





A decision to (still) celebrate

Two years later, the 2020 Supreme Court victory in *Rutledge v. PCMA* remains a landmark decision for independent pharmacy

by Matt Seiler

One of my favorite songs is “Celebration” by Kool & The Gang. The lyrics say, “*It’s time to come together...*” and that’s just what independent community pharmacists did from 2015 to 2020 in support of Arkansas. On Dec. 10, 2020, in *Rutledge v. Pharmaceutical Care Management Association*, the Supreme Court issued a unanimous decision supporting Arkansas’ right to regulate pharmacy benefit managers. For some 15 years, dating back to a 2005 case in Maine, it was like seeking the Holy Grail – in other words, the quest to see PBMs finally be held accountable for business practices that have often crippled community pharmacies, and in turn, the patients they serve daily. It was through the tireless efforts of NCPA, working in tandem with the Arkansas Pharmacists Association and other partners, and the support of Arkansas Attorney General Leslie Rutledge, that helped convince the court to make its decision.

“It was a historic victory for independent pharmacies and their patients,” NCPA CEO Douglas Hoey says. “And it confirmed the rights of states to enact reasonable regulations in the name of fair competition and public health.”

A NEW ERA

Well, now, two years later, it's time to celebrate that decision and all that has come from it. Two years post-*Rutledge v. PCMA* has ushered in a new era of state-led PBM regulations. Unfortunately, Congress still sits on the sidelines. But I guess that is the beauty of federalism, right? It makes me think back to law school and the case of *New State Ice Co v. Liebmann*, where Louis Brandeis wrote in his dissent "a state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." And try new experiments against PBMs states did! Red states and blue states — from Arkansas to California, and everywhere in between — have enacted or are considering legislation to further regulate PBMs.

"These legal decisions have cleared a very defined pathway for states to regulate PBMs," says Anne Cassity, NCPA vice president of federal and state government affairs. "Removing the uncertainty of a state's ability to regulate PBMs has given state

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legislatures the confidence to pass meaningful PBM reforms. And although legislative changes remain an important priority, NCPA is just as laser-focused on holding state departments of insurance accountable when it comes to enforcing regulations. Laws and regulations are only as strong as their enforcement."

North Dakota and Oklahoma stand out as two states that took the fight to PBMs and fought back against PCMA's tireless fight to keep PBMs unregulated. North Dakota won. Oklahoma is fighting hard. In *PCMA v. Wehbi*, the 8th Circuit Court of Appeals upheld North Dakota's PBM regulations saying that they were not preempted by ERISA (the *Employee Retirement Income Security Act of 1974*), and it created a clearer path for states to regulate under Medicare Part D. It was such a resounding win, PCMA chose to not challenge

the decision to the Supreme Court.

Robert T. Smith, a partner at Katten Muchin Rosenman LLP, was heavily involved in the *Rutledge* case and later argued in the 8th Circuit on behalf of the state of North Dakota in *Wehbi*. He says the court decisions sent clear messages to the PBMs.

"PBMs are not subject to any form of direct regulation under federal law. And yet, PCMA has claimed that federal law prevents states from filling the void," Smith says. "That argument was just too much for the Supreme Court in *Rutledge*, and it is proving too much for the lower courts. It would mean that PBMs are beyond any form of meaningful regulation."

Oklahoma is now in a battle similar to the one that North Dakota faced. In the matter of *PCMA v. Mulready*, PCMA is once again offering its tired arguments that PBMs should not be regulated. What is interesting though, is that PCMA has backed away from arguing that PBMs should not be entirely unregulated. Instead, it accepted the district court's decision on 10 of the originally challenged provisions and is now focusing on only four.

CHALLENGES REMAIN

Don't "...have a good time..." just yet though. The four challenged provisions are important ones. They focus on any willing provider and network adequacy. Because of how important these are, NCPA and several of its industry partners submitted an amicus brief in support of Oklahoma in this matter. We hope to have a decision sometime in 2023.

