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,

vs.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF OF AMICI CURIAE STATES OF MINNESOTA, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, OHIO, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH DAKOTA, TEXAS, UTAH, VIRGINIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

1. Whether ERISA preempts state laws that regulate pharmacy benefit managers (PBMs) by preventing them from cutting off rural patients' access, steering patients to PBM-favored pharmacies, excluding pharmacies willing to accept their terms from preferred networks, and overriding State discipline of pharmacists.

2. Whether Medicare Part D preempts state laws that limit the conditions PBMs may place on pharmacies' participation in their preferred networks.

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INTERESTS OF AMICI STATES[1]

The States of Minnesota, Arizona, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Texas, Utah, Virginia, Washington, and the District of Columbia, support the petitioners' request for certiorari review because states have a compelling interest in preserving their traditional authority to protect their residents' access to healthcare and to regulate business practices in their states. To advance these interests, all states regulate pharmacy benefit managers (PBMs) to some degree. Despite this Court's partial clarification of states' authority to do so in *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020), PBMs have continued to challenge state PBM regulations on federal-preemption grounds. The Tenth Circuit's sweeping approach to ERISA and Medicare preemption would severely and unduly impede states' abilities to protect their residents and regulate businesses. And the circuit split that the Tenth Circuit expressly created has caused further uncertainty about the extent to which states may regulate PBMs.

SUMMARY OF ARGUMENT

Over the past several decades, PBMs have steadily entrenched themselves as middlemen in the healthcare

1. Pursuant to Rule 37.2, counsel for all parties received at least ten days' notice that this amicus brief would be filed.

system. While PBMs ostensibly control drug prices to benefit consumers, consumers have instead borne the brunt of PBM practices, facing increasing difficulties in affording their lives and accessing prescription drugs. Independent pharmacies have also struggled to stay afloat as PBMs have implemented low reimbursement rates and steered business away by limiting consumer choices. Amidst these problems, PBMs have reaped significant profits while claiming to be beyond the reach of state regulation. And they have persisted in these claims even after *Rutledge*, when this Court held that ERISA did not preempt state laws regulating pharmacy-reimbursement rates. *Rutledge*, 592 U.S.at 89-90.

While the Oklahoma regulations in this case may seem narrow, the Tenth Circuit's approach to ERISA and Medicare preemption was broad. *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183 (10th Cir. 2023). This approach is not only at odds with this Court's ERISA precedent, it also conflicts with the Eighth Circuit's approach to federal preemption of state PBM regulations. As states nationwide continue to regulate PBMs to protect their residents' access to healthcare, clarity from the Court is needed on these important preemption issues.

ARGUMENT

The Court should grant certiorari review for two key reasons. First, the Tenth Circuit decided important questions of federal law in a manner that conflicts with the Eighth Circuit's resolution of the same issues. Sup. Ct. R. 10(a). Second, the Tenth Circuit's decision conflicts with this Court's precedent. *Id.* 10(c). States have a significant interest in knowing the extent to which

ERISA and Medicare may preempt their regulations of PBMs. By contradicting the Eighth Circuit's holdings and adopting a substantially broader view of ERISA preemption than what this Court endorsed in *Rutledge*, the Tenth Circuit's decision throws that knowledge into substantial doubt. The result is nationwide uncertainty for regulators, a corresponding increase in consumer harms, and a substantial likelihood of continued litigation on the topic in light of the deep circuit split. The Court should grant review to put an end to that uncertainty and its corresponding harms.

I. This Case Presents Important Questions Because Every State Has Enacted PBM Regulations to Protect Consumers.

Prescription drugs are an inescapable and increasingly prevalent facet of modern healthcare. Between 2015 and 2018, 48.6% of people in the United States took a prescription drug in the preceding thirty days.[2] Need for prescription drugs is even greater among those over age 65, with 88.5% having taken a prescription drug in the last thirty days.[3] In 2022, annual American prescription-drug spending grew to $405.9 billion.[4] Healthcare spending is projected to continue increasing.[5]

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2. Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Human Servs., *Health, United States,* Table 39 (2019), https://perma.cc/54DK-3BTG.

