

## What To Watch As Push To Rein In PBMs Advances

By Kellie Mejdrieh

*Law360 (June 10, 2022, 6:49 PM EDT)* -- The Federal Trade Commission's recent decision to investigate whether pharmacy benefit managers are engaged in anticompetitive business activity is the latest in a series of developments benefits attorneys and others who deal with PBMs should be watching.

The FTC's unanimous vote Tuesday to investigate PBMs, which act as intermediaries between pharmacies and insurers when filling patient prescriptions, comes as the U.S. Supreme Court is poised to decide whether to accept two Employee Retirement Income Security Act lawsuits that could be game-changers for the PBM field.

At the same time, states are passing legislation in the wake of the high court's 2020 decision in *Rutledge v. Pharmaceutical Care Management Association*, in which the justices upheld an Arkansas regulation as not preempted by ERISA, spurring more lawsuits over state policy.

Still, other federal policy changes could soon be on tap from Congress, where top lawmakers have proposed legislation to modify how PBMs operate, including regarding pricing activities that could affect employer group health plans.

"It would be great for all parties if the FTC can promote a balanced approach that reduces drug costs while not having the unintended consequence of increasing costs elsewhere in the health care system. Legislative reforms and litigation have pitted industry segments against each other, so what we need is a different type of process that balances the equities," said Todd D. Rosenberg, a partner at Crowell & Moring LLP who works with health plans and PBMs.

Here's an overview of the legal and legislative fronts where battles over PBMs are brewing.

### Litigation

A proposed class of employee health plan beneficiaries accusing Anthem Inc. and pharmacy benefit manager Express Scripts Inc. of violating federal benefits law by setting higher prices for prescription drugs asked the Supreme Court to take up their case in a petition filed in June 2021, which justices have scheduled for a conference on June 23.

Health care policyholders have asked the high court to reverse the Second Circuit's decision from December 2020, arguing in their petition that PBMs must act as fiduciaries under ERISA when setting drug prices. But the health companies argue, and the Second Circuit held, that the activity constituted a

business decision exempt from those obligations under ERISA.

James Gelfand, senior vice president for health policy at the ERISA Industry Committee, a group that lobbies for corporations' interests in the benefits realm, said he's closely watching the petition's outcome.

"This case is a prime example of, you have these intermediaries in the market, and the things they do most certainly do have an effect on patients. But is it enough of an effect that they should be held to the standard that they need to be working on behalf of those patients?" Gelfand said.

Still, the federal government told the high court in a brief filed in late May not to take up the case in favor of evaluating the issues afresh in a future lawsuit.

Another major Supreme Court petition involving PBMs is expected in early July after Justice Brett Kavanaugh granted an extension in April for an industry lobbying group to make its case for why the high court should revive its lawsuit, which seeks to invalidate a North Dakota state law regulating the PBM industry in the case *Pharmaceutical Care Management Association v. Nizar Wehbi et al.*

PCMA, which is a lobbying group for the PBM industry, has asked for more time to petition the high court after the Eighth Circuit denied a rehearing in the case in February. PCMA said the statutes attempt to tamper with benefit plan design, even though ERISA says states should not interfere with that.

The North Dakota laws, passed in 2017, bar pharmacy benefit managers from holding pharmacies to accreditation standards that exceed government requirements, limit their ability to impose performance fees on pharmacies, and regulate the claim-processing fees they can charge pharmacies, among other things.

PCMA had originally won its case in the Eighth Circuit but saw that victory reversed after the Supreme Court ruled in 2020 that ERISA doesn't preempt states' ability to regulate the rates PBMs pay pharmacies.

Gelfand said he's also tracking roughly a dozen cases similar to the Wehbi dispute before the high court in states that have passed their own PBM laws.

"PBMs are all trying to use ERISA as their shields," Gelfand said, referring to ERISA preemption.

A petition in that case is now due July 11.

### **State Legislative Activity**

Benefits attorneys say they've seen a flood of state legislation attempting to regulate PBMs following the *Rutledge decision* as well as the Eighth Circuit rehearing denial in the Wehbi case, given that both decisions upheld state regulations as not preempted by ERISA.

"Since then, we've seen a lot of states taking action," said Xavier Baker, an attorney at Sheppard Mullin Richter & Hampton LLP who represents group health plans. Baker said he's keeping a close eye on the high court petition in the Wehbi case given the potential impact on state regulations.

Baker said it's possible the FTC study may also result in "increased activity by the states, particularly

post-Rutledge, where there's perhaps less robust preemption."

The National Academy For State Health Policy, a nonprofit advocacy group that tracks PBM legislation nationwide, has tracked more than a dozen state legislatures that have passed bills this year affecting PBMs, up from three states having passed such laws this year that the NASHP tracked in April.

Baker said he's kept an eye on state actions this year, including in Iowa, Michigan, Vermont and New York, which have largely been focused on price transparency as well as disclosure and regulation. Employers and others involved with ERISA health plans should watch those developments, Baker said, as the changes could also end up providing employers with more information about PBMs overall.

Julie K. Lappas, attorney at Hall Render Killian Heath & Lyman PC, said the topics the FTC agreed to investigate on Tuesday "are mirroring what we've seen states begin to regulate with new PBM legislation."

That includes regulations on business practices by PBMs that are now subject to the FTC inquiry, such as clawbacks and fees, steering patients to PBM-affiliated or -owned pharmacies, or reporting on rebates and pricing, she said.

"These are important issues for employers, and really all industry stakeholders — whether it's a pharmacy, a PBM, a health plan — to keep their eye on and consider when they're contracting with one another for services," Lappas said, referring to the FTC inquiry and changes in state law.

Lappas said all the movement on regulation means those working with PBMs may want to "consider adding language to their contracts to give them flexibility to amend their agreements if there is a change in law or regulation."

### **Congress Mulls Changes for PBMs**

Another potential avenue for PBM changes comes from Congress, where lawmakers have introduced legislation aimed at changing how PBMs are allowed to do business, including by giving the FTC more power and authority to regulate them.

Bipartisan legislation, S. 4293, that would broaden the FTC's authority to oversee PBMs and restrict certain pricing practices was introduced in May by Sen. Maria Cantwell, D-Wash., with Iowa Republican Sen. Chuck Grassley signing up as an original co-sponsor. Arkansas Republican Sen. John Boozman, whose state has led the charge in cracking down on PBMs through regulations, joined as a co-sponsor on Cantwell's bill on June 8.

Democratic Rep. Elijah Cummings of Maryland has also sponsored legislation, H.R. 3, instituting new drug-pricing transparency policies that could have a major impact on PBMs. The bill would require the federal government to negotiate the price of the most frequently prescribed drugs under Medicare and require those prices to be offered to private insurers.

The bill would also institute transparency requirements, including reporting obligations, for high-cost drugs and direct the U.S. Department of Labor to study drug prescription costs among group health plans, which could form the basis for future policy changes affecting PBMs.

Lappas said all the activity around PBMs, including in Congress, is also affecting how patients ask about

their prescription health benefits.

"We're seeing this activity on the state level, we're seeing it on the federal level through this investigation and proposed legislation. I think it's bringing more awareness to the average American patient just about who a PBM is," Lappas said.

"Given the focus on transparency in health care and the increased media coverage that we're seeing around PBMs and drug pricing issues, patients are more savvy. They're more likely to ask questions about their coverage and reimbursement for prescription drugs," Lappas said. "And employers are seeing that, pharmacies are seeing that."

--Editing by Philip Shea.