No. 23-1213

IN THE

Supreme Court of the United States

GLEN MULREADY, IN HIS OFFICIAL CAPACITY AS INSURANCE COMMISSIONER OF OKLAHOMA, 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 *AMICUS CURIAE* PATIENTRIGHTSADVOCATE.ORG, INC. IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

PatientRightsAdvocate.org, Inc. (PRA) is a 501(c)(3) nonprofit, non-partisan organization that provides a voice for consumers—patients, employees, employers, and taxpayers—to have competition, transparency, and meaningful choices in healthcare. PRA advocates for patients to have easy, real-time access to complete health information and real price transparency. PRA further aims to support patients and employers in ensuring that health plan assets are spent prudently, transparently, and in the best interests of health plan participants.

PRA believes, and research has shown, that transparency and accountability will usher in price, quality, and outcome differentiation and allow for competition and innovation. Empowered with such information, patients and employers will shop for the best quality of care at the lowest possible price. Consumers will then be in control through choice to reduce their costs of care and coverage, and eliminate the large disparities charged to different patients for the same care. With price certainty, patients can protect their health and wealth for themselves, their families, and the generations to come.

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[1] Under this Court's Rule 37.6, counsel for *amicus curiae* certifies that this brief was not authored in whole or in part by counsel for any party and that no person or entity other than *amicus* or its counsel has made a monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.2, counsel of record received notice of *amicus*' intent to file this brief.

PRA embraces free market principles. PRA believes that price transparency will foster a competitive, functional marketplace and restore trust and accountability to the healthcare system. PRA's website, PatientRightsAdvocate.org, shines a light on both the problem and the free-market solution, and features patients and innovative employers who are already saving substantially by using price transparent providers.

PRA has participated as *amicus curiae* in several prior cases to promote price transparency and ensure that health plan assets are being spent prudently and in the best interests of patients. *See Mass. Laborers' Health & Welfare Fund v. Blue Cross Blue Shield of Mass.*, 66 F.4th 307 (1st Cir. 2023); *Am. Hosp. Ass'n v. Azar*, 983 F.3d 528 (D.C. Cir. 2020); *Am. Hosp. Ass'n v. Azar*, 468 F. Supp. 3d 372 (D.D.C. 2020); *Su v. BCBSM, Inc.,* No. 24-cv-99 (D. Minn.).

SUMMARY OF THE ARGUMENT

For years PBMs have claimed that they support patients by providing health plans with a vast network of pharmacies that sell a wide array of drugs that are discounted through PBM-negotiated rebates. *See, e.g.*, CVS, *Why PBMs? Lower Drug Costs, Better Health Outcomes* (Nov. 28, 2023), bit.ly/4bQ64Uy. That is the *theory* of how PBMs work, but the State of Oklahoma began to realize that the *facts* were quite different. PBMs were driving up drug prices, limiting drug selection, and steering patients away from retail pharmacies to mail-order pharmacies that maximized PBM profit.

Oklahoma passed the Patient's Right to Pharmacy Choice Act to address these issues. The Act required PBMs to expand their pharmacy networks to include willing and able pharmacies and to give covered patients access to a minimum percentage of local, brick-and-mortar pharmacies. The Act also prohibited PBMs from penalizing covered patients for choosing one pharmacy over another. These new rules promoted patient choice and expanded pharmacy competition.

The PBMs, knowing that increased patient access and choice would hurt their bottom-line, sued to stop Oklahoma's law through their trade association, PCMA. In an ironic twist, PCMA asserted preemption under ERISA and Medicare Part D—laws designed to help patients—to ensure that its PBMs could continue to profit at the expense of patients. Yet PBMs typically take the view that they are not fiduciaries under ERISA. In other words, PCMA wants to have its cake and eat it too—no state regulation because it is preempted by ERISA, and no federal regulation because ERISA regulates only plans. Despite the Court's clear rebuke of this litigation strategy in *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80 (2020), the Tenth Circuit sided with PCMA and invalidated four provisions of Oklahoma's law.

The Tenth Circuit's decision is a green light for PBMs to continue their abuses without fear of legal oversight in Oklahoma and beyond. The threat that this decision poses to patients underscores the importance of granting certiorari here. This Court should declare that laws like Oklahoma's are not

preempted so that states remain free to curb PBM abuses. While PBMs were once minor players in the pharmaceutical market, they have now become the gatekeepers of access to life-saving drugs, and PBMs have sought profit and monopolistic power at the expense of patient access and choice. States like Oklahoma thus have good reason to regulate PBMs to "[de]crease costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage," and States should not be preempted when they do so. *Id.* at 88. This important federal question at the heart of the circuit split below warrants this Court's review.