3. *Id.*

4. U.S. Dep't of Health & Human Servs., *National Health Expenditure Fact Sheet* (2022), https://perma.cc/JW74-PBKH.

5. *Id.*

PBMs "are a little-known but important part of the process by which many Americans get their prescription drugs." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 83 (2020). They act as intermediaries between pharmacies and prescription-drug plans. *Id.* In their simplest form, PBMs reimburse pharmacies for drugs covered by prescription-drug plans. *Id.* Their role steadily expanded over the past fifty years to control nearly every aspect of health plans' pharmacy benefits.[6]

PBMs' central position has enabled them to foster a complex and interdependent web of relationships within the healthcare industry. PBMs have then used this complex system to impose self-serving protections that have reduced reimbursement rates to pharmacies, maximized rebates to PBMs, and imposed various confidentiality requirements to hide PBMs' business practices. PBMs have thrived behind the scenes, exploiting the lack of transparency that they designed into the system.[7] Consolidation of the PBM market in recent years has raised a host of new concerns and challenges for market participants and regulators. The top three PBMs control 80% of the PBM market.[8] This market consolidation, and vertical integration, have led to PBMs being described as "dominant gatekeepers who have outsized power to decide

6. Oversight Hearing of the S. Comm. on Bus., Professions & Econ. Dev., *Pharmacy Benefit Managers 101* 2 (Cal. Mar. 20, 2017), https://perma.cc/D4SL-PBB6.

7. Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 Pharmacy & Therapeutics 206-08 (2015), https://perma.cc/G8RX-TP54.

8. A.J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger* (Apr. 5, 2022). https://perma.cc/Z6DC-X9T8.

how people do or don't receive the life-saving prescription drugs they depend on."[9] With this landscape in mind, states across the political spectrum have stepped in to regulate PBMs to protect the public. These regulations have been met with significant resistance from the PBM industry.

A. All States Have Some Form of PBM Regulation and PBMs Continue to Challenge Those Regulations.

In the absence of federal regulation of PBMs, states have stepped in to address PBMs' concerning business practices and outsized influence in the prescription-drug field. Every state has enacted some form of PBM regulation.[10] As of 2023, states had enacted at least 156 laws regulating PBMs.[11] Types of regulations vary, but typically aim to limit patient cost-sharing, prohibit gag clauses on pharmacies, prohibit discrimination against non-affiliated pharmacies, require certain reports, and establish requirements for maximum allowable costs and reimbursements. *Id.* For example, Oklahoma prohibits PBMs from steering patients to favored pharmacies by offering discounts only at those pharmacies. Okla. Stat. tit. 36, § 6963(E). It also requires PBMs to accept any willing pharmacy into their preferred networks if the pharmacy

9. Lina M. Kahn, Chair, Fed. Trade Comm'n, *Remarks Prepared for the White House Roundtable on PBMs* (Mar. 4, 2024), https://perma.cc/M7SV-9Z4L.

10. *See, e.g.*, Nat'l Acad. State Health Pol'y, *State Pharmacy Benefit Manager Legislation* (2023) (summarizing some state laws), https://perma.cc/U56G-TDPY.

11. *Id.*

is willing to accept the network's terms and conditions. *Id.* § 6962(B)(4). While specific approaches vary, at least twenty-three states have some form of legislation that prohibits PBMs from discriminating against non-affiliated pharmacies.[12]

States have also urged Congress to act, with thirty-nine state attorneys general seeking PBM reform.[13] States and federal regulators could then "work together to better meet their shared responsibility to hold PBMs accountable and improve the country's health care system overall."[14] But without federal PBM regulation, states are left to navigate this area by exercising their traditional regulatory authority.

In response the PBM industry has fought state regulation (usually acting through its trade association, PCMA), consistently asserting that federal law—specifically ERISA and Medicare Part D—preempt state action. For example, before suing Oklahoma in the underlying case, PCMA challenged PBM regulations in North Dakota, Arkansas, Iowa, Washington D.C., and Maine. *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956 (8th Cir. 2021); *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018), *rev'd and remanded*, 592 U.S. 80 (2020); *Pharm. Care Mgmt. Ass'n v. Gerhart*,

12. *Id.*

13. Nat'l Ass'n of Att'ys Gen., *A Bipartisan Coalition of 39 State Attorneys General Urge Congressional Action on Pharmacy Benefit Manager Reform* (Feb. 21, 2024), https://perma.cc/Z58R-XJ9P.