NAIC includes NCPA suggestions in updated *Rutledge* analysis

The National Association of Insurance Commissioners released an updated analysis of the U.S. Supreme Court *Rutledge* decision for inclusion in its influential ERISA Handbook. The ERISA Handbook is a powerful tool in state efforts to enforce PBM regulations because it is the go-to resource for state insurance commissioners looking for information on the federal ERISA statute's effect on their ability to regulate PBMs controlling employer and union-based plans. In *Rutledge*, the Supreme Court determined that the federal ERISA statute does not preclude the state from regulating PBMs serving ERISA plans. In the updated analysis, NAIC incorporated suggestions from NCPA and 41 state pharmacy associations addressing the fact that the ruling has implications for all 50 states and U.S. territories, not just Arkansas, the subject of the specific lawsuit. The analysis is still working its way through NAIC for final approval. This is important because state enforcement of PBM laws is lackluster. A roadmap provided by NAIC to state departments of insurance when it comes to PBM regulation could be game changing.

Rutledge v. PCMA: 15 Years in the Making



'05

PCMA v. Rowe, No. 05-1606, (1st Cir.).

- Maine's Unfair Prescription Drug Practices Act ("UPDPA"), enacted in 2003, was one of the first PBM laws in the nation to be challenged by PCMA.
- NCPA provided support to Maine attorney general in successfully defending statute before the First Circuit.

'14

PCMA v. Gerhart, No. 14-cv-345 (D. Iowa), on appeal, No. 15-3292 (8th Cir.).

- PCMA files lawsuit against an Iowa law regulating PBM-pharmacy relationships arguing federal ERISA preemption.

'15

NCPA works with the Iowa Pharmacy Association to oppose PCMA.

- The District Court dismisses PCMA's lawsuit.
- PCMA appeals to the Eighth Circuit.

'16

- NCPA and IPA file an amicus curiae brief with the Eighth Circuit defending Iowa's PBM regulations

PCMA v. Rutledge, No. 15-cv-510 (E.D. Ark.), on appeal, No. 17-1609 (8th Cir.), pet. for cert. granted, No. 18-540 (U.S.).

PCMA files lawsuit against an Arkansas law regulating PBM-pharmacy relationship arguing federal ERISA preemption.

'17

- Eighth Circuit reverses the District Court, ruling that Iowa's law is preempted by ERISA.
- NCPA and IPA support Iowa's effort to seek rehearing, Eighth Circuit denies the state's petition.

- District Court rules that Arkansas's law is preempted by ERISA and Arkansas appeals to Eighth Circuit.
- NCPA and IPA file an amicus curiae brief with the Eighth Circuit defending Arkansas's PBM regulations.

'18

- Eighth Circuit rules Arkansas's law is preempted by ERISA, and in response, attorney general's office files a petition with the Supreme Court to review the Eighth Circuit's decision.
- NCPA helps secure an amicus curiae brief from 32 states and the District of Columbia urging the U.S. Supreme Court to review the case.

'19

- Supreme Court calls for the U. S. Solicitor General to file a brief expressing the views of the federal government.
- Solicitor General files brief on behalf of the United States arguing that the Eighth Circuit's decision was wrongly decided and urges Supreme Court to take the case.

'20

- Supreme Court agrees to review case and its decision could have far-reaching implications for the authority of the states to regulate PBMs that process claims for employer- or union-sponsored health plans.

PCMA v. Rowe

PCMA v. Gerhart

PCMA v. Rutledge

This summary is not an all-inclusive analysis of our efforts, but a highlight of major NCPA activity.



“Addressing unlawful business practices that are depriving Americans of affordable medicines and impeding fair competition is a top priority.”

Two years post-*Rutledge*, the fight continues. However, we know some things now that we didn't before the Supreme Court's decision. We know that insurance commissioners and attorneys general should not be afraid to enforce the PBM laws that are on the books. ERISA preemption is not a concern for states that have or want to enact laws that regulate the amounts that PBMs reimburse pharmacies. ERISA will not preempt laws that require PBMs to pay minimum dispensing fees or prohibit PBMs from taking clawbacks. Additionally, there is a good chance that ERISA and Medicare Part D will not preempt any-willing-provider, anti-steering, and pharmacy network provisions, accreditation and recertification requirements, and laws regulating copayment and coinsurance amounts, but states are still fighting those fights.

