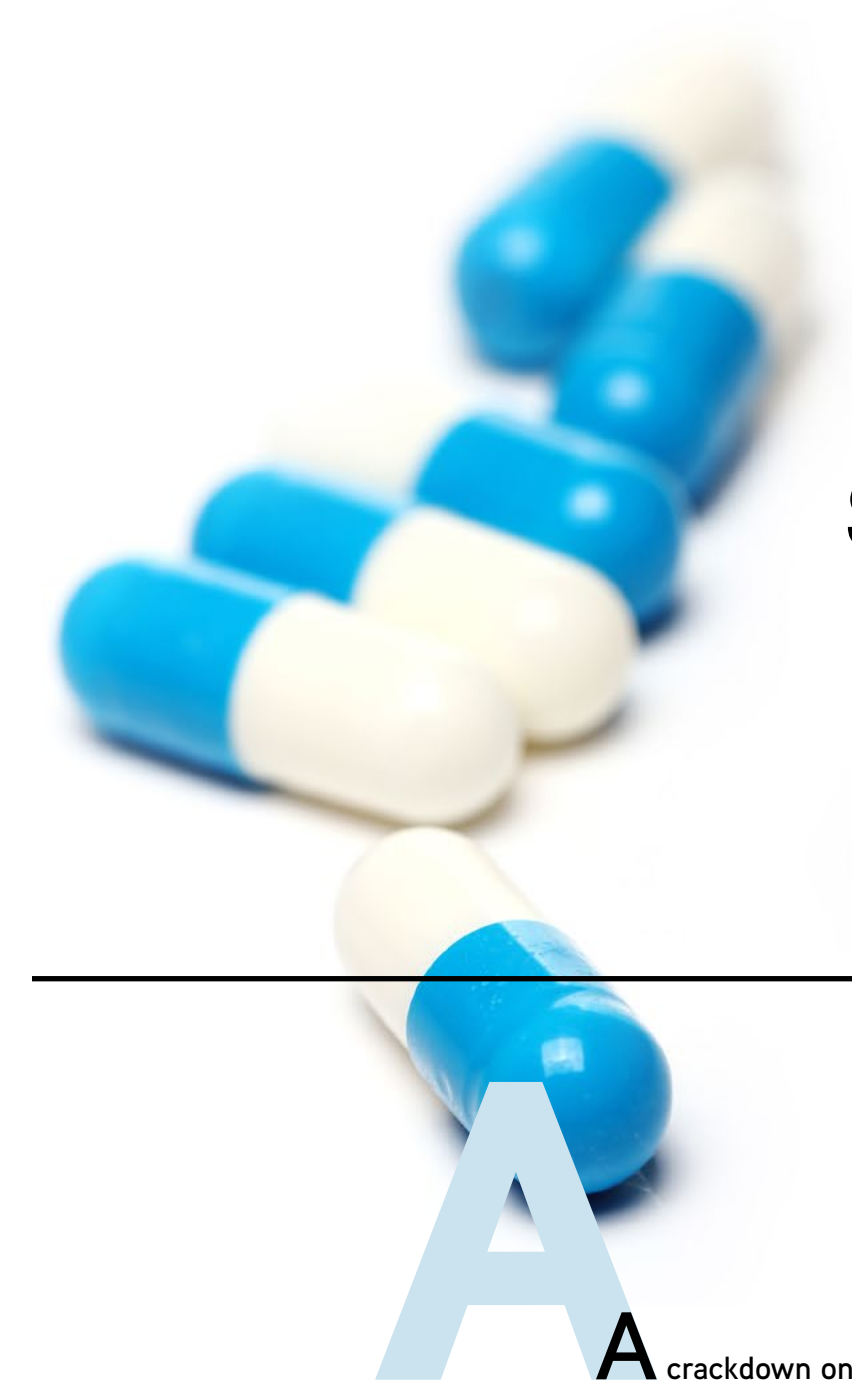


How PBM Scrutiny Threatens Self-Insurance

State action seen as challenge to ERISA protection, while a crackdown on revenue sharing could drive up service costs

Written By Bruce Shutan

A crackdown on pharmacy benefit managers, three of which control about 80% of the market, may prove to be a double-edged sword for self-insured health plans.