14. Letter from Tim Griffin, Ark. Att'y Gen., et al., to the Honorable Mike Johnson, et al. (Feb. 20, 2024), https://perma.cc/3FWX-UJNG.

852 F.3d 722 (8th Cir. 2017); *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005). And PBMs have likewise raised ERISA and Medicare preemption as a defense when states bring enforcement actions. *See, e.g.*, *Alaska v. Express Scripts, Inc.*, No. 3:23-cv-00233, 2024 WL 2321210, at *9-11 (D. Alaska May 22, 2024).

Due to the prevalence of state regulation of PBMs, and the resulting lawsuits, whether ERISA or Medicare Part D preempts certain PBM regulations, and the extent of that preemption, are important questions.

B. State PBM Regulations Are Critical to Protect the Public from PBM Business Practices That Adversely Affect Independent Pharmacies and Consumers.

The questions presented in this matter are not only important because of the prevalence of PBM regulations and related litigation. They are also critical for states to protect the public from harmful business practices. Local and independent pharmacies and end consumers are particularly vulnerable to the harms of the system that PBMs have fostered and continue to benefit from.

One PBM practice that harms local pharmacies is increasing costs resulting from "spread pricing." PBMs profit from the "spread" between the amount they charge health plans for a drug and the amount they reimburse pharmacies.[15] Local pharmacies must work with PBMs,

15. Elizabeth Seeley & Aaron Kesselheim, Commonwealth Fund, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead* (2019), https://perma.cc/4Q36-B5YE.

which have outsized bargaining power as the PBM market continues to consolidate.[16] All major health insurers now operate their own PBMs.[17] The four major health insurers operate four PBMs that control 88% of the PBM market.[18] All but the largest retail pharmacies receive only "take it or leave it" offers from PBMs.[19] This bargaining disparity results in independent pharmacies effectively having no meaningful choice but to accept financially detrimental terms.

Another way that PBMs' business practices harm consumers and independent pharmacies is by steering business to PBM-owned or -affiliated pharmacies. In addition to limiting consumers' choice and creating potential conflicts of interest, this reduces non-affiliated pharmacies' business. Again, a lack of transparency perpetuates the problems. In 2018, for example, the Ohio Auditor of State issued a report regarding Ohio's Medicaid Managed Care Pharmacy Services.[20] The Auditor noted that Ohio pharmacists reported a number of concerns about PBM practices, including the use of spread pricing

16. Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 36 (2007).

17. *Fortune 500–2020*, Fortune Mag. (2020), https://perma.cc/2CKZ-VQ93; Bruce Japsen, *Express Scripts Boosts Cigna as Employers Stick with Larger Insurer*, Forbes Mag. (Aug. 1, 2019), https://perma.cc/C2W3-7JC2.

18. *See* Fein, *supra* note 8.

19. Garrett & Garis, *supra* note 16, at 46.

20. Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* (Aug. 16, 2018), https://perma.cc/V29P-DRA3.

and the conflicts of interests associated with PBMs requiring customers to obtain prescriptions from PBM-owned pharmacies.[21] The Auditor observed that the lack of transparency in the PBM industry was so pervasive that the Auditor could not determine the exact terms of the PBMs' financial arrangements.[22] Related to steering, PBMs also divert prescriptions to their own pharmacies by "prescription trolling": after local pharmacists work with patients, insurers, and doctors to obtain prior authorization for expensive medications, PBMs can divert the prescriptions to their own mail-order pharmacies by filling the prescription themselves after an independent pharmacy has consulted with the patient and obtained a prior authorization.[23]

These PBM practices discussed here are injurious to rural and urban communities alike. Local pharmacies are critical to providing healthcare in rural communities; nearly half of rural pharmacies are independently owned.[24] When PBMs restrict the payments to those independent pharmacies or steer business away from them, it harms these businesses and their communities.

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21. *Id.* at 1.

22. *Id.* at 1-2, 13.

23. Hearing on HF 728 Before the H. Commerce Comm., 2019 Leg., 91st Sess., at 1:52:25 (Minn. 2019) (statement of Randy Schindelar), https://www.lrl.mn.gov/audio/house/2019/com022719.mp3.

24. Edmer Lazaro, et al., RUPRI Ctr. For Rural Health Pol'y Analysis, *Update on Rural Independently Owned Pharmacy Closures in the United States, 2003-2021.* https://perma.cc/AR3B-HRD6.