When I say states, plural, I mean states. In *Mulready*, 34 states and the District of Columbia came together to support the state of Oklahoma. I see tweets from attorneys general, like the one from Pennsylvania's Josh Shapiro that said, "It's simple: we need more small mom-and-pop pharmacies in our hometowns, without big corporations taking them down." Louisiana took on Express Scripts, challenging its refusal to reimburse pharmacies for fees they are required to collect to help fund the state's Medicaid program. Tennessee's attorney general intervened in a matter to help an independent

pharmacy, ThriftyMed, fight the maker of Little Debbie Snack Cakes in enforcing Tennessee's PBM reform laws.

FEDERAL GOVERNMENT ACTIONS

Following *Rutledge*, the federal government has not been entirely impotent. The Centers for Medicare and Medicaid Services took action to end the retroactive nature of pharmacy DIR fees. The Federal Trade Commission, potentially feeling the tide flowing against PBMs, voted to undertake a 6(b) study of PBMs. FTC Chair Lina Khan and Commissioner Alvaro Bedoya have been outspoken about the need to investigate their actions. In case you missed Khan's tweet following her fireside chat at the NCPA 2022 Annual Convention, it said, "Addressing unlawful business practices that are depriving Americans of affordable medicines and impeding fair competition is a top priority."

So, when I reflect on my 18 months as NCPA general counsel and the two years since the *Rutledge* decision, and I talk with my colleagues here at NCPA, we are hopeful that the next two years will usher in more

change and disruption to the PBMs' stranglehold on pharmacy. We want to see insurance commissioners and attorneys general enforcing the laws on the books. We want to see attorneys general take action against anticompetitive activities of PBMs. We want to see the FTC engage in rulemaking to stop PBM anticompetitive activity. We want to see the FTC file standalone Section 5 cases against PBMs. We want to see federal legislation passed that further reinforces the FTC's ability to rein in the antitrust activities of PBMs. And at the end of the next two years, we want to be able to look back and "*celebrate and have a good time!*" ■

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Flipping the PBM narrative

by Chris Linville

On Dec. 27, 2019, then-New York Gov. Andrew Cuomo (D) vetoed legislation passed by the state legislature the previous June designed to license and oversee pharmacy benefit managers. At the time Cuomo says one reason he vetoed the bill (S. 6531) was because provisions would be preempted by ERISA and the *Medicare Modernization Act*, as applied to Medicare Part D.

At the time that was the conventional wisdom regarding ERISA at the state government level. That all began to change a few weeks later. On Jan. 10, 2020, the U.S. Supreme Court agreed to listen *Rutledge v. Pharmaceutical Care Management Association*. Exactly 11 months later, on Dec. 10, 2020, the reckoning arrived, when the court ruled 8-0 in favor of the interests of patients and community pharmacies, who had been fighting for years to regulate PBMs, Medicare Part D drug plans, and large employers.

Anne Cassity, NCPA vice president of federal and state government affairs, says the climate was different when Cuomo vetoed the New York PBM legislation.

“And then a year later we got a very clear decision from the Supreme Court that said states have the authority to regulate ERISA plans,” Cassity said.

According to Matt Magner, NCPA senior director of government affairs, in the immediate aftermath of *Rutledge* in 2021, 11 state bills were enacted that were influenced by the *Rutledge* decision. Overall he says 17 bills have been enacted that were directly influenced by *Rutledge*.

“What those did was essentially regulate PBM reimbursements to pharmacies,” Magner said.

In the two years since *Rutledge*, NCPA's approach has shifted a bit to making sure the laws that were passed are being followed.

“We have a bigger focus on enforcement, so we're working with insurance commissioners,” Magner said. “It's not that we don't still advocate for legislation, but I think our focus has changed in that we are working directly with the insurance commissioners.”

