No. 18-540

In the
Supreme Court of the United States

LESLIE RUTLEDGE, ATTORNEY GENERAL OF ARKANSAS,
Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF FOR THE NATIONAL ASSOCIATION OF SPECIALTY PHARMACY AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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The National Association of Specialty Pharmacy submits this brief in support of Petitioner, Leslie Rutledge, in her official capacity as Attorney General of the State of Arkansas.[1]

INTEREST OF AMICUS CURIAE

The National Association of Specialty Pharmacy ("NASP") was founded in 2012 to represent the rapidly growing specialty pharmacy industry in the United States. Specialty pharmacies solely or largely provide medications and medication management services to individuals with serious health conditions requiring treatment with complex medication therapies. NASP's members are committed to the practice of specialty pharmacy, with a focus on patients to ensure better clinical outcomes while reducing overall healthcare costs.

NASP represents the nation's leading independent specialty pharmacies and practicing pharmacists, technicians, nurses and support staff; small and mid-size pharmacy benefit managers; pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems, hospital and health systems and health plans; and technology and data management companies (collectively referred to herein

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[1] Pursuant to Sup. Ct. R. 37.2(a), amicus curiae provided timely notice of its intention to file this brief. The parties have consented to the filing of this brief. Counsel for amicus curiae authored this brief in whole. No other person or entity other than amicus curiae, its members or counsel, made a monetary contribution to the preparation or submission of this brief.

as "specialty pharmacies"). With over 125 corporate members and 2,000 individual members, NASP is the unified voice of specialty pharmacy in the United States.

The Court's decision in this case will impact the nationwide efforts by States to regulate the manner in which pharmacy benefit managers conduct themselves toward specialty pharmacies, which are serving the most vulnerable residents of such States. As a result, this case will substantially affect the day-to-day business of specialty pharmacies and their patients. NASP is well positioned to help the Court understand this complex industry and the impact its decision will have on specialty pharmacies and the millions of individuals in this country who rely so heavily on their valuable services.

SUMMARY OF ARGUMENT

At stake in this case is whether States may regulate the abusive and anticompetitive business practices occurring within their borders at the hands of select pharmacy benefit managers ("PBMs"). These destructive practices now threaten our health system's ability to provide critical pharmaceutical care to the most fragile and ill patients in the United States. Nothing in ERISA compels States to stand by and accept such a result.

PBMs control prescription drug benefits for over 250 million Americans. They are "middle-men" that operate at the intersection of drug manufacturers, payors and pharmacies. Among other things, PBMs establish pharmacy networks for beneficiaries under insurance

plans and set the reimbursement rates that pharmacies receive for providing medications and comprehensive patient care support services to insurance beneficiaries.

In order to ensure comprehensive patient care, PBMs include specialty pharmacies in the pharmacy networks that they create on behalf of their insurance company clients. Specialty pharmacies provide medications for individuals with serious health conditions requiring complex therapies, such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. Total U.S. expenditures for specialty drugs have almost doubled from $83 billion in 2013 to $157 billion in 2017.[2] Specialty pharmacies are vital as specialty medications are trending to account for a significant portion of the overall drug spend. Specifically, while only representing 1.3% of total drug claims, specialty drugs account for 48.7% of the drug spend nation-wide.[3]

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[2] Pedram Pahlavan, *Specialty Pharmacy By the Numbers, Pharmacy Times, April 10, 2019*, *available at* https://www.pharmacytimes.com/news/specialty-pharmacy-by-the-numbers.

[3] Pharmacy Benefits Management Institute, Data Deep Dive: Using Data Science and Visual Analytics to Identify Industry Trends and Drive Clinical Innovation, PBMI 2020 National Conference.

Traditional retail community pharmacies cannot routinely dispense specialty medications because such medications may be extremely expensive to maintain in inventory, typically require special handling and mandate substantial patient support and education, which only specialty pharmacies are able to provide.