Rural independent pharmacies are generally closing at a higher rate than those in metropolitan areas.[25] This is particularly concerning because local pharmacies may be the only source of healthcare services in those rural communities.[26] Even in major metropolitan areas, certain communities are hit harder than others. One study suggests that pharmacies in neighborhoods with majority Black or Hispanic/Latinx residents were less likely to open and more likely to close.[27] That same study found that independent pharmacies accounted for 34.8% of all pharmacies in majority White neighborhoods, while accounting for 53.1% and 57.4% of pharmacies in majority Black and Hispanic/Latinx neighborhoods, respectively.[28] These trends are concerning as the most vulnerable populations are being disadvantaged by PBM practices that are increasing costs to, and steering business away from, independent pharmacies.

PBMs' practices also contribute to the crisis of increasing medical costs nationwide, ultimately harming the end consumer. Prescription drugs continue to increase in price, averaging a 15.2% increase from 2022 to 2023.[29] One contributing factor to rising drug costs is

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25. *Id.*

26. *Id.*

27. Jenny S. Guadamuz et al., *Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007-15,* 40 Health Affairs 802, 805 (2021).

28. *Id.* at 806.

29. Arielle Bosworth, et al., Health & Hum. Servs. Off. of the Ass't Sec'y for Planning & Evaluation, *Changes in the List Prices of Prescription Drugs, 2017-2023* (Oct. 6, 2023). https://perma.cc/42RG-VYKX.

PBMs demanding increasingly large rebates from drug manufacturers. These rebates are essentially discounts paid by the manufacturer directly to the PBM. One study found a positive correlation between increases in PBM rebates and list prices.[30] This result is not surprising; profiting from rebates incentivizes PBMs to push consumers into higher priced drugs that demand higher rebates and increase profits.[31]

The situation for independent pharmacies, and the consumers that rely on them, is so dire that some are opting out of the insurance system all together. "Cash-only" pharmacies opt out of the insurance system (and thereby PBMs) and sell (usually generic) drugs for just above cost directly to consumers.[32] This scenario may potentially save patients substantial money in the short term, but it requires patients to forgo already paid-for insurance benefits. Additionally, this work around is not effective for branded drugs that have no generic

30. Neeraj Sood et al., USC Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., *The Association Between Drug Rebates and List Prices* (Feb. 11, 2020), https://perma.cc/L7GA-SA86.

31. Rena M. Conti, M.D., Statement Before the U.S. House Committee on Oversight and Accountability (Sept. 19, 2023). https://perma.cc/Q3HW-HF33; Lori M. Reilly, COO, Pharmaceutical Research and Manufacturers of America, Testimony Before the U.S. House Committee on Oversight and Accountability, at 5-6 (Sept. 19, 2023). https://perma.cc/2P3X-EYYE.

32. Adiel Kaplan, Kenzi Abou-Sabe, & Vicky Nguyen, NBC News, *Frustrated Pharmacists are Opting Out of the Insurance System, Saving Some Customers Hundreds of Dollars a Month* (Aug. 19, 2022), https://perma.cc/HC8Y-24GD.

alternatives.[33] That these cash-only pharmacies exist highlights the harms that PBMs cause to consumers and independent pharmacies.

While the sources of rising drug costs are complex, they should not be beyond the states' traditional police power. States' PBM regulations have allowed states to concretely address these problems. Minnesota, for example, prohibits PBMs from steering business to pharmacies owned by the PBM. Minn. Stat. § 62W.07. After learning that CVS Caremark had a program that required consumers to use a CVS-owned retail or mail-order pharmacy to refill maintenance medications, the Minnesota Department of Commerce started an enforcement action. The case resulted in an order for Caremark to open its preferred network to all willing pharmacies.[34]

States have done the work to identify and regulate problematic facets of the PBM industry that have developed over years, and states play a critically important role in this sphere. Granting certiorari and addressing the questions presented will give states important guidance about the contours of their authority to regulate.

II. The Court Should Grant Certiorari to Clarify the Law Regarding ERISA and Medicare Preemption as They Relate to State PBM Regulations.

