NO. 23-1213

In the
Supreme Court of the United States

GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma; OKLAHOMA INSURANCE DEPARTMENT, *et al.*,
Petitioners,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Respondent.

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

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

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The National Association of Specialty Pharmacy submits this brief in support of Petitioner, Glen Mulready, in his official capacity as Attorney General of the State of Oklahoma.[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 specialty pharmacies and practicing pharmacists, technicians, nurses and support staff; some 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 as "specialty pharmacies"). With over 180 corporate members and 3,000 individual members,

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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. 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.

NASP is unifying the voices 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 continue to regulate the anticompetitive business practices occurring within their borders at the hands of select pharmacy benefit managers ("PBMs"). These destructive practices threaten our health system's ability to provide critical pharmaceutical care to the most vulnerable and ill patients in the United States. As this Court recognized in *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020), nothing in ERISA compels States to stand by and accept such a result.

PBMs control prescription drug benefits for over 250 million Americans by operating as "middle-men" 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.

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-accredited specialty pharmacies are able to provide. Specialty pharmacies are thus vital to the most vulnerable patient population—individuals living with life-altering, sometimes life-threatening diseases and rare conditions that can require ongoing management. They often serve as the lifeblood between the patient's healthcare team and life-saving medication treatment regimens. Without specialty pharmacies, patients may experience disruption in treatment, poorer health outcomes, and significant health complications, resulting in emergency department visits, hospital admissions, and avoidable costs to patients and the State.

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, some PBMs often impose costly requirements upon specialty pharmacies in order to become part of their networks. And, once pharmacies become participants in PBM networks and provide their patient data to the PBMs, some of 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 anticompetitive practices has been to line the offending PBMs' pockets with billions of dollars in profits and subject specialty pharmacies to enormous financial pressures, forcing

many of them to stop dispensing certain specialty medications or to have no choice but to be acquired, commonly by one of the largest PBMs.

States have historically regulated the kind of anticompetitive conduct PBMs engage in. Since *Rutledge*, states have been encouraged to further curb the tactics of PBMs: 81 new laws have been enacted by State legislatures geared towards regulating PBMs.[2] All 50 States have recognized that certain market-dominating PBMs directly threaten the most ill and vulnerable residents by undermining the viability of specialty pharmacies.[3]

Oklahoma passed the Patient's Right to Pharmacy Choice Act, 36 Okla. Stat. § 6958, *et seq.* (the "Act"), which was accompanied by various regulations from the Oklahoma Insurance Department. The Act curbs PBM tactics by, among other things: (1) increasing access to retail and specialty pharmacies within a PBM's network (*id.* § 6961(A)-(B), the "Access Standards"); (2) reducing a

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[2] National Academy for State Health Policy, *State Laws Passed to Lower Prescription Drug Costs: 2017-2024, Pharmacy Benefit Managers,* (Updated May 23, 2024), https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/.

[3] *Id.* The Federal Government has also stepped up its scrutiny of PBMs. Fed. Trade Comm'n, *FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy* (July 20, 2023), https://bit.ly/4b1EkMq. Additionally, the House Oversight Committee launched an investigation into the "anticompetitive" practices of PBMs. Committee on Oversight and Accountability, *Comer Launches Investigation Into Pharmacy Benefit Managers' Role in Rising Health Care Costs* (Mar. 1, 2023), https://bit.ly/3y9E674.

PBM's ability to offer discounts and incentives to certain (of its own) pharmacies over independent (non-affiliated) pharmacies (*id.* § 6963(E), the "Discount Prohibition"); (3) requiring a PBM to offer providers the opportunity to participate in its preferred pharmacy network on the same terms it has established for other providers (*id.* § 6962(B)(4), the "Any Willing Provider" or "AWP Provision"); and (4) by prohibiting a PBM from terminating a provider's contract based on the employment status of any employee's probation status with the Oklahoma State Board of Pharmacy (*id.* § 6962(B)(5), the "Probation Prohibition").

These provisions—at their core—regulate the conduct of PBMs and have nothing to do with plan administration or substantive coverage. Allowing the Tenth Circuit's decision to stand, and potentially proliferate, will strip States of their ability to meaningfully regulate and remedy the tactics of some large PBMs and would be inconsistent with this Court's conclusion in *Rutledge* that "ERISA does not preempt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." *Rutledge*, 592 U.S. at 88.