Specialty pharmacies are thus vital to the most vulnerable patient population—individuals living with chronic diseases and rare conditions. They often serve as the lifeblood between the patient's healthcare team and life-saving medication treatment regimens.

An absence of meaningful regulation and a lack of transparency in the PBM market has allowed large PBMs with market dominance to deviate from their original purpose of acting as honest brokers to lower medical costs. Today, certain PBMs, as a matter of course, require that specialty pharmacies accept reimbursement rates far below their actual costs as a condition to participating in their networks. The losses that these PBMs seek to impose on specialty pharmacies are even more egregious based on fees that PBMs charge specialty pharmacies months and sometimes years after reimbursement has been remitted. These fees, while purportedly tied to certain performance metrics, are based on criteria which are oftentimes impossible for specialty pharmacies to satisfy. Moreover, certain PBMs impose costly and unfairly rigorous standards upon pharmacies to become part of their specialty networks. And, once such pharmacies become participants in PBM specialty networks and expose their patient data to the PBMs, these large PBMs, as a matter of course, go to great

lengths to divert such specialty patients to their own affiliated pharmacies. The result of these practices has been to line the pockets of the largest PBMs with billions of dollars in profits and subject specialty pharmacies to enormous financial pressures, forcing many of them out of business.

The Federal Government has long deferred to the States to regulate the business of insurance. And dozens of States have recognized that market-dominating PBMs directly threaten the most ill and vulnerable residents by undermining the viability of specialty pharmacies. Accordingly, many States have implemented laws requiring that PBMs act fairly towards the pharmacies doing business in their States. Any ruling affirming the Eighth Circuit will strip States of their ability to regulate and remedy abusive insurance practices perpetrated by large PBMs. Without allowing States to require fair reimbursement to specialty pharmacies, such pharmacies will continue to be forced out of business and individuals who rely upon them to help properly treat their ailments, will be left to suffer.

ARGUMENT

I. The Role Of Specialty Pharmacies Is Vital To Individuals Living With Rare And Chronic Diseases

Specialty drugs are medications that have a complex profile that require intensive patient management. They are far more complex than most prescription medications and are used to treat patients with serious and often life-threatening conditions,

including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders.

A specialty drug may be complex because of the way the drug is administered, the management of its side effect profile, the disease or condition it is used to treat, special access conditions required by the manufacturer, payer authorization or benefit requirements, patient financial hardship or any combination of these characteristics. As a result, patients being treated with specialty medications require comprehensive patient care, clinical management, and product support services. Specialty pharmacies are the pharmacy type best capable of providing these services.

Specialty pharmacies serve a unique and distinct role, as compared to traditional retail pharmacies. They not only connect patients who are severely ill or have complex chronic diseases with the medications prescribed for their conditions, but they also serve more broadly as members of patients' healthcare teams to consult on treatment options and regimens. Specialty pharmacies provide the patient care services that are required for complex and high-cost medications. They also provide medication management services, education on drug use, management of side effect profiles, training on drug administration, comprehensive treatment assessments, patient monitoring and support for patients who are facing financial challenges. And NASP member specialty pharmacies help patients start their therapy days or weeks faster than the large PBM-affiliated pharmacies,

due their patient-centric focus. The faster therapy start time is crucial for patients dealing with a diagnosis of progressive diseases such as cancer or cystic fibrosis, for example.

Specialty pharmacies provide expert services that improve patient care. These services drive adherence to medication regimens, proper management of medication dosing and side effects, and ensure appropriate medication use. Specialty pharmacies use a patient-centric model that provides a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieves superior clinical and economic outcomes, and expedites patient access to care. They employ a personalized approach to patient care and typically have a dedicated, trained staff of professionals to help review, dispense, and monitor patients' medication treatments, twenty-four hours a day, seven days a week.