ARGUMENT

I. The high price of drugs is a serious problem that requires innovative public policy solutions.

The status quo of sky-high pharmaceutical prices in the United States is unacceptable. "More than three in four adults in the United States think the costs of prescription drugs are unaffordable and nearly one in three adults say they haven't taken their medications as prescribed due to costs." Nisha Kurani et al., *How Do Prescription Drug Costs In The United States Compare To Other Countries?*, Health System Tracker (Feb. 8, 2022), bit.ly/4bP7m27. "Individuals with annual household income of less than $40,000 are also more likely than adults with higher incomes to report difficulty affording their prescription medications." Ashley Kirzinger et al., *Public Opinion On Prescription Drugs And Their Prices*, KFF (Aug. 21, 2023), bit.ly/4bcJiVX. A staggering 40% of those

patients say it is hard to afford the cost of their prescription medicine, compared to only 11% of patients making $90,000 or more. *Id.*

And this is a uniquely American problem. Simply put, drugs are more expensive in America. "In 2019 … the U.S. spent $1,126 per capita on prescribed medicines, while comparable countries spent $552 on average." Kurani, *supra*. "In the U.S., per capita insurer payments and out-of-pocket spending on prescribed medicines ($963 and $164, respectively in 2019) are both higher than in any other comparable country." *Id.* Moreover, "[t]he prices of many brand-name prescription drugs used to treat conditions including diabetes, cystic fibrosis, and cardiovascular disease are more expensive in the U.S. than in" other similar countries, such as "Germany, the Netherlands, Switzerland or the U.K." *Id.* "For instance, the price of Humira in the U.S. is 423% more expensive that the price in the U.K. and 186% more than that in Germany." *Id.*

There are many reasons for this disparity. "Countries' prescription drug policies can vary based on a number of factors, including the regulation or benchmarking of prescription drug prices, the numbers of and types of payers, the role of pharmaceutical benefit managers, patent protections of drugs, and the availability and prices of generic or biosimilar alternatives." *Id.* But there is now little doubt that PBMs play a significant role in the high price of drugs in the United States. *See, e.g.*, Susan Morse, *PBMs Are Driving Up Drug Prices Through Fees, PhRMA Report Claims*, Healthcare Finance

(Sept. 18, 2023), bit.ly/3xccgXP. "[T]he dirty secret of drug pricing" in America is that "[t]here is a shadowy third player in the transaction between patients and their pharmacists"—PBMs that profit from driving up drug prices. Alex Azar, *How Team Trump Is Bringing Drug Prices Down*, New York Post (Feb. 7, 2019), bit.ly/3RjiXya.

II. PBMs now play a central role in providing patients with pharmaceuticals.

PBMs were "a once obscure segment of the health care financing landscape." Kevin A. Schulman, MD & Barak D. Richman, JD, Ph.D., *The Evolving Pharmaceutical Benefits Market*, JAMA (June 12, 2018), bit.ly/45hnGX6. Their role was minor because the prescription drug market was relatively small and "prescription drug coverage was … administered separately from medical and hospital benefits of health insurance." *Id.* In 1960, "the outpatient prescription drug market was only $2.7 billion, and 96% of the retail US prescription drug market was financed out of pocket by individuals." *Id.* But that changed as "medications became more effective and expensive" and "employers began to offer prescription drug coverage, often administered by PBMs." *Id.* In 1990, the prescription drug market increased to $38 billion, with only 57% financed out of pocket. *Id.* By 2017, the market increased to $360 billion, with only 13% financed out of pocket. *Id.*

PBMs now play a central role in the healthcare market by serving as middlemen between health plans, pharmaceutical manufacturers, insurers, and pharmacies. *See, e.g.*, Nicole Rapfogel, *5 Things To*

Know About Pharmacy Benefit Managers, Center for American Progress (Mar. 13, 2024), bit.ly/3RgODEm. And PBMs are closely affiliated with health insurers, as all the major PBMs are owned by a company that also owns one of the major insurers. *See* Adam J. Fein, PhD, *Mapping the Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers: A May 2023 Update*, Drug Channels (May 10, 2023), bit.ly/3X7Jqm6

