with modeling costs utilizing the three theoretical UPL points as above. OHA's Office of Health Analytics pulled coordinated care organization (CCO) encounter and fee-for-service (FFS) claims data for the year ending June 2024 from OHA's Decision Support and Surveillance Utilization Review System (DSSURS)/Medicaid Management Information System (MMIS) database. The Office of Actuarial and Financial Analytics (OAFA) built models for each payer and claim type, comparing actual payment levels against an estimate of payments limited by a UPL. Savings were estimated on a gross (total payments) and net (Oregon Health Plan [OHP] payments) basis. Changes to rebates were not considered in the calculation. First-dollar savings were expected to apply to OHP.

In terms of budgetary impact, the FFS costs are presumed savings, but would be offset by any reduction in pharmacy rebates. Due to timing and data constraints, OAFA did not attempt to model any rebate impacts. In assessing budgetary impact, OHA would also want to look more closely at members' category of aid to determine what proportion of the total will be state funds – 25 percent to 30 percent would be the likely proportion of state funds. In addition, there appear to be some Indian Health Care Provider claims (based on payment amounts) that should potentially be excluded from analysis. Put together, these factors suggest the $2.26 million in net FFS savings under the tightest UPL scenario might result in state budget savings of less than half a million dollars.

For CCOs, the financial impact is likely to be "absorbed" in capitation rate setting. Each year OHA tries to set capitation rates approximately 3.4 percent higher than the prior year. To the extent there are benefits or costs expansions that are not separately funded by the legislature (which happens regularly), OHA prices those into capitation rates but still fits the overall rates within the 3.4 percent budgetary increase. This process essentially subjects all other services or policy levers to a lower level of increase within the capitation rates.

In the case of the UPL application, the opposite could become true: any material expected savings to CCOs would be reflected in capitation rate development, but in absence of any direction to the contrary OHA would still target a 3.4 percent overall increase, which would leave more room for inflationary or policy increases in other areas of rate setting. However, if OHA were expecting a decrease in pharmacy rebates, the 3.4 percent target might be adjusted to offset the loss of pharmacy revenue. Therefore, unless the Legislature asks OHA to bank the savings (of which perhaps 25 percent to 30 percent would be the state's to retain), a UPL likely would not result in savings to the state but rather lead to reinvestment of the proceeds into other CCO expenditures.

For context, the CCO system is expected to incur around $6.2 billion in service costs during calendar year 2025. A savings of $56 million represents around 0.9 percent of costs, which is a significant impact in the context of rate setting. Again, offsetting for rebates foregone would reduce that potential savings/reinvestment.

Medicare Maximum Fair Price Analysis

On August 14, 2024, CMS provided an update on its progress in the Medicare Drug Pricing Negotiation Program. This program stems from the enactment of the Inflation Reduction Act of 2022, which affords CMS the "ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition." The CMS negotiated price for a given drug is known as the Maximum Fair Price (MFP).

As CMS continues its MFP program, Oregon's PDAB may be able to draw parallels and model similar effects if a UPL is used in the state. PDAB staff completed an analysis to examine the potential estimated savings to health plans using the recent CMS negotiated drug prices.

It is important to note this analysis was not a comprehensive comparison based on the entire Oregon pharmaceutical marketplace. The Oregon data was limited to commercial insurance carrier reporting to the Drug Price Transparency program. This only includes specific plan types (i.e., large, small and individual) while excluding groups such as Medicare, Medicaid, self-insured, PEBB, and OEBB. The analysis was only intended to model the potential savings based from the MFP negotiated pricing.

The analysis utilized carrier data and pricing from 2023 and identified potential savings per drug to be between 51 percent and 88 percent of the 2023 spend when using the MFP negotiated prices. Overall, the analysis identified approximately $37 million in savings across the 11 modeled drugs.