Certiorari review is appropriate because the Tenth Circuit created a circuit split and misapplied this Court's

33. *Id.*

34. Minn. Dep't of Comm., *Commerce Fines CVS Caremark $500,000 after 2022 Case Alleging Violations of Pharmacy Benefit Manager Act,* (May 1, 2023), https://perma.cc/PC6Z-G5BH.

guidance on ERISA preemption. Sup. Ct. R. 10(a), (c). The Tenth Circuit's decision conflicts, in important ways, with the Eighth Circuit's Medicare-preemption decisions in *Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956 (8th Cir. 2021) and *Pharmaceutical Care Management Association v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018) (*Rutledge I*), *rev'd on other grounds sub nom.*, *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020) (*Rutledge II*) (addressing ERISA preemption). The Tenth Circuit's decision also conflicts with this Court's decision in *Rutledge II* as to ERISA preemption, as well as the Eighth Circuit's application of that decision in *Wehbi*. Moreover, it more broadly disregards amici states' broad police powers to regulate to promote the health and welfare of their constituents.

A. The Tenth Circuit Decision Conflicts with Eighth Circuit Decisions and Creates Uncertainty in States' Ability to Regulate PBMs.

The Tenth Circuit expressly acknowledged its disagreement with the Eighth Circuit regarding both ERISA and Medicare Part D preemption of state PBM regulations. *Mulready*, 78 F.4th at 1203, 1208. This circuit split creates uncertainty regarding states' regulatory authority. There are undoubtedly PBM regulations that would be permitted in the Eighth Circuit but not in the Tenth. For example, states in the Eighth Circuit may prohibit PBMs from imposing pharmacist-qualification requirements beyond state or federal licensure; but states in the Tenth cannot enforce similar regulations. *Id.* at 1202-03; *Wehbi*, 18 F.4th at 968. This Court should

grant certiorari to provide a uniform and consistent interpretation of the federal preemption questions as they relate to state regulation of PBMs.

1. The Tenth Circuit's Medicare-preemption analysis conflicts with the Eighth Circuit's.

While this Court reviewed the Eighth Circuit's *Rutledge I* decision with respect to ERISA preemption, this Court did not review that court's holding regarding Medicare Part D preemption of state PBM regulations. *Rutledge II*, 592 U.S. at 83 (noting that the question presented addressed only ERISA preemption). Following *Rutledge II*, the Eighth Circuit revisited Medicare preemption of state PBM regulations in *Wehbi*. 18 F.4th at 970. In both cases, the Eighth Circuit held that Medicare does not preempt a state PBM law unless the state law regulates the same subject matter as a Medicare standard or otherwise frustrate a standard's purpose. *Id.* at 972; *Rutledge I*, 891 F.3d at 1113 (requiring existence of "'standards' in the area regulated by the state law" for preemption).

This holding flatly contradicts the Tenth Circuit's resolution of the same issue. Labeling the Eighth Circuit test as "fastidious," the Tenth Circuit rejected the same-subject test and instead applied a field-preemption approach to Medicare's treatment of PBMs. *Mulready*, 78 F.4th at 1208. Under that approach, any state law that is "not a licensing law or a law relating to plan solvency" is preempted. *Id.* Nor was the Tenth Circuit shy about the significant impacts its decision would have, recognizing that it would not allow "[s]tates to regulate Part D plans above what Part D already requires." *Id.*

These diametrically opposed holdings create uncertainty as to the preemptive scope of Medicare. This uncertainty is particularly acute because "the scope of Medicare Part D preemption is largely an open question," which this Court has not previously spoken on. *Wehbi*, 18 F.4th at 970. Left unresolved, this circuit split will likely deepen as further PBM litigation forces more circuits to take sides in the circuit split this case has created. Moreover, states that otherwise might enact further PBM regulations to curb the abuses described above may be more reluctant to do so in light of the uncertainty of the permissible scope of regulations. States should not be left to legislate in this uncertainty, nor waste resources relitigating these issues throughout the circuits. A decision from this Court would provide needed guidance to states and help reduce further litigation of this issue. Accordingly, the Court should grant certiorari review in this case.

2. The Tenth Circuit's ERISA-preemption analysis conflicts with the Eighth Circuit's.

The Tenth Circuit also parted ways with the Eighth Circuit regarding ERISA preemption. In *Wehbi*, the Eighth Circuit rejected PCMA's ERISA challenge and upheld a state prohibition on PBMs imposing pharmacy-accreditation standards beyond those required for state licensure. *Wehbi*, 18 F.4th at 968. The Tenth Circuit, meanwhile, held that ERISA preempts Oklahoma's similar prohibition. *Mulready*, 78 F.4th at 1204.