NCPA is also encouraging members to make their voice heard.

“When they notice what they think are violations they should really start filing complaints with insurance commissioners,” Magner said. “Because the commissioners do listen, and they take the complaints seriously. Even if there's nothing that can be done, it's good for them to at least know that there was an issue if there comes a time when the legislature wants to take it up.” (See sidebar below on NCPA's online complaint tool.)

A lot has happened since Cuomo's veto in late December 2019 (in more ways than one, of course).

“It's amazing how things have changed in three years,” Cassity said. “The narrative then compared to what it is now is completely different. Obviously, we have to stay vigilant because the PBMs aren't going to give up, but *Rutledge* has certainly helped spur positive change in the states.” ■

Chris Linville is managing editor of *America's Pharmacist*®.

NCPA online tool can help make sure states are enforcing PBM regulations

Almost every state has passed some form of pharmacy benefit manager regulations over the last several years. Although there have been significant strides forward with comprehensive state PBM regulations and court victories, this is all irrelevant if the state departments of insurance are not enforcing these laws. You must be proactive and hold your insurance regulator's feet to the fire. You do that by filing complaints when the insurers/PBMs are NOT following the law in your respective state. It happens all the time (shocking, we know, PBMs not following the law in your state). The more legitimate, fact-based complaints a department of insurance receives, the more likely it is to investigate and ENFORCE the law. Visit NCPA's online resource at [ncpa.org/pbm-complaints](https://www.ncpa.org/pbm-complaints) to learn how to file a complaint.

State legislation influenced by *Rutledge v. PCMA*

A number of states passed legislation in the immediate aftermath of the *Rutledge* decision in December 2020. More than 25 percent of states have passed legislation addressing rates or reimbursement since the *Rutledge* decision.

Alabama SB 227

Prohibits a PBM from reimbursing its affiliated pharmacies at higher rates than non-affiliated pharmacies.

Arizona SB 1356

Prohibits a PBM from holding a pharmacy responsible for a fee for any step, component, or mechanism related to the claims adjudication process.

Arkansas HB 1804

Makes changes to align existing law with the *Rutledge v. PCMA* decision, thereby granting the insurance department enforcement authority over existing fair pharmacy audit laws.

Iowa HF 2384

Prohibits a PBM from collecting any form of remuneration from a network pharmacy; prohibits a PBM from reimbursing its affiliated pharmacies at higher rates than non-affiliated pharmacies; and prohibits a PBM from retroactively reducing a claim.

Maine LD 686

Requires PBMs and other drug supply chain entities to disclose certain drug pricing information to the state.

Maryland HB 601

Removes provisions exempting ERISA plans from regulations addressing the provision of pharmacy benefits, thereby increasing the number of patients protected by those regulations.

Michigan HB 4348

Requires PBMs to obtain a license from the state; establishes fair pharmacy audit and MAC transparency procedures; requires a PBM to disclose potential conflicts of interest to plan sponsors; requires a PBM to

establish reasonable and adequate retail pharmacy networks; prohibits a PBM from conducting spread pricing; prohibits a PBM from discriminating against non-affiliated pharmacies; prohibits gag clauses and co-pay clawbacks; requires PBMs to file transparency reports; prohibits a PBM from establishing pharmacy accreditation standards that are more stringent than those required by the state; and protects a pharmacy's right to offer delivery services.

Nebraska LB 767

Requires PBMs to obtain a license from the state; establishes fair pharmacy audit and MAC transparency procedures; and prohibits gag clauses and co-pay clawbacks.

New Mexico SB 124

Requires a health plan to reimburse a pharmacy within 14 days of receiving the claim.

North Dakota HB 1492

Prohibits a PBM from holding a pharmacy responsible for a fee for any step, component, or mechanism related to the claims adjudication processing network.

Oklahoma SB 737

Prohibits a PBM from engaging in spread pricing; prohibits a PBM from charging a pharmacy a network participation fee; requires a PBM to file drug pricing transparency reports with the state and plan sponsors; and strengthens the insurance commissioner's authority to penalize PBMs that violate the law.