II. Market-Dominating Pharmacy Benefit Managers Threaten The Existence Of Specialty Pharmacies

A. PBMs Have Enormous Market Power That They Have Abused

States recognize that specialty pharmacies in their communities are essential to patient welfare. Laws such as Arkansas Act 900, codified at Ark. Code Ann. § 17-92-507 ("Act 900"), simply require that PBMs reimburse pharmacies at levels that allow them to avoid losses, and more often than not, simply break even on the medications they dispense. However, large PBMs continue to throw up roadblocks at specialty

pharmacies by "rewarding" those pharmacies who invest substantial amounts of time and money to become members of their specialty networks with lower reimbursement, all while requiring comprehensive services to members that go unreimbursed.

Health plans and employers contract with PBMs to secure prescription drugs from pharmaceutical manufacturers, design and manage drug formularies, ensure appropriate drug utilization, contract with pharmacies to dispense the drugs and provide the required patient management services. The PBMs, however, have deviated from their original purpose of acting as honest brokers to lower medical costs and are now a key contributor to the increasing cost of prescription drugs. For example, PBMs are able to extract massive rebates from drug manufacturers. The massive rebates create an incentive for certain PBMs to support higher, artificial list prices for brand drugs (since drug companies will raise prices to provide bigger rebates). Indeed, rebates have more than doubled in the last five years and, in 2018, pharmaceutical manufacturers paid $166 billion in rebates and price concessions to PBMs, insurers, and the supply chain.[4] These outsized profits and control over the market are a result from massive concentration among the top PBMs.

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[4] Adam J. Fein, *The Gross Net Bubble Reached a Record $166 Billion in 2018*, Drug Channels, April 2, 2019.

The PBM market is highly concentrated with three PBMs (CVS Caremark, Express Scripts and OptumRx) controlling 85% of the market share for PBM services.[5] The White House Council of Economic Advisors found that the "big three" PBMs' control of the PBM market "allows them to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."[6] Indeed, the three largest PBMs have a higher gross profit than any other players involved in the drug supply chain (distributors, insurers, or pharmacies),[7] with profits increasing at a rapid pace, now exceeding $6 billion annually.[8]

The concentrated market is not just limited to PBM services. Rather, the three major PBMs are each affiliated with a major health insurance company and they each own specialty pharmacies, mail order pharmacies and, in the case of CVS Health, the largest retail and specialty pharmacy chain and long-term care

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[5] The White House Council of Economic Advisors, White Paper, Reforming Biopharmaceutical Pricing at Home and Aboard (February 2018).

[6] *Id.*

[7] Charlie Grant, *Hidden Profits in the Prescription Drug Supply Chain*, Wall Street J., February 24, 2018.

[8] The White House Council of Economic Advisors, White Paper, Reforming Biopharmaceutical Pricing at Home and Abroad (February 2018).

pharmacy.[9] Indeed, the largest specialty pharmacies in the U.S., defined by share of prescription revenues from specialty drugs, are owned by PBMs, accounting for fifty (50%) percent of the specialty pharmacy market share.[10]

When a PBM is commonly owned with the entity it is supposed to bargain with, or one that has its own insurer and specialty pharmacy, there is an inherent conflict of interest that can lessen consumer choice and quality of care. Select PBMs have taken advantage of their vertical structures and unfettered market

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[9] The three big PBMs are all vertically integrated entities, either owning or owned by the largest insurance companies in the United States, and each having its own affiliated specialty pharmacies. CVS Health owns Aetna, a transaction which cleared in 2019 for $69 billion. It also owns CVS Specialty/Aetna Specialty Pharmacy, the largest specialty pharmacy with 25% of the market and $37 billion in prescription revenue from specialty drugs in 2018. It also purchased five (5) specialty pharmacies in 2018: Apothecary By Design, Central Drugs, EncompassRx, EntrustRx and SimplictyRx. Adam J. Fein, *Specialty Pharmacy M&A: Our Look at 2018's Deals*, Drug Channels, January 3, 2019. Cigna purchased Express Scripts in a 2019 $54 billion transaction. Express Scripts owns Accredo, Freedom Fertility and Cigna Specialty Pharmacy, which are all specialty pharmacies earning 2018 revenues of $30.7 billion from specialty drug prescriptions, and controlling approximately 20% of the specialty pharmacy market. OptumRx is owned by UnitedHealth Group. It owns Briova, a specialty pharmacy, and in 2018 and 2019 respectively purchased Avella and Diplomat, two formerly-independent specialty pharmacies.