Future Analysis of Potential Costs and Savings

Work by Horvath Health Policy has found that upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the prescription product to which a UPL is applied comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The product with a UPL is then available to everyone, including individuals without insurance. Under this scenario, a wholesaler negotiates with the manufacturer to buy the product at or below the UPL and the UPL replaces the wholesale acquisition cost for in-state transactions.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operates consistent with current practice and each participant in the supply chain realizes some margin (profit) on the product. The product (ingredient) reimbursement made by the payer is the amount of the UPL (professional fees are not part of the UPL).[52]

While Senate Bill 192 requires an analysis of the costs of implementing the plan with respect to various constituent groups, a detailed analysis is premature at this time. As specific UPL approaches are identified and finalized for specific drugs or drug classes, future analytics may be performed to estimate the cost to each of the various constituent groups. It should be noted that the discussions with specific focus groups, as detailed in other documents, provide some insight into issues or concerns that warrant additional consideration or evaluation.

Pharmacy

Assessing the impact of a UPL on pharmacies includes modeling pharmacy acquisition costs and reimbursements. With access to wholesaler drug purchasing and sales data, as well as pharmacy dispensing and reimbursement data, it would be possible to model different UPL acquisition costs and quantify savings at the pharmacy level. However, pharmacies and wholesalers are not obligated to provide

[52] Horvath Health Policy, *Upper Payment Limits*, March 2024.

drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Oregon Actual Average Drug Acquisition Cost (AAAC) and the NADAC benchmarks. Additionally, the state may not have full access to non-public payer data specific to Oregon. Modeling could potentially use data from state-administered plans and summary data from state-regulated entities. Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and State Drug Utilization Data (SDUD) for Medicaid programs (which can be obtained at the Oregon-specific level). However, data from cash payers may not be accessible. Pharmacy reimbursement data from PBMs and patients will be difficult to obtain and will vary by pharmacy organization. Aggregating pharmacy reimbursement data across different pharmacies would be necessary to project statewide effects. Projecting pharmacy acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current pharmacy acquisition costs and pharmacy reimbursements from PBMs and patients as a percentage of WAC.

Commercial Insurance Carriers

Assessing the impact of a UPL on carriers includes an analysis to quantify total gross and net prescription drug spending and the total rebates generated. Under a UPL model, total prescription drug gross spending for a specific UPL product is expected to decrease, along with a corresponding decrease in rebates generated. The overall impact on health plans will depend on the relative change in reimbursements resulting from the UPL and any reduction in rebates after UPL implementation, which may offset each other. Pharmaceutical manufacturers would likely decrease rebates in proportion to the reduction from WAC to UPL. Consequently, once a UPL is set, current claims data could be adjusted to simultaneously decrease total payments in claims to pharmacies and reduce manufacturer rebates, resulting in a net "wash" on prescription drug net spending. Claims data for Oregon State Employee Plans (OEBB and PEBB) could serve as a representative data source for commercially insured health plans. Other data, if made available from commercial health plans with members in Oregon, could also be analyzed. However, this analysis may be limited as actual claims data and rebate data correlated with the same claims are generally considered proprietary to health plans and PBMs and may be difficult to obtain.

Patient Out Of Pocket Spending

Drug affordability often centers on patient out of pocket spending. Assessing the impact of a UPL on patients could be conducted with access to detailed carrier claims data, including pharmacy reimbursement, patient out of pocket amounts, remaining deductible, and remaining out of pocket maximum for each claim. Aggregated data will not be useful in modeling changes to patient out-of-pocket spending due to the numerous variables involved in determining where a patient stands concerning their deductible and out of pocket maximums at any given time. Existing claims data could be modeled using a UPL instead of the current total reimbursement to the pharmacy, potentially lowering patient out of pocket spending and slowing progression through deductible and out of pocket maximum phases. However, the necessary claims data to fully model the effects on patient out-of-pocket spending may not be available. Deductibles and out of pocket maximums can vary from one health plan to another, so calculations based on assumptions from one health plan should not be extrapolated to others. However, the cost to patients either at the point-of-sale or through cost-sharing or coinsurance could be expected to be reduced based on the lower list price of the drug. The availability of patient assistance programs currently provided by drug manufacturers should also be considered in an assessment of UPL impacts to patient out-of-pocket spending.

Hospitals

Assessing the impact of a UPL on inpatient and outpatient hospital charges and associated reimbursements would require various data including inpatient and outpatient standard drug charges,

mark-up methodologies, and reimbursement methodologies for hospitals. The implementation of UPLs may alter the standard charges set by hospitals to the extent that UPLs are incorporated into the mark-up methodologies for setting standard charges. Reimbursements from third parties may or may not be directly impacted by UPLs, depending on the reimbursement methodologies, which will vary by hospital, third-party payer, and whether the drug was used in an inpatient or outpatient setting.
The complexity and variability in methods for setting hospital standard charges, along with the complexity and variability in inpatient and outpatient bundled payment methodologies, present significant limitations in realistically modeling the impact of UPLs on hospital charges and associated reimbursements.