PBMs amass a network of pharmacies and offer this network to manufacturers in exchange for rebates to insurers to reduce the cost of the manufacturer's drugs. *See, e.g.*, T. Joseph Mattingly II, PharmD, MBA, Ph.D., et al., *Pharmacy Benefit Managers History, Business Practices, Economics, And Policy*, JAMA Health Forum (Nov. 3, 2023), bit.ly/4aNrj88. PBMs then develop drug formularies (lists of covered prescription drugs developed and maintained within the PBM network) that they offer to health plans. *See id.* And PBMs reduce red tape for plans by processing insurance claims from drug sales to covered patients. *See* Zoe Kemp, *Health Insurance 101: What Is A PBM?*, Sana (Sept. 15, 2022), bit.ly/4aSlHcW. In theory, then, PBMs lower the price of drugs through rebates, expand access to drugs through their formularies, and reduce costs for plans by managing reimbursements.

That's the theory. But this enormously complicated system comes with a catch. PBMs make their money by siphoning off a portion of the rebates that they negotiate with drug makers and by taking a cut of the insurance reimbursements that are paid out to pharmacies for drug purchases. *See* Rapfogel, *supra*.

In practice this creates perverse incentives that harm patients.

III. PBMs increase the cost of drugs by taking a percentage of manufacturer rebates.

First, PBMs "[c]aptur[e] some of the savings from the rebates they negotiate" with manufacturers and "retain a portion of the rebates for their own profit instead of passing the full value of the rebates on to the insurer." Rapfogel, *supra*. Knowing this, manufacturers are incentivized to artificially inflate the list price of a drug, so that the negotiated "rebate" creates the illusion of a discounted price (a common sales tactic in other markets). *See, e.g.*, Testimony of Prof. Robin Feldman, *Hearing On Pharmacy Benefit Managers And The Prescription Drug Supply Chain: Impact On Patients And Taxpayers*, U.S. Senate Committee on Finance (Mar. 30, 2022), bit.ly/3RfmRIk. Meanwhile, patients with high-deductible plans are forced to pay the full inflated list price toward their deductible. *See id.* And PBMs are incentivized to ignore this tactic, because the higher the list price, the higher the rebate, and the more profit the PBM makes. *See, e.g.*, Alex Chan, MPH, MS & Kevin Schulman, MD, *Examining Pharmaceutical Benefits In The United States—A Framework*, JAMA Health Forum (Mar. 13, 2020), bit.ly/4cc8e0o. PBM profit growth is thus driven mainly by "the growth of rebate dollars" and not by "[plan] fees." *Id.*

This problem of divided loyalties has at times led to outright collusion among PBMs to negotiate with drug makers in way that *increases* prices to maximize rebates. According to the Ohio Attorney General, in

2019, "Express Scripts formed Ascent, a group purchasing organization … [to] allo[w] Express Scripts to coordinate pricing and other activities with its competitors." Compl. ¶6, *Ohio v. Ascent Health Servs. LLC*, Dkt. 1-3, No. 2:23-cv-01450 (S.D. Ohio). Express Scripts then "invited its putative competitor, Prime Therapeutics LLC … into Ascent's ownership," which enabled the companies to "share drug pricing and rebate information … [and] to fix rebate prices among them." *Id.* ¶7. "Ascent, Express Scripts, and Prime" then "negotiate[d] with manufacturers with the intent of *increasing* the price of pharmaceuticals, including insulins, biologics, and cancer-fighting drugs." *Id.* (emphasis added).

Coordination between PBMs and manufacturers is not always this overt. Drug manufacturers already know that PBMs "prefer products with high list prices for which it can negotiate high rebates, rather than comparable drugs with lower list prices and smaller rebates." Mattingly, *supra*. "These pricing incentives have led multiple manufacturers, such as Amgen and Viatris, to launch the same drug products at different list prices—a low-price product with no rebate and a higher-price version with rebates—to appeal to different purchasers." *Id.* "Although it seems counterintuitive that any purchaser would prefer a higher price, both companies expect the high-list-price/high-rebate option to be more attractive to PBMs that retain some of the rebates." *Id.*

That PBMs profit from rebates also creates "an incentive to further maximize profits by steering patients to higher-priced drugs with higher rebates."