[10] Adam J. Fein, *The Top 15 Specialty Pharmacies of 2018: PBMs Keep Winning, Drug Channels*, April 9, 2019, *available at* https://www.drugchannels.net/2019/04/the-top-15-specialty-pharmacies-of-2018.html.

positions to engage in anticompetitive conduct that harms rival pharmacies and, ultimately, consumers, thereby crippling specialty pharmacies and enriching themselves.

Market-dominating PBMs make it nearly impossible for specialty pharmacies to stay in business. Operating as a specialty pharmacy requires access to substantial funds just to be able to purchase specialty medications. Specialty drugs are typically far more expensive than those drugs traditionally dispensed by other pharmacies. The average monthly specialty pharmacy outlay for a specialty drug is often more than $3,000.[11] However, many of the most commonly prescribed specialty drugs cost far more and typically have no generic drug alternatives.

For example, the average wholesale cost of Hepatitis C drug Harvoni averages $1,125 per pill, equating to $94,500 for a 12-week treatment course; and the average pharmacy cost for Neulasta, which helps prevent infection in cancer patients receiving chemotherapy, is $6,231 per dose.[12] Compare this to a drug typically carried by a traditional retail pharmacy, such as atorvastatin, a generic statin drug used to

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[11] Julie Cook Ramirez, *How to Get a Handle on Specialty-Drug Costs*, Humana Resources Executive, July 24, 2019, available at https://hrexecutive.com/how-to-get-a-handle-on-specialty-drug-costs.

[12] *Id*.

lower cholesterol, for which the average cost to the pharmacy only $2.10 for a month's supply.[13]

In addition to the high cost of specialty drugs, in order to provide such drugs to PBM members, PBMs impose extremely rigorous criteria on specialty pharmacies that need to be satisfied in order to participate in PBMs' specialty pharmacy networks. Certain criteria requires multiple accreditations, licensure in all 50 states and substantial reporting requirements ranging from clinical outcomes for new therapeutic categories associated with clinical management programs to call wait time and patient satisfaction, just to name a few. Satisfying these requirements requires substantial investments by specialty pharmacies in the range of hundreds of thousands, if not millions, of dollars.

Further, in the "fortunate event" that specialty pharmacies are granted access to PBMs' specialty pharmacy networks, the reimbursement rates to such pharmacies then, as a matter of course, become even lower than the rates received by standard pharmacies in PBM retail networks. Such declining reimbursement is particularly onerous, given all of the additional services that are provided by specialty pharmacies to patients that go unreimbursed by PBMs, including the provision of nursing services and patient coordinators, assistance with drug administration, specialized education on drug use, management of side effective

[13] National Average Drug Acquisition Cost, Centers for Medicare and Medicaid Services.

protocols, medication therapy monitoring and financial assistance services, by way of example.

As set forth below, as a matter of course, large PBMs may employ a number of schemes to put additional financial pressure on and eliminate specialty pharmacies as competition to their own affiliated pharmacies including, (1) imposing base reimbursement rates for specialty drugs that deny specialty pharmacies the ability to even recoup their wholesale costs; (2) implementing burdensome performance fees, retroactively clawed back after the point-of-sale, based on measures inapplicable to the drugs they dispense and disease states they manage; and (3) steering patients to their own affiliated pharmacy and placing significant restrictions on network access for their members, often denying their members the ability to select the pharmacy of their choice. These tactics that make it nearly impossible for specialty pharmacies to stay in business, thus threatening pharmacy access and choice and ultimately the lives of individuals who require immediate access to medication and services that only specialty pharmacies can provide. And they render the need for State regulation of PBMs that much more important.