On the one hand, new or proposed laws at both the federal and state level are designed to transform an opaque part of the U.S. health care system with transparency for payers and patients alike. They are in lockstep with federal Transparency-in-Coverage rules, No Surprises Act and Consolidated Appropriations Act – all of which have been fully supported across the self-insurance community.

A growing appetite to regulate PBMs stem from a larger effort to curb out-of-pocket Rx costs for health plan members that keep rising 13 years after the Affordable Care Act was enacted. It doesn't help that the cost of specialty drugs coming down the R&D pipeline are expected to further raise prices.

Another culprit is consolidation of these services. The so-called Big Three PBMs – CVS Caremark, Express Scripts and Optum – boast massive scale and ownership that includes health insurers, physician practices, retail pharmacies and specialty pharmacies.

But with PBMs now firmly in the crosshairs of U.S. congressional representatives, regulators, statehouses and jurists, well-intentioned reform efforts also pose a serious threat to Employee Retirement Income Security Act (ERISA) protections for self-insured employers. Moreover, employers worry that curtailing or eliminating PBM revenue-sharing agreements will result in higher-priced services.

Since a 2020 U.S. Supreme Court decision pertaining to PBMs, industry observers fear that an invitation to unintended consequences could widen. An overly broad interpretation of *Rutledge v Pharmaceutical Care Management Association* is responsible for a fresh assault on ERISA. In upholding an Arkansas law requiring PBMs to pay pharmacies no less than their acquisition costs for prescriptions, the high court ruled that it was not preempted by ERISA. That decision allows states to regulate health care costs, including health plan contractors such as PBMs.

Ryan Work, SIIA's VP of government relations, says the case to some extent opens the floodgates for states to regulate PBMs, "and what they've done along the way is started cracking at that ERISA firewall. You can regulate PBMs and pharmacy benefits, but at what point does that stop and then it starts actually regulating ERISA-protected self-insured plans?"

