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States' Drug Pricing Boards Could Brew New Legal Tests

By **Mark Payne**

Law360 (May 27, 2025, 7:14 PM EDT) -- Amgen Inc.'s ongoing challenge to a Colorado law regulating retail drug prices could serve as a litmus test for widespread state government efforts to keep medication costs low.

Following the enactment of H.B. 424 in Maryland on May 20, the state became the fourth in the country after Colorado, Minnesota and Washington to allow a prescription drug affordability board, or PDAB, to set upper limits on medication costs for their denizens.

Maryland's law expanded the power of its PDAB to set upper limits on how much consumers pay for medications in the commercial market and not just for in-state payors.

Eleven states currently have some form of PDABs, according to the National Alliance of State Pharmacy Associations, and according to the National Academy for State Health Policy, 14 states have 19 pieces of pending legislation to either create or expand their own PDABs.

Colorado's law, which became effective in 2022, became the target of a lawsuit from Amgen after the state board set an upper payment limit on one of the drugmaker's patented drugs for treating certain autoimmune conditions.

The law's failure to make exceptions for patented drugs unlawfully infringes on the federal government's authority to boost investments in the pharmaceutical sector and control Medicare costs, Amgen alleges.

Even though Maryland's law doesn't set upper payment limits for Medicare drugs, the PDAB expansion allows for oversight of branded and generic drugs, bringing the Old Line State in line with Colorado and leaving it open to the possibility of a similar lawsuit.

"The biggest differences across these state laws are whether the boards actually have authority to set upper payment limits, or can only kind of assess and make recommendations about how to make drugs more affordable and to the scope of the population that the board's actions can impact," said Amy Pauli, counsel at Crowell & Moring LLP, who represents drugmakers in pricing disputes.

Amgen's lawsuit was initially thrown out in March, with a Colorado federal judge finding that the California-based drugmaker is not directly affected, since the upper payment limit applies only to

consumer prices, not the prices wholesalers pay manufacturers. Amgen has appealed the decision to the Federal Circuit.

While that case works its way through the appellate system, states and drugmakers are in a "holding pattern," according to Michael S. Kolber, a partner at Manatt Phelps & Phillips LLP who litigates drug pricing issues.

"We're still in somewhat of an in-between stage in this whole policy and litigation area," he said. "One way or another we will eventually get a merits decision, but at this point, we kind of remain in this liminal state."

However, because Amgen's lawsuit was only assessed for the drugmaker's standing and a decision was never reached on the merits of the arguments, pharmaceutical companies could be looking to challenge other states' laws and get a more substantive decision in another district court.

While a decision in Colorado doesn't bind a court in Maryland or other states, judges will take it into consideration, according to Zachary Baron, director of the Center for Health Policy and the Law at Georgetown University's O'Neill Institute and an adjunct law professor.

"States believe that they have authority to protect their consumers, to protect their residents from a broken prescription drug market," he said.

While Maryland has expanded its law and others look to form their own PDABs, they may have to proceed with caution as drugmakers test the laws in court.

"States will have to walk a tightrope in trying to establish laws related to PDABs since there are fundamental legal limits on whether and how states can regulate drug prices, particularly given the national market for pharmaceuticals," said Margaux Hall, a partner at Ropes & Gray LLP.

Because the laws across the country are new, they will likely face more legal tests.

"I would certainly expect plenty more sort of twists and turns when it comes to PDAB litigation going forward," Baron said, adding that no decision so far has suggested that states don't have the authority to establish drug affordability boards.

That doesn't mean that authority isn't in question and won't be challenged when Amgen argues before the Federal Circuit. The drugmaker is seeking to invalidate Colorado's statute that established the state's PDAB.

In an amicus brief filed while the case was in district court, the Biotechnology Innovation Organization, a trade group that represents companies that develop biotech products including medicines, argued similarly to Amgen that Colorado's law obstructs federal statutes that give drugmakers patent exclusivity rights.

"If Colorado (and every state) is free to deprive a patent holder of its right to price its patented drug free of state law mandates simply by making the law apply as a technical matter to the wholesaler's resale of the product into the state, then Colorado can deprive manufacturers of the incentives provided by these other federal provisions as well," the group argued.

Baron said that until an appellate court or the U.S. Supreme Court definitively rules that states don't have the authority to set up PDABs, states are unlikely to stop creating PDABs despite any potential litigation.

A Federal Circuit decision, which hears all patent cases, is unique, however, because it's binding to all district courts across the country.

"It will have a broader impact than even an ordinary federal appellate decision," he said.

--Additional reporting by Lauraann Wood, Yeji Jesse Lee and Hailey Konnath. Editing by Linda Voorhis.