B. PBMs Drive Down Reimbursement Rates For Medications Dispensed By Specialty Pharmacies To Crippling Levels

PBMs use their market power and an historic absence of regulation to drive down reimbursement to specialty pharmacies below their cost of doing business. States recognize the severity of this concern.

For example, a study recently commissioned by the New York Senate concluded that the declining reimbursement to pharmacies is so severe that "it is the opinion of the [Committee on Investigations and Government Operations] that legislation ensuring pharmacy reimbursements *at the very least* cover the cost to dispense is crucial to combat the anti-competitive practices of PBMs" that are impacting pharmacies.[14] The same study explicitly found that the average decrease in pharmacy reimbursement by PBMs to sampled New York pharmacies resulted in a 98% reduction in reimbursement in the first quarter of 2018 compared to the first quarter of 2016.[15]

Further, the State of Arkansas found that CVS Caremark had significantly decreased reimbursement rates for medications to pharmacies below rates provided their own affiliated pharmacies to the level at which such reductions resulted in severe financial hardship. The reimbursement rate reductions were inexplicably followed by buyout letters to pharmacies.[16] Arkansas' findings are in line with a recent Business Insider report that specifically found that for a Fentanyl Patch 100, CVS Caremark, the largest PBM,

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[14] Final Investigative Report: Pharmacy Benefit Managers in New York, Committee on Investigations and Government Operations, New York Senate at 67, May 31, 2019. (emphasis in original).

[15] *Id*. at 49.

[16] See *Rutledge to Investigate Reimbursement Rates From CVS Caremark*, Press Release (February 8, 2018), available at https://arkansasag.gov/media-center/news-releases/rutledge-to-investigate-reimbursement-rates-from-cvs-caremark.

reimbursed its own CVS pharmacies $400.65, while pharmacies were reimbursed $75.74.[17]

At the same time that PBMs are artificially driving down reimbursement rates, they are also charging specialty pharmacies significant fees, often in the millions of dollars.[18] PBMs have increasingly charged fees to pharmacies under the guise of Direct and Indirect Remuneration ("DIR") pharmacy price concession fees.[19] Pharmacy DIR fees have traditionally been fees a Medicare Part D plan/PBM may collect to offset its costs. However, PBMs have also begun expanding DIR fees for commercial plans. Pharmacy DIR fees are arbitrary and appear in numerous forms, including service fees, network access fees, administrative fees, post point-of-sale performance fees, etc. The Center for Medicare and Medicaid Services ("CMS") defines pharmacy DIR fees as additional compensation paid to Medicare Part D prescription drug plans or PBMs after the point-of-sale that serves to change the final cost of the drug for the insurer, or the price paid to the pharmacy for the

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[17] Linette Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the US Will Make Your Blood Boil*, Business Insider, Mar. 30, 2019.

[18] *See, e.g.,* Michael Carrier, *A Six-Step Solution to the PBM Problem*, Health Affairs (August 30, 2018), available at https://www.healthaffairs.org/do/10.1377/hblog20180823.383881/full/; *see also*, Adam J. Fein, *Pharmacy DIR Fees Hit a Record $9 Billion in 2019 – That's 18% of Total Medicare Part D Rebates*, Drug Channel, February 13, 2020 (noting that pharmacy DIR payments reached $9.1 billion in 2019).