Physician Offices and Clinics

A UPL could impact both pharmacy payments and payments for drugs administered in an office setting. To model any UPL impacts in this setting, the board would require detailed purchasing data from wholesalers and reimbursement data from insurance carriers. Providers and wholesalers are not obligated to provide drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Average Sales Price (ASP). Additionally, the state may not have full access to non-public payer data specific to Oregon. Data from state-administered entities (e.g., Medicaid, PEBB/OEBB) could be obtained from the state. Data from state-regulated entities may be available in summary form through data calls (e.g., commercial insurance). Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and SDUD for Medicaid programs (which can be obtained at the Oregon-specific level). Data from cash payers may not be available. Provider reimbursement data from carriers and patients will be difficult to obtain and will vary by provider. Aggregating reimbursement data across different provider organizations would be necessary to project statewide effects. Projecting acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current provider acquisition costs and reimbursements from carriers and patients as a percentage of WAC.

340B Covered Entities

To model the effect of a UPL on a 340B covered entity, the board would need access to 340B acquisition costs, dispensing fees, prescription drug volume and costs, as well as reimbursement data from insurers. The implementation of a UPL should not affect 340B acquisition costs for covered entities. However, a UPL would decrease total payments for drugs, thereby reducing the amount of 340B savings or revenue generated from any prescription for a drug with an applied UPL. 340B acquisition costs, contract pharmacy dispensing fee information, and utilization (by NDC) could be provided by participating covered entities. However, 340B covered entities are generally reluctant to disclose this information, and there are confidentiality concerns associated with sharing their acquisition costs.

Appendices

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Legal Considerations

Federal Patent Preemption

Importantly, upper payment limits do not regulate manufacturer list pricing. Instead, a UPL is a payment rate limit on state regulated entities that buy, sell, bill or reimburse prescription drugs. The UPL does not govern a manufacturer's price, and a manufacturer can decide to forego a state's market for the product entirely. The Medicare MFP negotiation with manufacturers is also a voluntary process and federal circuits have thus far (as of the date of this document), found that manufacturer rights are not violated by voluntary government programs. . If there is a challenge to UPLs based on patent law, a state in that case should use federal healthcare/prescription laws to show that Congress does not intend that patent rights supersede the need for affordable prescription drugs.[53] Examples of Congress' intent that patent rights should not impede access to healthcare include thirty years of the 340B program and the new Medicare MFP program.[54] Both these programs would seem to indicate that when it comes to access to pharmaceuticals and affordable healthcare, patent rights are not top of mind. In fact, the new Medicare program specifically targets drugs with exceptionally extended patents and other market protections.[55]

In *Biotechnology Industry Organization v. District of Columbia*, pharmaceutical and biotechnology trade associations, PhRMA and BIO, challenged a DC law directly prohibiting drug manufacturers from selling patented prescription drugs at excessive prices in the District as unconstitutional due to federal preemption (and Dormant Commerce Clause). The Federal Circuit agreed, reasoning that the law's exclusive focus on patented drugs would penalize high prices and restrict the full exercise of patent rights. A National Academy for State Health Policy (NASHP) white paper regarding PDABs asserts that states can mitigate preemption concerns by designing PDABs to analyze and review the affordability of both patented and non-patented products, and, if necessary, impose upper payment limits on them.[56] The judge in BIO v. DC explicitly differentiated his ruling on the DC law from potential future cases involving non-patented drugs. Consequently, a UPL law encompassing both patented and non-patented products would be legally stronger.

Dormant Commerce Clause

The Federal government, by virtue of the Constitution's Commerce Clause, regulates commerce between the states.[57] States regulate in-state commerce.[58] State regulation can have ancillary out-of-state business impacts that do not reach a threshold of regulating interstate commerce.[59] State authority to regulate commerce is not written in the Constitution but state authority to regulate commerce, or the limit of that authority, has evolved over time through court decisions and is referred to as the Dormant Commerce Clause (DCC).[60] Specifically, relying on *Dep't of Revenue of Ky. v. Davis*, manufacturers may claim that states attempts to set reimbursement rates for drugs are "designed to benefit in-state economic interest

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[53] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023).