Perhaps most significantly, the Tenth Circuit's decision implicates the validity of "Any Willing Provider" laws, which have been used by States to ensure pharmacies not affiliated with a PBM, including non-affiliated specialty pharmacies, are not driven out of business by discriminatory pricing terms. The Tenth Circuit's overly broad reading of ERISA preemption has cast a dark shadow over Any

Willing Provider laws across the nation; this Court has the opportunity to shed light on the validity of those laws by reiterating *Rutledge's* limitations on ERISA preemption. Without allowing States to regulate PBMs' discriminatory conduct against independent retail and non-affiliated specialty pharmacies, patient choice to access their pharmacies will suffer as more pharmacies are forced to limit the drugs they can dispense or will continue to be forced out of business.

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 and require intensive patient management. They are far more complex than most other 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 effects; 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 have the clinical experience, expertise, staff and infrastructure required to provide these services and coordinate care.

Specialty pharmacies serve a 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 often high-cost medications. They also provide medication management services, education on drug use, management of side effects, 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 some large PBM-affiliated pharmacies, due to their smaller patient volumes and close engagement with the patient's broader care team. 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. 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. Some Market-Dominating PBMs Threaten the Existence of Specialty Pharmacies

A. PBMs Have Enormous Market Power

States recognize that specialty pharmacies that serve patients in their states are essential to patient welfare. Laws such as Oklahoma's Act preserve access to specialty pharmacies for all Oklahomans and prohibit unfair, discriminatory practices that have forced specialty pharmacies to stop dispensing specific drugs and sell their business to certain vertically-integrated PBMs and their vertically-integrated networks.

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. Today, the PBM market is highly concentrated with three PBMs (CVS Caremark, Express Scripts and OptumRx) controlling 80% of the market share for PBM services.[4] In 2018, 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

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[4] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2023: Market Share and Trends for the Biggest Companies – And What's Ahead*, DRUG CHANNELS (Apr. 9, 2024), https://www.drugchannels.net/2024/04/the-top-pharmacy-benefit-managers-of.html.

supposed to be representing, thus generating outsized profits for themselves."[5]

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 pharmacy.[6] Indeed, the largest specialty pharmacies in the U.S., defined by share of prescription revenues from specialty drugs, are owned by PBMs, accounting for 67% of the specialty pharmacy market share.[7] Overall, the pharmacies of the three largest PBMs account for over 50% of the total prescription dispensing revenues for 2023, amounting to over $315 billion annually.[8]

When a PBM is commonly owned with the entity it is supposed to bargain with, or one that has

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[5] The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Aboard* at 10 (February 2018), https://bit.ly/3VneWLJ.

[6] The three big PBMs are all vertically integrated entities, either owning or owned by the largest insurance companies in the United States, and each has its own affiliated specialty pharmacies that comprise approximately 67% of the share of prescription revenues from specialty drugs. Adam J. Fein, *The Top 15 Specialty Pharmacies of 2023: Market Shares and Revenues at the Biggest PBMs, Health Plans, and Independents*, DRUG CHANNELS (Apr. 16, 2024), https://bit.ly/3UEV9qu.

[7] *Id.*

[8] Adam J. Fein, *The Top 15 U.S. Pharmacies of 2023: Market Shares and Revenues at the Biggest Chains and PBMs*, DRUG CHANNELS (Mar. 12, 2024), https://bit.ly/4bWagSg.

its own insurer and specialty pharmacy, there is an inherent conflict of interest that can ultimately limit the network, lessening consumer choice and quality of care. Some major PBMs have taken advantage of their vertical structures and unfettered market positions to engage in anticompetitive conduct that eliminates access to a network of specialty pharmacies, harms rival pharmacies and, ultimately, consumers, thereby crippling specialty pharmacies and enriching themselves.

Market-dominating PBMs make it nearly impossible for specialty pharmacies they do not own or control 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.[9]

In addition to the high cost of specialty drugs, in order to provide such drugs to PBM members, some PBMs impose extremely rigorous criteria on non-affiliated specialty pharmacies that need to be satisfied to participate in their networks. Certain criteria require multiple and often duplicative accreditations rather than a single accreditation by a national independent specialty accreditor, licensure in all 50 states and substantial reporting requirements,

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[9] Julie Cook Ramirez, *How to Get a Handle on Specialty-Drug Costs*, HUMANA RESOURCES EXECUTIVE (July 24, 2019), https://hrexecutive.com/how-to-get-a-handle-on-specialty-drug-costs.

including clinical outcomes for new therapeutic categories associated with clinical management programs, call wait time, and patient satisfaction. 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' pharmacy networks, the reimbursement rates are typically grossly insufficient to cover the cost to acquire, dispense and manage the drug with the patient. Such declining reimbursement is particularly onerous, given all 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 effect protocols, medication therapy monitoring and financial assistance services, by way of example. The result for specialty pharmacies is that they face significant financial uncertainty from underwater reimbursement, in addition to post-sale fees and performance measures that are often irrelevant to specialty pharmacy operations. NASP has witnessed significant, forced consolidation in the specialty pharmacy market resulting from pressures imposed by such tactics.