[19] 83 Fed. Reg. 62174 (November 30, 2018).

drug.[20] DIR compensation include rebates provided by manufacturers and concessions paid by pharmacies. DIR fees were originally supposed to be a way for CMS to have an accurate reconciliation of what the Medicare Part D program was paying for prescriptions drugs inclusive of all financial transactions able to be accounted for at the point-of-sale, but now they are being used as a way for PBMs to "claw back" money from pharmacies and the practice is under scrutiny.[21]

Large PBMs impose DIR fees on specialty pharmacies, requiring that they meet certain vague performance standards. Instead of focusing on clinical outcomes, these DIR fees are typically assessed months – and sometimes up to a year – after claims are submitted and reimbursed, and are based on wholly inapplicable performance or quality metrics tied to drugs that are not dispensed by specialty pharmacies and disease states not being managed by specialty pharmacies. For example, specialty pharmacies that dispense medications and provide patient care services for conditions like cystic fibrosis, hemophilia, or multiple sclerosis encounter DIR-related pharmacy performance scores associated with conditions like diabetes and cardiovascular disease applied against them with the purpose of reducing their reimbursement in the form of claw back fees. As applied to specialty pharmacies, DIR fees are entirely punitive, categorically inappropriate and do not

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[20] *Id.*

[21] Davy James, *Legislators Push HHS to Stop Pharmacy DIR Fees*, Specialty Pharmacy Times, August 6, 2018.

enhance the quality of pharmacy performance or clinical outcomes.

Such fees force specialty pharmacies to face significant financial uncertainty, because their actual reimbursement rates cannot be determined until well after they have dispensed the medications. Oftentimes when the reimbursement is reconciled, it is far less than the actual cost of the drug, which is further complicated by the cost of the requisite, yet unreimbursed, services needed to support the treatment of a specialty patient. These fees threaten the ability for specialty pharmacies – particularly those that do not have the means to offset lost revenues or costs with other portions of their business – to remain network providers, risking access for patients. For specialty patients, lacking access to a specialty pharmacy could be catastrophic, as missing or delaying doses or stopping therapy altogether often results in serious setbacks in treatment and increased hospitalization.

Specialty pharmacies have found themselves in a no-win situation, being disproportionately affected by reduced reimbursement rates and so-called performance measure cuts. Non-transparent and often excessive pharmacy price concessions in the form of claw-backs, well after the point-of-sale, limit a specialty pharmacy's ability to remain in-network. Less market competition ultimately results in higher costs to the plan sponsor and restricted patient access for beneficiaries, especially specialty patients with complex medication needs that often require the care management provided by specialty pharmacies. The

inability to enact protective measures against such conduct would be detrimental to the specialty pharmacy market and their patients.

C. PBMs Dictate The Pharmacies Its Members Can Utilize

PBMs may also utilize their market power to divert patients from specialty pharmacies to narrow networks that exclude specialty pharmacies. PBMs have access to every prescription drug claim that is adjudicated at every network pharmacy for their members. In turn, where PBMs see lucrative prescription drug claims, they have the incentive to intervene through the individual member's insurance plan and require that the patient use their affiliated specialty pharmacy. A pattern of patient steering by PBMs has been identified, for example, in a recent study of Florida's Medicaid Managed Care Organizations, which are run by large PBMs, including OptumRx, specifically noting "we also identified growing trends of expansive brand prescriptions being steered to PBM/MCO-affiliated pharmacies, and once dispensed at those affiliated pharmacies, the claims appear to be more expensive than those filled at other pharmacies."[22] The study confirmed what has been found by other states, that PBMs "are data mining patient data to steer patients to pharmacies affiliated with such PBMs and insurers

[22] 3 Axis Advisors, Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis (January 30, 2020).

resulting in limited patient choice, waste of resources, increased costs, and lower quality of care to patients."[23]

PBMs also frustrate patients' access to rival pharmacies through the design and implementation of restrictive formularies and tiering policies, designation of captive pharmacies as preferred providers, implementation of narrow networks for specialty pharmacies, and implementation of financial incentives to use the PBMs' specialty or mail order pharmacies. Through these processes, patients are diverted to PBM-affiliated pharmacies. Not only does this steering financially impact the pharmacy, but it oftentimes jeopardizes the care of patients who are stabilized on therapy and disrupts the relationship built between the patient and pharmacy/pharmacist.