[54] Id.

[55] Id.

[56] https://www.nashp.org/wp-content/uploads/2022/08/White-Paper_NASHP-Proposal-for-State-Based-PDABs_Sachs_042622.pdf

[57] Horvath Health Policy, State Prescription Drug Affordability Board and the Dormant Commerce Clause (DCC), April 2023.

[58] Id.

[59] Id.

[60] Id.

by burdening out-of-state competitors" therefore violating the DCC.[61] To further support their claim, manufacturers may point to the recent case, *Association for Accessible Medicines v. Frosh*, in which the court struck down a Maryland law that prohibited "price gouging in the sale of an essential off-patent generic drug" on the grounds that it "directly regulates transactions that take place outside of Maryland."[62] In the NASHP white paper cited above, the authors argue that there are at least two reasons that manufacturers' DCC claims are likely to fail. First, PDABs can choose to limit their UPLs to sales made or products distributed within the state thus limiting DCC concerns. Second, the Association for Accessible Medicines decision applied a more restrictive reading of the DCC than previous courts and therefore is arguably a departure from existing DCC precedent. Also, the branded drug industry operates differently than the multi-manufacturer generic drug product industry and those supply chain distribution differences are substantial. Remediation in the *Frosh* and other price gouging legislation allows a state to require a roll back of prices for multi-source generic product sold in the state at the unacceptable price as one example of a Commerce Clause question.

Medicaid "Best Price"

The Medicaid Drug Rebate Program (MDRP), authorized by Section 1927 of the Social Security Act, requires that drug manufacturers enter into a rebate agreement with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. The rebate formula is set in statute and is designed to ensure that the Medicaid program receives the "best price" available in the marketplace (i.e., the lowest price offered to any U.S. purchaser or payer during a rebate period) or if greater, a flat rebate percentage as specified in federal law. In effect, if a UPL is lower than the deepest price concession in the market, this would create a new national best price available to all Medicaid programs. A UPL that would create a new national Medicaid best price would likely be challenged as a dormant commerce clause violation with implications for the UPL program. A State would presumably obviate a UPL that created this situation.

ERISA Preemption

ERISA is a federal law that sets minimum standards for private, employer-sponsored retirement and health plans. ERISA preempts "any and all state laws" to the extent that they "relate to" employee benefit plans.[63] Whether state laws are preempted by ERISA has been debated by federal courts through the years, leading to a complex web of competing judicial decisions surrounding the issue.

The question of whether a UPL set by a state PDAB is preempted by ERISA has not yet been considered by the courts. Perhaps the most instructional case for how courts may rule on an ERISA challenge to a UPL methodology is *Rutledge v. Pharmaceutical Case Management Association*. In *Rutledge*, the Court held that "state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA."[64] As long as the state law does not bind plan administrators to any particular choice, a state law will not be preempted by ERISA. Establishing a UPL methodology is a rate setting measure, and the court in *Rutledge* held that state rate setting is not preempted by ERISA.

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[61] *Dep't of Revenue of Ky. v. Davis,* 553 U.S. 328, 338 (2008) (quoting New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273-274, (1988)).

[62] *Association for Accessible Medicines v. Frosh* 887 F.3d 664 (4th Cir. 2018).

[63] 29 U.S.C. § 1001 Et. Seq.

[64] *Rutledge v. Pharmaceutical Case Management Association*, 141 S.Ct. 474 (2020).

On the other hand, a Supreme Court case from 2016, *Gobeille v. Liberty Mutual,* upheld the ERISA plan objection to reporting data to the Vermont All Payer Claims Database.[65] The Court found that the administrative burden of complying with various state claims payment, enrollee data, and other plan data reporting laws affected the heart of plan administration, and, therefore, the state law was preempted by ERISA.[66] Unlike in *Gobeille*, where the state law affecting reporting was struck down because it interfered with nationally uniform plan administration, establishing a UPL in Oregon likely will not interfere with the administration of ERISA plans. A UPL is a requirement to buy and bill at the UPL. The ERISA plan benefits and basic administrative functions are not affected.[67] Implementing a UPL using rebates to plans may be complicated by ERISA preemption.