Rapfogel, *supra*. "This is done by placing drugs at more favorable formulary positions (on a tier with lower cost-sharing levels), which encourages beneficiaries to opt for those drug products." *Id.* Even though patients that purchase brand-name drugs could obtain generic equivalents that cost 80% to 85% less, *see* Dan Wagener, MA, *What's The Difference Between A Brand-Name Drug And A Generic Name Drug?*, GoodRx Health. (Dec. 23, 2021), bit.ly/3RjsmWy, those generics and biosimilars are often excluded from prescription drug plans because of PBM formularies, *see* Megan Van Etten, *It's PBMs, Not Patents, Blocking Competition*, PhRMA (Sept. 14, 2023), bit.ly/45etdxm.

PBM manipulation of formularies to exclude low-price alternatives has ratcheted up in recent years. "In 2022, 1,156 unique prescription medicines were excluded from the standard formularies of at least 1 of the 3 PBMs, a 961% increase from 2014, when 109 medicines were excluded." *Skyrocketing Growth In PBM Formulary Exclusions Continues To Raise Concerns About Patient Access*, Xcenda (May 2022), bit.ly/4eovgTU. And these exclusions have not only led to higher prices but have also impacted the "quality of care" by leaving patients with limited drug options "to treat complex conditions such as cancer, HIV, and autoimmune disorders, for which variation in patient response to treatment is well documented." *Id.* This could mean life or death for some patients. If a PBM uses a "closed formulary," prescribers and patients of a drug that is not included in the formulary must request "prior authorization" from the PBM. ACMP, *Prior Authorization* (July 18, 2019), bit.ly/3Kvqfeu.

"This causes lengthy delays for approval of prescriptions," and "[p]atients suffer, and even die, while they wait for 'authorization.'" Arthur Gale, MD, *If Pharmacy Benefit Managers Raise Drug Prices, Then Why Are They Needed?*, Missouri Medicine (2023), bit.ly/4ecEzWG.

Insurers and plan sponsors have struggled to stop collusive rebates and manipulated formularies because PBMs contend that they have no legal obligation to disclose the details of these practices. PBMs claim that they don't have to tell insurers "how [they] determin[e] formulary placements, why some drugs in the formulary are more costly than others, [or] what proportion of the rebates and negotiated drug payments [they] keep." Rapfogel, *supra*. To address this problem, States have begun to "pas[s] laws that require PBMs to disclose pricing and cost information such as data on rebates, payments, and fees collected from manufacturers, insurers, and pharmacies." Matthew B. Roberts & Benjamin Bosmans-Verdonk, *Pharmacy Benefit Managers: The Market Demands Transparency And Perhaps A Whole Lot More*, Maynard Nexsen (June 16, 2023), bit.ly/3RoR0F9.

PBMs' convoluted rebate system has thus done little, if anything, to control the skyrocketing price of drugs. "Total inflation-adjusted expenditures on prescription drugs grew from $520 billion in 2016 to $603 billion in 2021, a 16 percent increase," with "[d]rug spending … heavily driven by a relatively small number of high-cost products." Sonal Parasrampuria & Stephen Murphy, *Trends In*

Prescription Drug Spending, 2016-2021, HHS Office of Science & Data Policy (Sept. 30, 2022), bit.ly/3RhII20. And drug prices continue to rise year-by-year at a staggering rate. Between 2017 and 2023, each year thousands of drugs have increased in price, with many or most of those prices rising beyond the rate of inflation. *See* Arielle Bosworth et al., *Changes In The List Prices Of Prescription Drugs, 2017-2023*, HHS (Oct. 6, 2023), bit.ly/3VzzVd9. Between January 2022 and January 2023, "more than 4,200 drug products had price increases, of which 46 percent were larger than the rate of inflation," resulting in an average price increase of 15.2% or $590. *Id.* That drug prices continue to rise even as PBMs expand has led to the "growing belief … that PBMs *increase* drug costs," despite their boasts of lowering costs through rebates. Gale, *supra*.

IV. PBMs increase the cost of drugs and cause retail pharmacy closures by taking a cut of insurance reimbursements.

PBMs also make money by engaging in "[s]pread pricing"—the practice of taking a portion of insurance reimbursements for covered drug purchases. When a patient purchases a drug from a pharmacy in the plan's PBM network, the insurer does not reimburse the pharmacy directly. Instead, it reimburses *the PBM* with "a higher payment" than the cost of the drug to the pharmacy. Rapfogel, *supra*. The PBM then reimburses the pharmacy for a reduced amount and pockets the difference. *Id.* Of course, this encourages PBMs to try pay pharmacies as little as possible in reimbursements. "[T]he profit margin on prescription drug sales is [already] slim, and it continues to narrow

due to low reimbursement rates." RxSafe, *Components That Determine Pharmacy Reimbursement In 2020* (Sept. 22, 2020), bit.ly/4bTwmFu. Spread pricing also directly harms patients because the added spread payments made by insurers to PBMs are "passed on to patients as higher premiums and cost sharing." Rapfogel, *supra*.