This concern is not theoretical. PBMs are able to mandate the use of specific pharmacies for many of their members. Large PBMs affiliated with insurance companies have demonstrated the ability to force patients to obtain their medications only at captive pharmacies, thus denying patients the freedom of choice of pharmacy providers.[24]

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[23] Amy Jeon McCullough, *Georgia Leads the Way with Enactment of Pharmacy Anti-Steering Law*, Health Law Rx, May 30, 2019.

[24] *See, e.g.,* Steven Pearlstein, *CVS Bought Your Local Drugstore, Mail-Order Pharmacy and Health Insurer. What's Next, Your Hospital?*, The Washington Post (Jan. 31, 2019). ("CVS often requires consumers to buy drugs for chronic conditions from its mail-order pharmacy, or makes it more expensive not to do so.").

III. Affirmance Of The Decision Of The Court Of Appeals Would Leave States Powerless To Regulate PBM Conduct That Impacts Public Health

The goals of State insurance regulation are, among other things, preventing unfair pricing by insurance companies and ensuring availability of insurance coverage.[25] In other words, State departments of insurance exist to ensure that residents of their States have access to appropriate health care under their insurance policies. Specialty pharmacies are in need of protection through State oversight because the individuals they serve are the most fragile and vulnerable individuals who reside in their States. Just like States need to be able to ensure that individuals have appropriate coverage to obtain antibiotics they need, States have an even greater need to protect the availability of specialty pharmacies to allow State residents to access specialty drugs that require high-touch services, education, monitoring and care coordination for which traditional pharmacies are not suited to provide.

Historically, States have acted to ensure the appropriate provision of healthcare in their borders.[26] Once health insurance companies, whose control over

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[25] Susan Randall, Insurance Regulation In The United States: Regulatory Federalism And The National Association of Insurance Commissioners, 26 FLA. STATE UNIV. L. REV. 625, 629 (1999).

[26] *See, e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (acknowledging the "historic primacy of state regulation of matters of health and safety").

prescription drug benefits were regulated by State departments of insurance, handed control of prescription drug benefits to PBMs, there was nothing inherent in such arrangements that immunized PBMs from the same State regulations. PBMs are now carrying out the same functions previously handled by their health insurance company clients. PBMs, therefore, should be subject to State insurance regulations that are similarly applicable to health insurance companies operating in a given state. Act 900 is an appropriate and legally valid attempt by the State of Arkansas to help protect vulnerable patients by ensuring fair reimbursement to pharmacies equal to at least what the pharmacy paid for medication it is dispensing to patients. Dozens of other states have acknowledged the need for such protections as well to ensure that residents of their States have access to quality and necessary healthcare.

At least thirty-eight (38) States, recognizing the power wielded by PBMs, have enacted some form of PBM regulation.[27] Moreover, in 2019 alone, thirty-two (32) States implemented or strengthened some form of legislation/regulation relating to PBM conduct. That legislation/regulation included, among other things,

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[27] *See, e.g., Rutledge v. Pharmaceutical Care Management Association*, Case No. 18-540 (U.S. Sup. Ct. 2020) (Brief for the States of California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Texas, Utah, Vermont, Virginia, Washington, Wyoming and the District of Columbia as Amici Curiae in Support of Petitioner).

Medicaid Managed Care reform, PBM registration/licensure, fair PBM audits of pharmacies, enhanced transparency requirements and patient protections including, provisions broadening pharmacy delivery services and patient rights to choose the pharmacy of their choice.[28] Such regulation of PBMs is a response to the predatory practices imposed upon pharmacies. It is also consistent with public policy in favor of individuals being able to obtain needed healthcare.