Medicare Preemption

Recent case law has expanded interpretations of federal preemption of state laws that might affect Medicare Parts C and D plans. The preemption is arguably broader than ERISA. Regardless of preemption, a UPL is designed for the passive participation of ERISA and Medicare plans as they are billed at the UPL by pharmacies, clinics, and other providers. Presumably the UPL is less than the prevailing market rate that would otherwise be used in provider billing, so ERISA and Medicare plans have no incentive to reimburse higher, but they could. However, because the preemption is broad and can be litigated by any constituent group, such as drug manufacturers, it is best to specify in law that a UPL cannot be enforced in Medicare Part D. Medicare preemption may complicate implementing a UPL via rebates.

[65] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits,* (2023). Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016).

[66] Id.

[67] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits,* (2023).

Upper Payment Limit Operational Features, Horvath Health Policy

In General

Upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the UPL prescription product comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The UPL product is then available to everyone, including people without insurance. The wholesaler negotiates with the manufacturer to buy the product at or below the UPL.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operate the same way as they always have and the supply chain makes some margin (profit) on the product along the way. The acquisition cost to the pharmacy/other providers should not be more than payer reimbursement formulas. In a statewide scenario, the payer product reimbursement is the UPL (professional fees are not part of the UPL).

In setting the UPL for a drug product of concern, the Board will take into consideration whether there are exceptional handling or storage requirements for the drug of concern, among many other considerations.

Oregon may want to consider utilizing the services and expertise of the Office of Pharmacy Policy, Purchasing and Programs within the Oregon Health Authority. This would be in lieu of creating a new government function or enlarging the PDAB to manage implementation. If needed, the Office could contract with wholesalers dedicated to supply UPL products into Oregon and work with manufacturers to prevent diversion.

Enforcement

A Statewide UPL is generally self-enforcing. Suppliers, pharmacies, hospitals have no incentive to buy a UPL product at cost higher than the UPL because subsequent purchasers will not pay more than the UPL and public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State; consumers will be aware of what they should be charged when paying for a drug. The potential enforcement challenge could be diversion: a supplier might buy a quantity of UPL product and then sell the product at market price into another state. This will be easy to track once the federal 'track and trace' program is fully implemented and will diminish the feasibility of diversion. The Oregon Attorney General's office would have general authority to pursue violations of laws.

Self-Funded Employer Plans and Medicare

Because providers and suppliers buy and bill at no more than the UPL, ERISA plans and Medicare will be billed at the UPL, like all other insurers/payers in the State. Oregon cannot enforce a UPL against Medicare but there is no obvious reason for Medicare to reimburse more than billed.

COLORADO
Prescription Drug Affordability Board
Division of Insurance

PDAAC Recommendations

PDAAC Meeting Recordings

- July 13, 2023
- July 31, 2023

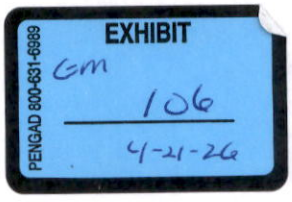
General Recommendations from PDAAC Deliberations (Staff Summary)

The PDAAC recommends the Board, within the top 50 prioritized drugs:

- Do not select prescription drugs with approved and marketed therapeutic equivalents and biosimilars.
- Combine drugs with the same name and different dosage and strengths and consider for selection together.
- When there are multiple drugs in the same class, do not pick multiple drugs from the same class. Pick a single drug from a single therapeutic class.
- Focus selection across three swim lanes within already prioritized list:
    - Highest Average Paid PPPY (to examine high-cost drugs and impact to system),
    - Highest Patient Count (to examine impact to highest number of Coloradans), and
    - Highest Change in WAC (to examine impact to behaviors).
        - Consider rebate information when examining this.
- This round, the Board should delay consideration of drugs that may be necessary to treat rare diseases, until it better understands how UPLs affect access.
- Consider the Social Vulnerability Index (SVI) score.