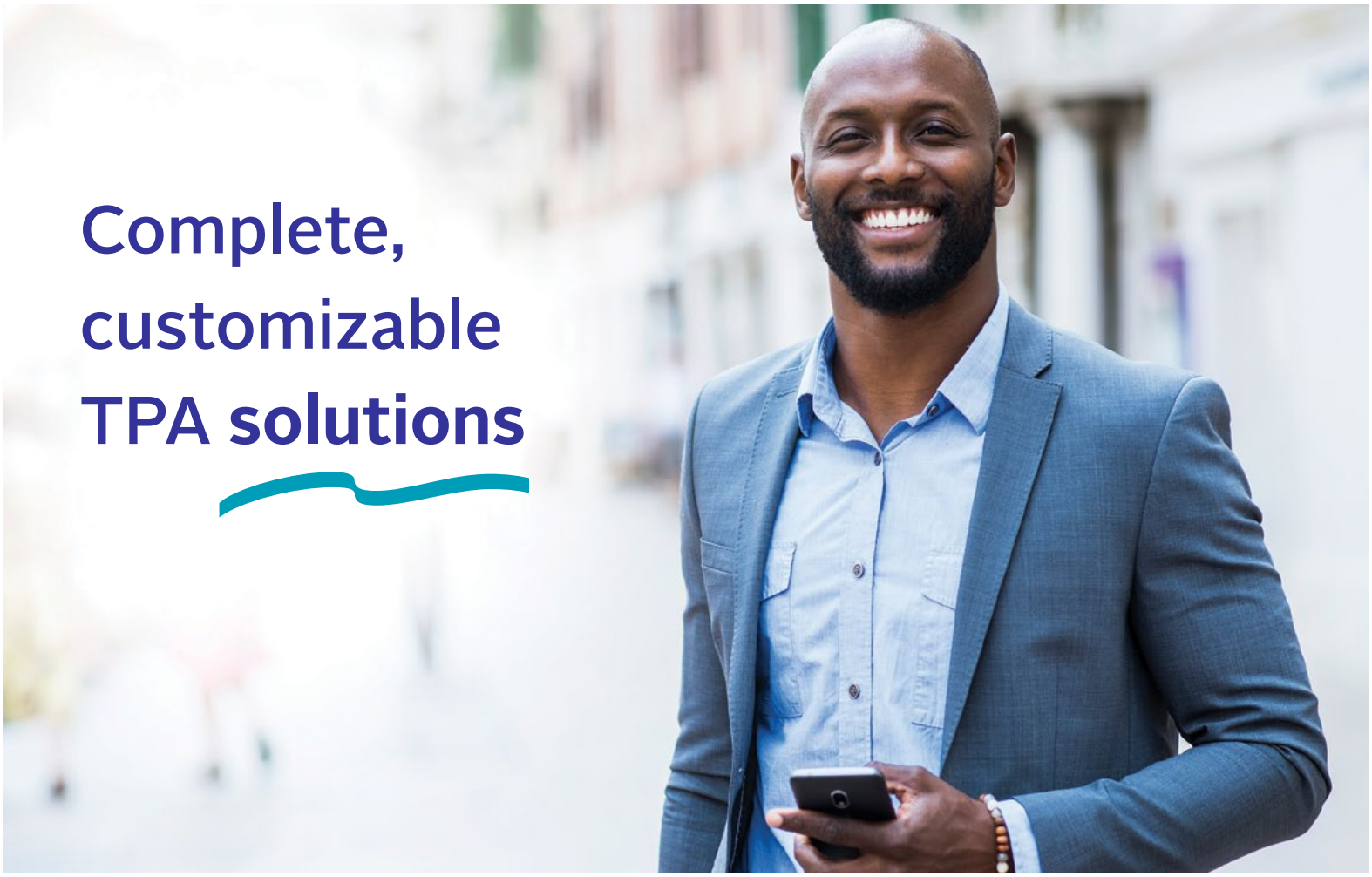
Ryan Work

His hope is that at some point the federal court is going to better define the Rutledge decision, "take up some of these ERISA arguments and create buttresses and firewalls around it that, while providing more transparency in the pharmacy space, will offer better protections for risk of self-insured plans." The case is currently seen as a way for state regulators to get their hands on self-insured plans, he explains, noting that Louisiana and Texas are among a few states that have tried to eliminate the word ERISA from some of their insurance statues related to PBMs.

Some regulators are using the decision to test how far they can go, he adds, while others are targeting PBMs without actually understanding that they're just a tool to help mitigate costs.

> "Pharmaceutical manufacturers are responsible for the high costs of drugs, and the PBMs are providing them the plans," Work notes, "and they're both pointing the finger at each other."

There has been growing scrutiny of PBMs at the state level. A dozen states enacted 19 pieces of legislation last year that imposed a variety of restrictions for PBMs, including licensing and reporting requirements, prohibitions on spread pricing and rules aimed to make costs more transparent enrollees. These bills, among a whopping 135 measures introduced in state legislatures across the nation, seek to curtail the influence that PBMs have



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Much of the state legislation is being driven by community pharmacists who feel under attack by the role of PBMs and the large retail pharmacy chains, according to Work. In Louisiana, for instance, they have shopped around model legislation for every state to pass. He references a campaign to file a complaint with the Louisiana Department of Insurance every time a PBM claim from a self-insured plan was submitted, which generated 30,000 cases in the past year.

"One of the problems that I've seen is that patients will go in with a prescription, and their community pharmacy is requiring that they pay in cash," Work reports. "In some cases, they are saying, 'we're not even going to take insurance. You do that on your own, and if you want to get reimbursed by your insurance, you need to do it on your own.'"

Similar efforts to regulate PBM activity are also afoot on Capitol Hill, including the Pharmacy Benefit Manager Reform Act (S. 1339), which was introduced in late April. Led by Sens. Bernie Sanders (I-VT) and Bill Cassidy (R-LA), it proposes several reforms that are universally reflected in other bills. They include a ban on spread pricing and certain PBM claw backs, as well as require rebates paid to PBMs be passed through to health plan sponsors.

Work predicts that Congress will pass federal PBM transparency legislation by the end of this year – an area that has garnered rare bipartisan support in divisive times. The wheels are already in motion. He says PBM legislation has been introduced in the Senate Finance Committee and Senate Health, Education, Labor and Pensions Committee, as well as the House on Ways and Means Committee,

House Committee on Education and Labor and House Committee on Energy and Commerce.