This Court has long recognized that "insurance is business coupled with public interest…[b]ecause the interests protected are so important…including an individual's future ability to…obtain necessary medical treatment."[29] The laudable goal to obtain necessary medical treatment through State regulation should equally apply to beneficiaries of Medicare, and other federally-funded health care programs, as it does to beneficiaries of State-controlled and private funded plans. While not identified in the State of Arkansas's petition for Writ of Certiorari, as the Eighth Circuit likewise held that Act 900 was preempted by Medicare Part D, the Court should also consider the question whether Medicare law preempts Act 900 and similar State laws. NASP submits that it does not. Similar to commercial health insurance plans, which are subject

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[28] National Community Pharmacists Association, 2019 State Legislative Wins for Community Pharmacists, January 17, 2020.

[29] Susan Randall, *Insurance Regulation In The United States: Regulatory Federalism And The National Association of Insurance Commissioners*, 26 FLA. STATE UNIV. L. REV. 625, 627 (1999) (citing *German Alliance Ins. Co. v. Lewis*, 233 U.S. 389 (1914)).

to far less scrutiny compared to federally-sponsored healthcare programs, there has been little-to-no transparency for pharmacies under the Medicare Part D payment system with final reimbursement often being far below a pharmacy's net costs.

Specialty pharmacies are unable to provide the extensive care management services needed to support medication therapy and oversight if reimbursement is below their cost. The net effect of unreasonable reimbursement is restricted pharmacy networks as pharmacies cannot accept network terms, limiting beneficiary and provider access to a specialty pharmacy needed to support beneficiary needs. For this reason, laws such as Act 900 are vital to protect specialty pharmacies' abilities to obtain fair reimbursement for services provided to all patients.

Should this Court affirm a ruling of ERISA preemption for Act 900, it will have a devastating impact on States' abilities to regulate the conduct of PBMs and to ensure that the most vulnerable and sickest residents will have access to needed care for their rare and chronic ailments. Many specialty pharmacies will be forced to close their doors. The effect will be to force State residents to turn either to more traditional pharmacies that do not stock such medications, are unable to obtain these medications and/or are incapable of providing the patient care and other coordination services that specialty medications require due to the lack of required infrastructure; or, out of state PBM-affiliated pharmacies that are not able to provide the high-touch services provided by specialty pharmacies, and whose clinical decisions are

motivated more by profit than positive health outcomes.

Additionally, affirming the Eighth Circuit's holding has the practical effect of foreclosing Act 900's applicability, even for non-ERISA plans. Although Act 900 continues to apply to non-ERISA plans under the Eighth Circuit's decision, as a practical matter, pharmacies are unable to easily discern the specific health plan of its patients. Rather, pharmacies, upon adjudication of a patient's prescription, are only given information of the PBM that controls the patient's pharmacy benefits. To the extent that a pharmacy is reimbursed below the cost it paid for a drug, it cannot distinguish if such a claim would be for an ERISA or non-ERISA plan, until it has gone through the exhaustive administrative burden of attempting to appeal the reimbursement to the PBM.

IV. Conclusion

Legislation such as Arkansas Act 900 is an important step in reigning in the anticompetitive conduct by select PBMs that disadvantages rival specialty pharmacies, and ultimately harms individuals in need of the care that only specialty pharmacies can provide. Ensuring that specialty pharmacies recoup at least their own costs on vital medication they are providing to patients in need is a step in the right direction. The Eighth Circuit's flawed interpretation of the principles of ERISA preemption will affect thousands of pharmacies and millions of patients across the United States. Left undisturbed, the Eighth Circuit's interpretation will dramatically increase the challenges to State laws by PBMs and

their lobbyists that attempt to regulate misconduct by PBMs occurring within their States, will force numerous specialty pharmacies out of business and will dramatically impact the health of the State's most medically-vulnerable residents.

For the foregoing reasons, the Court should reverse the decision below.

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