Oklahoma HB 2677

Strengthens existing fair pharmacy audit protections by limiting audit

periods and allowing a pharmacy to reverse and rebill discrepant claims; strengthens existing MAC list appeal procedures by allowing a PSAO to file an appeal on a pharmacy's behalf and requiring a PBM to adjust a MAC price if a drug is not available from wholesalers at the original price; permits a pharmacy to refuse to dispense a prescription if the reimbursement would be lower than the pharmacy's cost of acquiring the drug.

Tennessee HB 1398

Requires PBM reimbursement rates to reflect a pharmacy's actual acquisition costs.

Tennessee HB 2661

Prohibits a PBM from reimbursing a pharmacy in an amount that is below the drug's acquisition cost; requires a PBM to reimburse certain "low volume" pharmacies a professional dispensing fee that equals the Medicaid dispensing fee; prohibits a PBM from steering patients to a particular pharmacy; and requires a PBM to allow a pharmacy into a preferred network if it is willing and able to meet the terms of participation.

Texas HB 1763

Prohibits a PBM from retroactively reducing claim amounts through effective rates, quality assurance programs, or other means; prohibits a PBM from reimbursing its affiliated pharmacies at higher rates than non-affiliated pharmacies.

Vermont H.353

Establishes that PBMs owe a fiduciary duty to plan sponsors; prohibits a PBM from imposing gag clauses; prohibits a PBM from reimbursing its affiliated pharmacies at higher

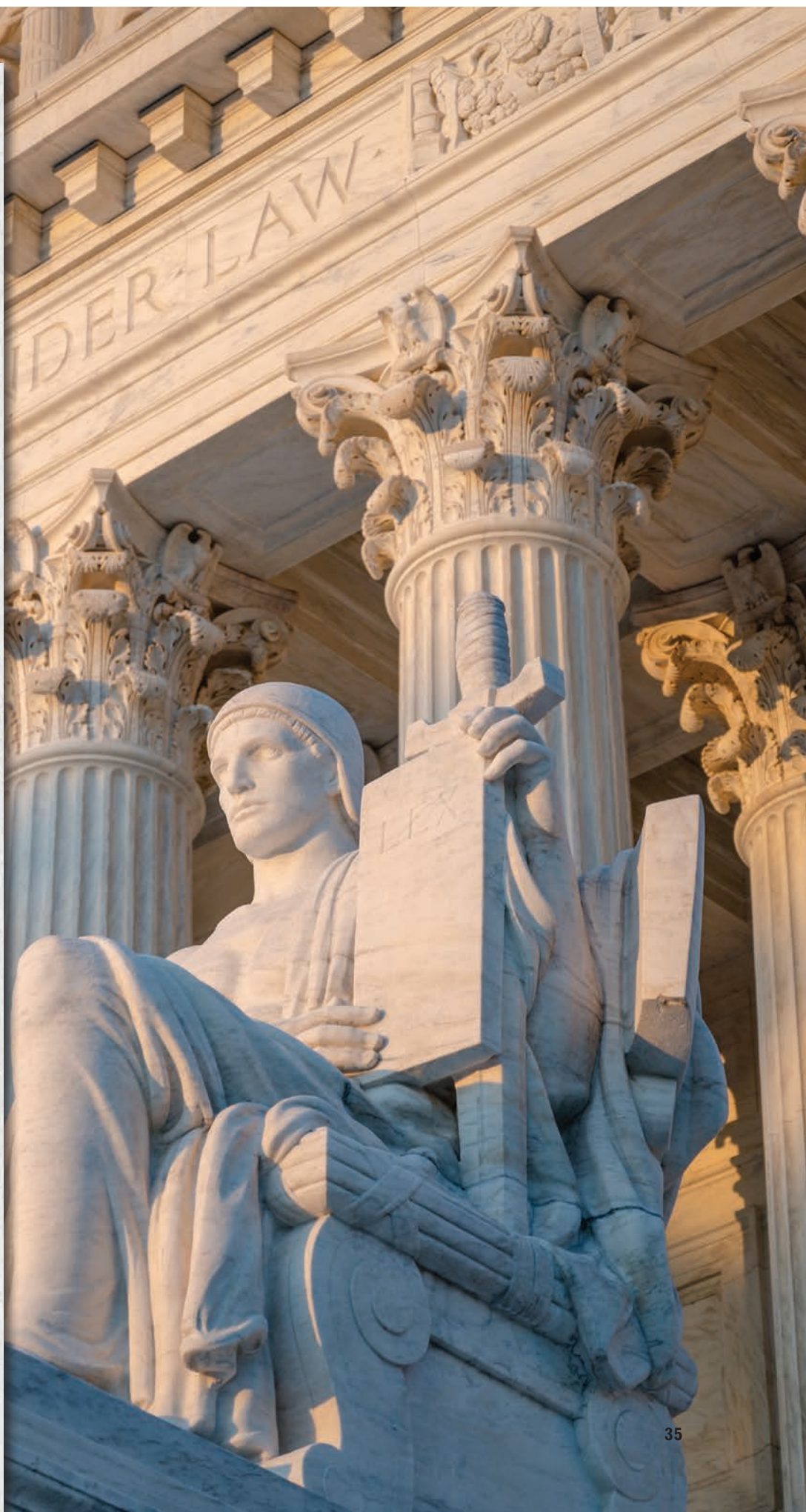
rates than non-affiliated pharmacies; prohibits a PBM from imposing additional requirements above those required by the state for network participation; requires a PBM to permit a pharmacy to dispense all drugs that the PBM's affiliate is permitted to dispense; prohibits a PBM from steering patients to a particular pharmacy; and requires the state to study the need for additional PBM regulations.

