CAPITOL STREET

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CO Drug Board Looks to Price Caps For 2024

Other States Drug Boards Move Slowly (MD, OR, WA, MN)

Relevant Companies

On August 4, Colorado's Prescription Drug Affordability Board (PDAB) released the list of the 5 drugs it would review for affordability. PDAB was given the authority to potentially establish an upper pricing limit in Colorado since 2022, without being required to. Much of last year was spent on creating policies and rules required for future regulations. 7-8 states including CO have enacted drug boards, but CO is moving much faster than the other states. Link to PDAB info here.

⋙ Our Take & Next Up

CO's drug board ("PDAB") is conducting affordability review on 5 drugs with public meetings 9/15 (here), **and late September (one mtg per drug, see schedule and links below to attend).** The Board is not required to set an upper limit and some drugs may be spared if their review concludes they can be affordable without a pricing cap. If payment limits are considered, we expect them to be released in 2024. Colorado is moving fast compared to other states that have enacted affordability boards. State pricing limits mirror federal Medicare negotiation (starts 2026, see our 8/29 memo), but also extend into other lines of business such as Medicaid and non-ERISA commercial. PDAB term has been extended once already (from Sept 2026 to Sept 2031) and it is possible that it continues to be extended.

⋙ Key Points

Colorado is one of ~8 states (Colorado, Maine, Maryland, New Hampshire, Ohio, Oregon, Washington, and Minnesota) to enact a Prescription Drug Affordability Board. Other, new states are looking to establish boards in 2024+ e.g., VA, NJ, PA, MI. The most recent state to pass a drug board is Minnesota (May '23). However, not all state drug review boards have teeth. Only CO, MD, WA, and MN allow their Boards to establish price limits. Next up is MD that approved its framework in July 2023. They are expected to evaluate drug costs start in the Fall and expected to determine a "substantial" list of drugs that could be evaluated, but only a few may have UPLs.

PDAB selected drugs (out of the 604 drugs that were eligible for affordability review) are below. The review list includes the following, which will each be the subject of stakeholder meetings through late September (19-27) to solicit both medical and patient & caregiver input.

- Genvoya (GILD) – Stakeholder meetings will be held on September 20: Individuals with Scientific or Medical Training (7-9 am MT) (here) and Patients & Caregivers (6-8 pm MT) (here)
- Enbrel (AMGN) – Stakeholder meetings will be held on September 19: Those with Scientific/Medical Training (7-9 am MT) (here) and Patients & Caregivers (6-8 pm MT) (here). *Also on Medicare Drug List*
- Cosentyx (NVS) – Stakeholder meetings will be held on September 21: Those with Scientific or Medical Training (7-9 am MT) (here) and Patients & Caregivers (6-8 pm MT) (here)
- Stelara (JNJ) – Stakeholder meetings will be held on September 26: Those with Scientific or Medical Training (7-9 am MT) (here) and Patients & Caregivers (6-8 pm MT) (here). *Also on Medicare Drug List*
- Trikafta (VRTX) – Stakeholder meetings will be held on September 27: Individuals with Scientific Medical Training (7-9 am MT) (here) and Patients & Caregivers (6-8 pm MT) (here)

Only 5 drugs/year will be evaluated, with incremental lists likely to come. Reviewing 5 drugs is a fraction of PDAB's statutory authority. The Board has the authority to review up to 18 drugs if the Board has sufficient staff support (which they won't). As policies are finalized and staffing is secured, PDAB is likely to stay under the 12 drugs a year limit that was enacted when the Board was established.

There are 14 components that the Board will consider in the affordability review which span from list price to non-adherence and utilization management trends. PDAB will consider factors including the WAC and changes in WAC, therapeutic alternatives and their costs in CO, effect on consumer access, financial impact on broader medical and social services, patient cost sharing, impact on safety net providers, orphan drug status, health equity impact, utilization management, and patient and provider input. The board may also consider pricing factors like rebates, life-cycle management, market competition, projected revenue, and estimated cost-effectiveness.

There is no statutory requirement for the Board – comprised of hospitals, physicians, pharmacists, with manufacturers only on the Advisory Board -- to set any pricing limit for any drug that is reviewed. They are just granted the authority to do so if necessary. Colorado law also establishes that an UPL is not a final agency action that is subject to judicial review until the board promulgates a rule

Lawsuits likely? Yes. If selected for a pricing cap, manufacturers will be unable to go to court until a final rule is released, likely in 2024. Pricing limits (if enacted) are expected to hit all eligible plans in Colorado, including non-ERISA commercial, and Medicaid. ERISA plans in Colorado are allowed to voluntarily engage in the payment limit, but not required.

Drug manufacturers have conveyed 3 major concerns with the Colorado affordability board process. Manufacturers have raised concerns over the board's methodology and data bias as the board had to rework its method for calculating the cost of a "course of treatment," affecting the list of eligible drugs. Manufacturers have also questioned the All-Payers Claims Database used by PDAB. While most insurances are required to report costs and utilization to the database, ERISA plans are exempt from reporting. Manufacturers have also criticized the speed of the review board as the law sets no statutory deadline for selecting drugs. Maryland, which established their affordability board in 2019, just recently finalized a drug review framework and has not selected any drugs for review yet.

Colorado's Prescription Drug Affordability Board authorities were further clarified in the passage of HB23-1225 with most of the provisions going into effect on August 7, 2023. This law builds on the 2021 law (SB21-17) with the establishment of PDAB. The law clarified staff members and contractors of the division must disclose any conflict of interest related to a prescription drug for which the board is conducting an affordability review or establishing an upper payment limit. The law also increased the number of drugs that can be reviewed from 12 to 18 drugs per year if the board determines that

there is a need and has sufficient staff support. Starting in 2025, the Board's scope of review also increases as it will be allowed to review any prescription drug that has a WAC of $3,000 or more and an increase of $300 or more a year, a drug with a WAC increases of 200% or more a year or have a WAC of more than $30,000 per year. Also starting in 2025, generic drugs are removed and no longer subject to affordability review.

Background

Colorado SB21-17

Colorado's Prescription Drug Affordability Board was established in 2021 with the passage of SB21-175. This law created the Colorado Prescription Drug Affordability Board and allowed the Board to set a maximum price for up to 12 drugs each year. Selected drug must be a brand name drug or a biological product that had a cost increase by more than 10% in one year or have a WAC of more than $30,000 per year. The board can also examine generic drugs with a WAC of more than $100 per month or a biosimilar that has a WAC that is more than 75% of the brand name.

The Board could start establishing upper payment limits starting April 1, 2022, applied retroactively. Starting January 1, 2022, any purchase or payer reimbursement for a prescription drug is prohibited from exceeding the upper payment limit established by the board for that prescription drug. The only insurance group that can participate voluntarily are self-funded ERISA plans. The law also granted the state attorney general to enforce the UPL as of January 1, 2023. The law also required non-ERISA, Medicare, MA, and Medicaid plans to report drug pricing, cost, and utilization data to the all-payer health claims database, starting in 2022.

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