But there's no guarantee that any reform efforts will actually lower prices. In fact, it may do just the opposite. If PBMs aren't able to share in claw backs, rebates or spread prices, then Work worries about higher fees being imposed on their services for self-insured customers. "You can bring transparency, but at the end of the day, is that really going to move the needle on cost? And the answer is probably no," he suggests. "It's just going to be a cost shift."

EDUCATION AND ADVOCACY

Given the elevated level of misunderstanding, or no understanding at all, about ERISA and how the nearly 50-year-old landmark law benefits self-insured plan sponsors and participants, Work points to the importance of education and advocacy. As this issue went to press, SIIA planned to release to an ERISA white paper to help policymakers and congressional staffers at both the federal and state level understand the importance of ERISA protection. It also will serve as a resource for SIIA members.

While SIIA's Drug Pricing Taskforce disbanded after several years of producing helpful checklists for members, other opportunities are expected to rise with regard to assessing PBMs. "One of the things that I'm trying to do is kind of create a smaller working group to better understand where our members come down on PBMs and regulation," Work says.

Marien Diaz, VP of stop-loss claims and medical management for Symetra who was part of the taskforce, expresses a related concern about state oversight. "The No. 1 concern that I see from a claims angle is how are employers able to even comply with some of these state regulatory requirements?" she wonders. "If you have a self-funded employer with multiple locations across the board, these reporting requirements may change from state to state. Anytime that you have to program or invest in meeting those requirements, there's additional cost."

Marien Diaz

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BENDING THE COST CURVE

Mike Baldzicki

While lawmakers and regulators hope that reining in PBMs ultimately will help reduce costs, it's clear that certain marketplace practices can have an immediate effect.

In the face of tremendous influence the Big Three PBMs wield, for example, some self-insured employer groups are peeling away from them contractually and embracing regionalized or midsize entities known as pharmacy benefit administrators, according to Mike Baldzicki, chief commercial officer, specialty pharmacy for Premier Pharmacy Services and member board of directors for the National Association of Specialty Pharmacy.

He says PBAs, whose business model reflects the service's late 1980s roots before layers of complexity were added, are driving fiduciary duties and defining clinically appropriately utilization. They understand the importance of providing transparency alongside eliminating hidden fees associated with direct and indirect remuneration, Baldzicki explains.

Plan sponsors, particularly TPAs, also are stepping away from brokers who pocket money from the large PBMs.

> "I even see brokers changing the way their model works to bring in other regionalized PBMs like CAP RX or App Rx and win some business for the smaller guys that are doing the right things to change the model," he reports.

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"I've seen it where medical benefits for an infusion drug still ranges gross profit margin 19% to 66%, depending on the drug, if you're truly not gaining insight on that claim," he says.

Diaz says it's important to create greater alignment between PBMs and claims administrators that support self-funded health plans, as well as offer transparent pricing. The Big Three have an opportunity to willingly create more disclosure in their billing practices and provide reasonable incentives to help employers mitigate their plans rather than rely on the regulatory environment to force them into adapting, she observes.

But there's another area where self-insured employers can gain considerable traction: having a solid contractual arrangement in place when engaging the services of a PBM.

"When we are underwriting stop-loss risk, one of the basic questions that we ask is, 'when was the last time that you reviewed and updated your PBM contract?'" notes Diaz, suggesting that an annual review be done. "It is shocking to me that although pharma expenses continues to grow exponentially, the review of contracts doesn't happen with enough frequency and discipline… So it's very difficult for us to provide competitive pricing in a meaningful way unless those agreements are reviewed and updated regularly. Sometimes we find employers that haven't even looked at their PBM arrangement in the past five years."

It all comes down to pursuing a proactive approach to engage in a meaningful relationship with PBMs, which Diaz believes "is in the long run a much better prescription, no pun intended, as an industry than to have to wait on regulatory mandates."

Whatever direction the Rx industry takes, experts agree that cooperation and collaboration need to displace divisiveness. Adds Baldzicki: "We have to stop bashing PBMs, which have a place in the healthcare ecosystem, because if you really rip that away the disruption would be huge." ■

Bruce Shutan is a Portland, Oregon-based freelance writer who has closely covered the employee benefits industry for more than 30 years.