West Virginia HB 2263

Requires a PBM to reimburse a claim in an amount that is not less than the drug's National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee of \$10.49; prohibits PBMs from charging a pharmacy a retroactive fee or from deriving revenue from a pharmacy or an insured; prohibits a PBM from reimbursing non-affiliated pharmacies at lower rates than it reimburses its affiliated pharmacies; removes a provision exempting PBMs serving ERISA plans from existing regulations.

Wisconsin SB 3

Prohibits a PBM from retroactively reducing claim amounts except in certain circumstances.



Delivering for pharmacy

In 2022, states stepped up to produce wins for community pharmacy.

Typically, legislation in the states moves much more quickly than at the federal level, and 2022 was no exception. Here's a roundup of pharmacy-friendly initiatives that passed in the last year. NCPA wants to thank all its champions, advocates, and allies in the states (with a particular shout-out to the state associations) who helped support and push measures to help independent community pharmacies and the patients they serve. There's plenty of work still to do, but 2022 created a foundation for success. Visit [ncpa.org/advocacy](https://www.ncpa.org/advocacy) to learn more about NCPA's advocacy efforts.

MEDICAID MANAGED CARE REFORM/PUBLICLY FUNDED PROGRAMS

Kentucky HB 1

Requires the state to issue reports on PBM performance in the Medicaid managed care program.

Kentucky SB 178

Requires the state to enter into a contract with an entity to monitor the PBMs serving the public employees' health benefit program.

Louisiana SB 83

Establishes the Council on Medicaid Pharmacy Reimbursement, which will review Medicaid reimbursement data and trends and recommend changes to cover the reasonable and appropriate costs of providing pharmacy services to Medicaid beneficiaries.

California

Effective Jan. 1, 2022, the California Medicaid pharmacy program transitioned (carved out) from managed

care to fee for service. California estimates the carve-out will save at least \$150 million a year.

Ohio

Effective Oct. 1, 2022, the Ohio Medicaid managed care program now has a single PBM administering the pharmacy benefit. This move will allow better state oversight of the Medicaid pharmacy program while continuing in managed care. Additionally, reimbursements will be more closely aligned with acquisition costs and include a professional dispensing fee.