The exact size of the PBM "spread" is often kept secret and hard to determine, but researchers and governments are slowly discovering that it is substantial. For example, a recent audit by the HHS Office of Inspector General of contracts between the DC government's managed care organizations and PBMs over a three-year period from 2016 to 2019 found that "PBMs kept $23.3 million in spread pricing during [the] audit period." Report, HHS OIG (Mar. 16, 2023), bit.ly/3RdUCtK. "Using spread pricing, PBMs … overcharged state Medicaid programs in Ohio, Kentucky, Illinois, and Arkansas more than $415 million." Gale, *supra*; *see* U.S. House Committee on Oversight and Reform, *A View From Congress: Role Of Pharmacy Benefit Mangers In Pharmaceutical Markets* at 4 (Dec. 10, 2021), bit.ly/4eb7x9z.

In one notorious case, a PBM billed an Iowa county $198.22 for a drug but reimbursed the dispensing pharmacy for just $5.73—a spread of more than 3,400 percent. *See* Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use To Rake In Millions*, Bloomberg (Sept. 11, 2018), bit.ly/4bQ9lmQ. "Audits and industry analysts have found some PBMs pocketing 50 percent or more of the price difference between what the PBM actually pays a pharmacy for

prescriptions and what they charge … the employer/consumer." Healthcare Value Hub, *Pharmacy Benefit Managers: Can They Return To Their Client-Centered Origins?* (Jan. 2018), bit.ly/4caku1t.

Sometimes this spread is so large that the PBM ends up reimbursing the pharmacy for *less* than the pharmacy's total costs in providing the drug. *See, e.g.*, Sen. Chuck Grassley, *The Pharmacy Benefit Manager Transparency Act Of 2022*, bit.ly/3x7IbIW. These "low reimbursement rates continue to be a driving force for pharmacy closures." Joseph L. Fink III, JD, DSC (Hon.), BSPHARM, FAPhA & Josephine M. Gresko, PharmD candidate, *Pharmacy Closures Spark Need For PBM Reform*, Pharmacy Times (May 24, 2024), bit.ly/3VvsAfK. "[B]etween 2009 and 2015, 1 in 8 pharmacies operating had closed, disproportionately affecting independent pharmacies and low-income communities." *Id.* But even when pharmacies are losing money from low PBM reimbursements, they have "little choice but to agree to these contracts, otherwise the PBM will not include them as an in-network pharmacy," which would also "likely pu[t] the pharmacy out of business." Rep. Buddy Carter, *Pulling Back The Curtain On PBMs: A Path Towards Affordable Prescription Drugs* (June 13, 2023), bit.ly/3X9Gx4c.

Making matters worse, PBMs have even tried to force pharmacies in their network to sign "gag clauses" that "prohibit pharmacists from voluntarily informing patients that their prescription medication may cost less if paid for directly by them instead of through

their insurance." Michael Gabay, *RxLegal: Pharmacist Gag Clauses*, Hospital Pharmacy (Sept. 22, 2018), bit.ly/4ch1zSV. "By concealing the least expensive way to purchase a medication, … gag clauses reduce transparency and medication affordability for patients and appear to be counterintuitive to one of the major activities of a PBM—negotiation of drug pricing." *Id.* The discovery of this self-serving tactic led to an uproar and eventually a bipartisan federal ban on the practice. *See* 42 U.S.C. §300gg-19b.

In theory a competitive PBM market would curb these abuses, because plans and pharmacies could "shop around" for a PBM that negotiated better rebates and had lower spread pricing. But the market is not competitive. "By 2015, industry consolidation had resulted in 3 PBMs—CVS Caremark, Express Scripts, and UnitedHealth's Optum—controlling a 73% share of the PBM market." Matan C. Dabora, MD, MBA, et al., *Financing And Distribution Of Pharmaceuticals In The United States*, JAMA (July 4, 2017). In 2022, "[s]ix PBMs accounted for 96 percent of the market share, and the top three made up 79 percent." Paige Twenter, *Top PBMs By 2022 Market Share*, Becker's Hospital Review (May 23, 2023), bit.ly/3RiAIxB.

