

Weekly Checkup

Prescription Drug Price Caps: Colorado Case Study

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Last Friday, Colorado's prescription drug affordability board (PDAB) met to discuss which prescription medications should be considered for a price cap. Indeed, Colorado and several other states are attempting to determine the cost-effectiveness of prescription drugs through arbitrary – and sometimes conflicting – data points and metrics with the aim of reducing consumers' out-of-pocket costs. No wonder, then, why these price caps will reduce access to and increase costs for these drugs: If Colorado sets price caps for prescription medications, drug manufacturers are likely pull their products from these state-specific markets. Let's dive into the PDAB's data methodology, regulatory authority, and how price caps limit access to essential medicines for vulnerable patients.

The Colorado Case: In 2021, Colorado established a PDAB and advisory council to determine if certain prescription drugs are, according to its Affordability Review, "unaffordable," and accordingly to set an upper payment limit (UPL) for those products. Setting a UPL is likely to be flawed and subjective, as the out-of-pocket costs a consumer pays depends heavily on their insurance coverage (or lack thereof) with the plan determining the consumer's cost sharing through deductibles, coinsurance, and copayments.

A Flawed Prescription Data Methodology: In its analysis to determine which prescription medications need a price cap, Colorado's PDAB is reviewing the state's All-Payers Claims Database, which is composed of a limited number of pharmacy and medical claims that were billed but, notably, might overlook the prescription drugs that were ultimately utilized. What's missing from this data set are commercial claims under the federal Employee Retirement Income Security Act of 1974 (which account for approximately 30 percent of all claims in the state) and the uninsured (approximately 6.6 percent of the state population). In other words, PDAB has an incomplete picture of Colorado consumers' costs as well as total utilization for specific pharmaceuticals in its effort to establish UPLs, which will carry real consequences to patients in the state.

Colorado's Retroactive Application of the Price Caps: In statute, the state attorney general has the authority to enforce the UPL as of January 1, 2023, at which point it is unlawful for any insurance payment to exceed a UPL (excluding for a person who purchased a drug for personal use). The problem, of course, is that the PDAB hasn't yet selected which drugs will be subject to these price caps, meaning that whatever violations of the UPL manufacturers commit would be applied retroactively. In response, manufacturers may be discouraged from selling products in the state if they feel that they are likely to exceed the UPL.

Limited Access to Essential Medicines: The underlying statute permits drug manufacturers to notify the insurance commissioner, state attorney general, and other contracted parties about their intention to withdraw their product at least 180 days prior. If the manufacturer fails to do so, it could face a financial penalty. Colorado PDAB's mission to establish prescription drug price caps is plagued by several problems, not least of which is that it is acting without robust data or comprehensive methodology, and that it is leaving manufacturers in the dark about what, exactly, it plans to do.

It isn't difficult to see how the Colorado PDAB's plan will work out. In fact, we've seen it before with the United Kingdom's proposed increase to the voluntary rebate scheme

, which resulted in manufacturers either leaving the <u>negotiation process</u> or announcing that their products will no longer be available. Celltrion, a South Korean company, for example, pulled its <u>anti-cancer biosimilar</u> from the market.
Congress should keep a close watch on Colorado and countries around the world that set drug price caps, developments which may very well create prescription medication shortages, potentially reducing access to essential products and increasing costs for vulnerable patients.