Investigations

In 2022, Centene has reached settlements with New Hampshire, Ohio, and Washington to resolve claims that the MCO overcharged the states' Medicaid managed care programs for pharmacy benefit management services. This builds on similar settlements from 2021, bringing total number of settlements to 11.

PBM REFORM

Florida HB 357

Permits a pharmacy to appeal the findings of a pharmacy audit and creates penalties for PBMs that fail to register with the state.

Iowa HF 2384

Prohibits a PBM from collecting any form of remuneration from a network pharmacy, prohibits a PBM from reimbursing its affiliated pharmacies at higher rates than non-affiliated pharmacies, and prohibits a PBM from retroactively reducing a claim.

Kansas SB 28

Requires a PBM to obtain a license from the state; strengthens the state's authority to penalize PBMs that violate the law.

Michigan HB 4348

Requires PBMs to obtain a license from the state, establishes fair pharmacy audit and MAC transparency procedures, requires a PBM to disclose potential conflicts of interest to plan sponsors, requires a PBM to establish reasonable and adequate retail pharmacy networks, prohibits a PBM from conducting spread pricing, prohibits a PBM from discriminating against non-affiliated pharmacies; prohibits gag clauses and co pay clawbacks, requires PBMs to file transparency reports; prohibits a PBM from establishing pharmacy accreditation standards that are more stringent than those required by the state, and protects a pharmacy's right to offer delivery services.

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West Virginia HB 4112

Prohibits a PBM from steering patients to a particular pharmacy and prohibits PBMs from creating arbitrary definitions of "specialty drug."

PREP AUTHORITIES

Florida HB 1209

Authorizes pharmacy technicians to administer vaccines listed on the CDC adult immunization schedule.

Pennsylvania HB 2676

Authorizes pharmacists to independently administer COVID-19 and influenza vaccines to individuals 5 years of age and older and extends vaccine authorities to pharmacy technicians under supervision.

Virginia SB 672

Allows pharmacists to administer vaccines on the CDC immunization schedule to individuals 3 years and older.

Wyoming SF 24

Authorizes the administration of immunizations by pharmacy technicians and pharmacy interns.

PROVIDER STATUS AND PAYMENT FOR SERVICES

Alaska HB 145

Clarifies pharmacists' ability to provide services for general health and wellness outside of a collaborative practice agreement and recognizes pharmacists as providers.

Maryland HB 1219

Includes pharmacists in the definition of "health care provider" and requires the state insurance commissioner to establish a workgroup to identify requirements necessary for the reimbursement for pharmacists within their scope of practice.

Oklahoma HB 2322

Includes pharmacists in the definition of "essential community providers" and authorizes that pharmacists receive direct payment or reimbursement from the state Medicaid program for services at no rate less than other providers for the same service.

Maryland

The state insurance commissioner established a workgroup to discuss the barriers to pharmacy reimbursement, the definition of "health care provider," and credentialing of pharmacists as medical care practitioners. A report on the commissioner's findings is due to the Maryland Senate Finance and Maryland House Health and Government Operations Committee on or before Dec. 31, 2022.

Nebraska

The Nebraska Department of Health and Human Services will review state statute to expand immunization authority among pharmacy technicians under the supervision of a licensed provider.

EXPANDING SCOPE OF PRACTICE

Illinois HB 4430

Authorizes pharmacists to initiate, dispense and administer drugs, laboratory tests, assessments, referrals, and consultations for HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

Kansas HB 200

Amends the *Pharmacy Act of Kansas* to include point-of-care testing for and treatment of certain health conditions, such as flu, strep and UTIs.

Maryland HB 229

Permits pharmacists to administer an "injectable medication for treatment of a sexually transmitted infection" that is not a biological product.

Maryland SB 62

Allows pharmacists to prescribe and dispense FDA approved "nicotine replacement therapy medication."

South Carolina S 628

Allows pharmacists to dispense self-administered and injectable hormonal contraception without a prescription. Pharmacists' services are covered by the state Medicaid program.

Wyoming SF 101

Permits pharmacists to prescribe epinephrine auto-injectors and opioid antagonists.