Response to Board Request: Vote Summary for Top 20 PDAAC Recommended Drugs (See Attached Spreadsheet)

**The list presented to the Board has not yet been filtered to incorporate all of these recommendations. Specifically, the list has not been vetted to exclude prescription drugs that treat rare diseases.*



COLORADO
Prescription Drug Affordability Board
Division of Insurance

Name	Representing	Vote
Kim Bimestefer	Executive Director of HCPF	Aye
Edward Dauer	Consumer Advocates	Aye
Gail deVore	Consumers	Absent
Maria Fenwick	Labor Unions	Absent
Chad Friday	Carriers	Aye
Drew Gonzales	Pharmacists	Aye
Kimberley Jackson	Consumers with Chronic Conditions	Absent
Katelin Lucariello	Brand Name Manufacturers	Abstain **After reiterating the concerns about accuracy in the eligible drug list as expressed in public comment by PhRMA*
Brett McQueen	Researchers	Aye
Neal MIller	Generic Manufacturers	Aye
Sarita Parikh	Consumers	Aye
Marc Reece	PBMs	Aye **With the caveat that his aye vote is not an endorsement for any drug on the list*
Thomas Tobin	Providers	Aye
Nathan Wilkes	Employers	Aye

Prescription Drug Affordability Advisory Council Conflicts of Interest Disclosures (PDAAC Recommended Drugs Highlighted)

The following members of the Advisory Council have disclosed a personal association with an eligible drug or a financial conflict of interest with respect to a drug manufacturer, for themselves or for an immediate family member. With respect to a drug manufacturer or specific drug, there

are potential conflicts of interest with the eligible drugs under consideration by the Prescription Drug Affordability Board (attached) as specified below.

GAIL DEVORE: Humira.

KATELIN LUCARIELLO: Benefix, Besponsa, Bosulif, Braftovi, Daurismo, Fragmin Genotropin, Ibrance, Inflectra, Inlyta, Lorbrena, Mektovi, Oxbryta, Panzyga, Silvadene, Somavert, Sutent, Talzenna, Vyndamax, Vyndaqel, Xalkori, Xtandi, Xyntha Solofuse, and Xyntha.

BRETT McQUEEN: Actemba, Activase, Alecensa, Cotellic, Emend, Enspryng, Erivedge, Esbriet, Evrysdi, Fosiprepitant Dimeglumine, Gazyva, Hemlibra, Herceptin, Hycela, Kadcyla, Keytruda, Koselugo, Lenvima, Lucentis, Lynparza, Mavenclad, Nutropin AQ NuSpin, Ocrevus, Ontruzant, Perjeta, Polivy, Recarbrio, Rozlytrek, Sivextro, Tecentriq, Venclexta, Welireg,and Zelboraf.

NATHAN WILKES: Alecensa, Cotellic, Enspryng, Erivedge, Esbriet, Evrysdi, Hemlibra,, Herceptin, Kadcyla, Novoseven, Nutropin AQ NuSpin, Ocrevus, Perjeta, Rozlytrek, Tecentriq, Venclexta, and Zelboraf.

In addition, EDWARD DAUER discloses that he is a volunteer member of several organizations whose constituents are often prescribed eligible drugs in the treatment of diseases such as cancer, and such treatment may include the eligible drugs Keytruda, Lenvima, Lynparza, Mvasi, Neulasta, Rubraca, and Zejula.

In addition, KATELIN LUCARIELLO discloses that she is a representative of PhRMA and has a general conflict with brand name drugs/ biological products on the eligible drug list that are manufactured by the following PhRMA members: Alkermes, Amgen, Astellas, Bayer, BioMarin, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, CSL, Daiichi Sankyo, Gilead, Eisai, Eli Lilly, EMD Serono, Genentech, GSK, Incyte, Ipsen, Johnson & Johnson, Lundbeck, Novartis, Novo Nordisk, Merck, Otsuka, Pfizer, Sanofi, Takeda, and UCB.

Finally, all Advisory Council members have been appointed on the basis of their positions as stakeholders with personal experience, professional expertise, or both, in the realm of prescription drugs.

The remaining Advisory Council members—Kim Bimestefer, Dr. Kimberley Jackson, Maria Fenwick, Chad Friday, Sarita Parikh, Marc Reese, Dr. Thomas Tobin, Neal Miller, and Andrew Gonzales—have disclosed that they have no potential conflicts of interest with respect to the eligible drugs or their manufacturers.