B. PBMs Have Abused Their Market Power to the Detriment of Non-Affiliated Retail and Specialty Pharmacies

Some 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 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 threaten the ability for specialty pharmacies to stay in network, thus threatening pharmacy access and choice and ultimately the lives of individuals who require immediate and consistent access to medication and services without network disruption. And they render the need for State regulation of PBMs that much more important.

Some PBMs may, for example, utilize their market power to divert patients from specialty pharmacies to narrow networks that exclude non-affiliated 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 and require that the patient use their affiliated specialty pharmacy. A pattern of patient steering by PBMs has been identified, for example, in a study of Florida's Medicaid Managed Care Organizations, which are run by large PBMs. The study "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."[10] The study confirmed what has been found by other states, that some PBMs "are data mining patient data to steer patients to pharmacies affiliated with such PBMs and insurers resulting in limited patient choice, waste of resources, increased costs, and lower quality of care to patients."[11]

PBMs also restrict patients' access to non-affiliated pharmacies through the design and implementation of restrictive formularies and tiered policies, designation of captive pharmacies as preferred providers, implementation of narrow networks for specialty pharmacies, and implementation of financial incentives for patients 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 non-affiliated pharmacies, 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. Certain large PBMs affiliated with

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[10] 3 Axis Advisors, *Sunshine in the Black Box of Pharmacy Benefits Management: Florida Medicaid Pharmacy Claims Analysis* (January 30, 2020), https://bit.ly/4aXBoj7.

[11] Amy Jeon McCullough, *Georgia Leads the Way with Enactment of Pharmacy Anti-Steering Law,* HEALTH LAW RX, JD SUPRA (May 30, 2019), https://bit.ly/3wWzzon.

insurance companies have demonstrated their ability to force patients to obtain their medications only at their own affiliated pharmacies, thus denying patients the freedom of choice of pharmacy providers.[12]

Oklahoma's Act is a meaningful effort to curb these practices. To avoid steering through discounts (only to later charge higher prices), Oklahoma limits PBMs' ability to offer discounts and incentives to certain (of its own) pharmacies over non-affiliated pharmacies. 36 Okla. Stat. § 6963(E). Rather than permitting PBMs to exclude specialty and retail pharmacies arbitrarily, it requires PBMs to offer them the opportunity to participate in their preferred networks on the same terms as the affiliated pharmacies. *Id.* § 6962(B)(4). It also eliminates an arbitrary basis to exclude non-affiliated retail and specialty pharmacies from their network—any one employee's probation status with the Oklahoma State Board of Pharmacy. *Id.* § 6962(B)(5). Finally, it seeks to solve the issue of access to pharmacies in rural neighborhoods, sometimes referred to as "pharmacy deserts."[13] Importantly, the Act does not seek to regulate the plan, plan administration, or substantive coverage. Instead, it is an effort to regulate *PBMs* and any conduct that affects the ability of specialty

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[12] *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.").

[13] Rachel Wittenauer, et al., *Locations and characteristics of pharmacy deserts in the United States: a geospatial study*, Health Affairs Scholar (2024), https://bit.ly/3KdMwgH

pharmacies to provide life-saving medicine to their patients.

III. Affirmance of the Decision of the Court of Appeals Would Weaken the States' Power to Regulate PBM Conduct That Impacts Public Health

Specialty pharmacies are in need of protection through State oversight because they serve the most vulnerable individuals who reside in each State. 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 management and care coordination for which non-accredited traditional pharmacies are not capable of or designed to provide.

Historically, States have acted to ensure the appropriate provision of healthcare in their borders.[14] PBMs are now carrying out the same functions previously handled by their health insurance company clients. PBMs, therefore, at a minimum, should be subject to State insurance regulations that are

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[14] *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"); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995) ("[N]othing in the language of the Act or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern.").

similarly applicable to health insurance companies operating in a given state.

The Act is an appropriate and legally valid attempt by the State of Oklahoma to help protect vulnerable patients by ensuring fair and equal access to specialty pharmacies in Oklahoma. All fifty States, recognizing the power wielded by certain PBMs, have enacted some form of PBM regulation.[15] Since this Court's decision in *Rutledge*, 81 new laws have been enacted by state legislatures geared towards curbing many PBM practices. That legislation has included, among other things, greater disclosure and registration requirements, anti-discrimination provisions, and bans on certain fees and charges by PBMs.[16] Such regulation is a response to the predatory practices too often imposed upon pharmacies and comports with this Court's recognition in *Rutledge* that "not every state law that affects an ERISA plan or causes some disuniformity in

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[15] *See, e.g., Rutledge v. Pharmaceutical Care Management Association*, Case No. 18-540 (U.S. 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); National Academy for State Health Policy, *State Laws Passed to Lower Prescription Drug Costs: 2017-2024: Pharmacy Benefit Managers* (Updated May 23, 2024), https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/.