And PBMs are not just consolidating with each other. They have vertically integrated with insurance companies that pay their enormous "spread." "Five of the six largest PBMs are now jointly owned by organizations that also own a health insurer." Adam J. Fein, Ph.D., *The Top Pharmacy Benefit Managers*

Of 2022: Market Share And Trends For The Biggest Companies, Drug Channels (May 23, 2023), bit.ly/4c5AgeF.

PBMs have also purchased their own pharmacies to reduce costs and increase the size of their "spread." *See, e.g.*, Mattingly, *supra*. PBMs "require patients to use a PBM-owned retail, mail order, or specialty pharmacy or disincentivize the use of non-affiliated pharmacies by requiring patients to pay higher cost sharing." Testimony of Lori M. Reilly, Esq., *The Role Of Pharmacy Benefit Managers In Prescription Drug Markets Part II: Not What The Doctor Ordered*, House Committee on Oversight and Accountability (Sept. 19, 2023), bit.ly/3VhZuz0. "By steering patients towards their affiliated specialty and mail order pharmacies, PBMs capture greater margins on each transaction and reduce dispensing fees and other costs associated with patients filling prescriptions at non-affiliated pharmacies." *Id.* "Vertically integrated pharmacies now account for more than half of PBM profits." *Id.* Thus, integration between PBMs and pharmacies creates an obvious "conflict[t] of interest," as the PBMs prefer that patients use their own pharmacies rather than the pharmacies that best serve the patient. Gale, *supra*.

The combined use of "spread pricing," which tightens the margin of in-network pharmacies, with steering incentives that push patients away from independent, local, or brick-and-mortar pharmacies to mail-order or other PBM-preferred options—has led to pharmacy closures and thus more consolidation. *See, e.g.*, Fink, *supra*. This trend has disproportionately

impacted rural communities because those areas are more likely to use independent pharmacies (those not affiliated with a chain or franchise) as "the sole source of pharmaceutical services," and independent pharmacies are the most likely to close from PBM pressure. Abiodun Salako, MPH, et al., *Update: Independently Owned Pharmacy Closures In Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis (July 18), bit.ly/3VxDWzT.

Independent pharmacies are "especially susceptible to closure" because more than other pharmacies they receive "low reimbursements stemming from a limited negotiating power and a greater reliance on drug sales as a primary source of revenue." *Id.* Between 2003 and 2018, "1,231 independently owned rural pharmacies (16.1 percent)" closed, and "630 rural communities that had at least one retail (independent, chain, or franchise) pharmacy in March 2003 had no retail pharmacy in March 2018." *Id.*

"Closure of pharmacies in rural communities can have grave implications for the population's access to health services, requiring them to travel to another community for pharmacy services or to rely on mail order services that cannot provide clinical services." *Id.* This is devastating for rural communities, because "rural pharmacies play an important role in alleviating … poor access to health services" by "not only provid[ing] access to medications but also deliver[ing] clinical services such as medication counseling, blood pressure and glucose monitoring, immunizations, patient consultation, treatment of

mild illnesses amenable to over-the-counter medications, and other counselling and educational services (including chronic disease and medication therapy management)." *Id.* Thus, in rural areas, the closure of a retail pharmacy means that "'the people living there … no longer have health care in a convenient manner.'" Paulina Firozi, *The Health 202: Here's Why Rural Independent Pharmacies Are Closing Their Doors*, The Washington Post (Aug. 23, 2018), bit.ly/3VceFK9.

The modern PBM business model has thus raised a "lingering question" for policymakers: is there *any* "underlying value of PBMs for payers and for patients"? Chan & Schulman, *supra*.

V. Oklahoma and other States have passed laws to address PBM abuses, but those laws are now endangered by the ruling below.

In view of these well-documented harms, every State has enacted laws regulating PBMs. *See* Pet.34. Those laws include regulations of pharmacy networks (like Oklahoma's here), of reimbursement rates, rules for price transparency, and laws against self-dealing. *See, e.g.*, Brief for 45 States as Amici Curiae in Support of Petitioner, *Rutledge v. Pharm. Care Mgmt. Ass'n*, No. 18-540 (U.S. Mar. 2, 2020); U.S. GAO, *Selected States' Regulation Of Pharmacy Benefit Managers* (Mar. 2024), bit.ly/3Rh6VFs. But most of these laws are now in danger of ERISA or Medicare Part D preemption if the Tenth Circuit's decision and the circuit split below is allowed to stand.

As explained in the petition (at 11), Oklahoma's Patient's Right to Pharmacy Choice Act establishes several important regulations of PBMs. It requires, among other things, that PBMs maintain in their pharmacy network a certain percentage of local retail pharmacies in urban, suburban, and rural areas; to open their networks to any pharmacy that wishes to join that can satisfy the network terms and conditions; to not terminate a contract with any pharmacy based on the pharmacy's probation status; and to not steer patients by penalizing them for using disfavored pharmacies. *See* 36 Okla. Stat. §§6961(A)-(B), 6962(B)(4)-(5), 6963(E). Oklahoma established these and other reasonable standards to guarantee patients "minimum and uniform access to a provider" and the "right to choose a pharmacy provider." *Id.* §6959.

The Tenth Circuit struck down these provisions as preempted by ERISA for having a "'connection with'" an ERISA plan, *Rutledge*, 592 U.S. at 86, and preempted under Medicare Part D for superseding federal Medicare standards, *see* App.14-51—even though Oklahoma's law regulated PBMs, not plans, and did not supersede any Medicare rule. If the Court allows this decision to stand, it will not only harm patients in Oklahoma but also jeopardize other important state laws that address PBM abuses.

For example, many other States have passed laws to protect patient access to pharmacies by regulating spread pricing. Brief for 45 States, *Rutledge*, No. 18-540 at 14-19 (citing statutes). Some of these laws require PBMs to reimburse pharmacies for a drug at a rate that is at least equal to the pharmacy's cost in

acquiring that drug. *See, e.g.*, Ark. Code §17-92-507(c)(4)(A)(i)(b). And most States have a law that provides pharmacies with some minimum procedural protections—such as a right to challenge or appeal PBM underpayments or a right to decline to dispense a drug if the pharmacy would be reimbursed at a rate below the acquisition cost. *See, e.g.*, Colo. Rev. Stat. §25-37-103.5(3). Many States also regulate PBM "maximum allowable cost" (MAC) lists, which are reimbursement caps that PBMs place on certain covered drugs. Kansas, for example, prohibits PBMs from placing a drug on a MAC list if alternative generic drugs are not "generally available for purchase by network pharmacies from national or regional wholesalers." Kan. Stat. §40-3830(a). Most States also require PBMs to regularly update their MAC lists to prevent inadvertent under-reimbursements. *See, e.g.*, Fla. Stat. §641.314(2)(a). Some States require PBMs to disclose their MAC lists to pharmacies. *See, e.g.*, Mont. Code Ann. §33-22-172(2)(c).

State laws also address the lack of transparency into PBM practices. Although gag clauses are now prohibited by federal law, many States have enacted laws aimed at increasing PBM transparency. *See* Brief for 45 States, *Rutledge*, No. 18-540 at 19-20 (citing statutes). For example, Colorado gives consumers a "right to know about options to reduce the amount of money they pay at a pharmacy for prescription drugs." Colo. Rev. Stat. §10-16-122.7(2)(a). California requires PBMs to disclose, among other things, the rebates and fees they receive from manufacturers, the contracts they have with manufacturers to exclusively dispense

certain drugs, and the payments they make to pharmacies. *See* Cal. Bus. & Prof. Code §4441(e).

States have also attempted to regulate conflicts of interest and self-dealing. *See* Brief for 45 States, *Rutledge*, No. 18-540 at 20-21 (citing statutes). For example, some States prohibit PBMs from steering patients to PBM-owned pharmacies or reimbursing PBM-affiliated pharmacies for higher amounts than independent pharmacies. *See, e.g.*, Ga. Code §33-64-11(a)(7); La. Stat. §22:1860.3(A). And other States require PBMs to exercise good faith and fair dealing in their contracts with plans or pharmacies. *See, e.g.*, Nev. Rev. Stat. §683A.178(1).

These and other reasonable state laws are now endangered by the Tenth Circuit's overly expansive application of ERISA and Medicare preemption. This Court should thus grant certiorari to ensure that these important state policy judgments are not jeopardized by an erroneous and atextual interpretation of ERISA and Medicare.

CONCLUSION

The Court should grant certiorari.

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