[16] *See id.*

plan administration has an impermissible connection with an ERISA plan." *Rutledge*, 592 U.S. at 87.

The Tenth Circuit went to great lengths to sidestep the clear import of *Rutledge* that ERISA does not preempt state laws that "merely increase costs or alter incentives for ERISA plans *without forcing plans to adopt any particular scheme of substantive coverage*." *Id.* (emphasis added). The Act does not force upon PBMs a particular plan or scheme of substantive coverage. It does not even address plan administration or substantive coverage, the target of ERISA's concerns. *See id.* at 86-87 ("ERISA is therefore primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status."); *PCMA v. Wehbi*, 18 F.4th 956, 967 (8th Cir. 2021) ("[T]he fact that a PBM must permit a pharmacy to fulfill mail orders or dispense all drugs allowed under its license does not mean that the PBM must *cover* mail orders or all drugs allowed under the pharmacy's license."); *Travelers Ins. Co.*, 514 U.S. at 658 (describing the target of ERISA preemption as "state laws that mandated employee benefit structures or their administration . . . [or] provid[ed] alternative enforcement mechanisms"); *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320-21 (2016) ("[ERISA] seeks to make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures."). Instead, it is a regulation directly targeting the offending PBMs and their historic anticompetitive practices. Perhaps most significantly, the Tenth Circuit's conclusion that

ERISA preempts Oklahoma's Any Willing Provider provision and the other network standards (App. 24-27), places other States' laws in jeopardy. Over thirty States have a version of Oklahoma's Any Willing Provider provision, which they use to ensure fair access to retail and specialty drugs.[17]

Strangely, the Tenth Circuit also made several factual findings about specialty pharmacies and how specialty pharmacies would be impacted by Oklahoma's Act. *See, e.g.* Op. at 30 ("Together, these three provisions effectively abolish the two-tiered network structure, eliminate any reason for plans to employ mail-order or specialty pharmacies, and oblige PBMs to embrace every pharmacy into the fold."); *id.* at 32 ("Oklahoma's network restrictions . . . impede PBMs from offering plans some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies."). It reached these conclusions, apparently, without any undisputed factual findings in the district court. In NASP's view, Oklahoma's Act would not eliminate the need or incentive to employ

[17] The following states have a version of an Any Willing Prover law: Alabama, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Hawai'i, Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. *See* National Academy for State Health Policy, *Pharmacy Benefit Manager*, *State Laws Passed to Lower Prescription Drug Costs: 2017-2024: Pharmacy Benefit Managers* (Updated May 23, 2024), https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/.

non-affiliated specialty pharmacies, but encourages their use across Oklahoma.

Permitting State regulation of PBMs is also consistent with public policy in favor of individuals being able to obtain needed healthcare. Specialty pharmacies are unable to provide the extensive care management services needed to support medication therapy and oversight if PBMs are permitted to offer preferential terms to their affiliated pharmacies and to unfairly discriminate against non-affiliated specialty pharmacies.

When specialty pharmacies are no longer able to serve patients in the state due to these anticompetitive practices that result in them having no choice but to restructure their operations, lay off staff members, cut back on higher-cost inventory or stop stocking and dispensing drugs for certain conditions due to practices like underwater reimbursement, patients ultimately lose access to their specialty pharmacy. This can result in disruption in treatment or delays in new treatment starts as patients are transferred to another pharmacy, and likely a vertically integrated, PBM-owned specialty pharmacy.

IV. Conclusion

The Act is an important step in reining in the anticompetitive conduct by select PBMs that disadvantages non-affiliated specialty pharmacies, and ultimately harms individuals in need of the care that only specialty pharmacies can provide. The Tenth Circuit's flawed interpretation of the principles of ERISA preemption and Medicare Part D

preemption will affect—not just thousands of Oklahomans—but thousands of pharmacies and millions of patients across the United States, who are relying on State legislatures and insurance regulators to curb the unfair practices of some PBMs. Left undisturbed, the Tenth Circuit's interpretation will dramatically increase challenges by PBMs and their lobbyists to the groundswell of State laws that attempt to regulate misconduct by PBMs occurring within their States, will limit patient access to numerous specialty pharmacies and will dramatically impact the health of the state's most medically-vulnerable residents.

For the foregoing reasons, the Court should grant Oklahoma's Petition and reverse the decision below.

Respectfully Submitted,

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