The basis of this disagreement is differing approaches for determining, for ERISA purposes, what constitutes a "central matter of plan administration" under this

Court's precedent. *Rutledge II*, 592 U.S. at 87. The Eighth Circuit held that regulations impacting PBMs' abilities to exclude pharmacies from their networks did not govern a central matter of plan administration and had only de minimis economic effects. *Wehbi*, 18 F.4th at 968. The Tenth Circuit, in contrast, held that network composition was a central matter of plan administration. *Mulready*, 78 F.4th at 1198. The Tenth Circuit did not dispute the Eighth Circuit's conclusion that similar laws had only de minimis economic effects. *Id.* at 1203. Yet it concluded that a challenged regulation with de minimis impact on plan design could nevertheless implicate a "central matter of plan administration" and trigger ERISA preemption. *Id.*

These conflicting results demonstrate a fundamental disagreement between the circuits regarding the scope of this Court's decision in *Rutledge II*. That case held that "the responsibility lies first with the PBM" when a benefit is denied due to failure to comply with state regulation. *Rutledge II*, 592 U.S. at 482. Based on that holding, the Eighth Circuit reasoned that, in some instances, benefit impacts are "therefore attributable to the independent actions of PBMs rather than to the law." *Wehbi*, 18 F.4th at 969. The Court extended this reasoning to impacts like a plan's inability to provide a covered drug because its PBM has an unlawful ownership interest in the supplying pharmacy. *Id.* Because such laws affect only what PBMs—not health plans—must do, the Eighth Circuit held they were not preempted. *Id.* at 968-69. This was so even though PBMs (though again, not plans) might include or exclude certain drugs or pharmacies from their networks as consequence of such regulation. *Id.*

The Tenth Circuit, in contrast, limited this Court's analysis in *Rutledge II* to cost regulations, without

considering the broader implications of this Court's actual analysis. *Mulready*, 78 F.4th at 1199-1200. The Tenth Circuit equated regulating PBMs with regulating health plans, casting PBM networks as "the structures through which plan beneficiaries access their drug benefits." *Id.* at 1200. And, because Oklahoma's regulation of those networks went beyond cost regulation, the court held it was preempted from imposing any restriction on PBMs' ability to include or exclude pharmacies from their networks. *Id.* The court reached this conclusion notwithstanding that the regulation only indirectly impacted ERISA plans. *Id.* ("We have thus overlooked this PBM–plan distinction and assessed the Act's substantial, indirect effects on ERISA plans.").

For the reasons discussed below, the Tenth Circuit's decision incorrectly narrowed *Rutledge II*. But regardless of whether that decision was correct, the significant divergence between the Eighth Circuit and Tenth Circuit's decisions on this issue means this Court should grant certiorari to correct the course of whichever circuit was incorrect.

B. The Tenth Circuit Decision Conflicts with this Court's ERISA-Preemption Decision in *Rutledge II*.

In addition to the conflict with another federal court of appeals, the Tenth Circuit's decision conflicts with this Court's ERISA precedent, particularly *Rutledge II*. The Tenth Circuit made two fundamental errors in applying *Rutledge II* to Oklahoma's PBM regulations. First, it disregarded *Rutledge II*'s holding that responsibility for complying with PBM regulations lies with PBMs,

not the ERISA plans they serve. Second, it ignored the Court's clarification that ERISA preemption concerns *who* receives benefits and *what* benefits they receive and that regulations that do not impact those questions (unless they impact central matters of plan administration) are not preempted.

In *Rutledge II*, the Court upheld regulations authorizing pharmacies to refuse to dispense prescriptions if the PBM's reimbursement would be less than the wholesale cost paid by the pharmacy. *Rutledge II*, 592 U.S. at 84. It did so over the PBMs' protests that the regulation governed central matters of plan administration because it effectively denied pharmacy benefits to plan beneficiaries. *Id.* at 91. Rejecting this argument, the Court recognized that the regulation did not dictate benefits when the pharmacy refused to dispense a prescription because "the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement." *Id.* This holding was consistent with the Court's past ERISA jurisprudence. *See, e.g.*, *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 815 (1997) (recognizing that "myriad state laws of general applicability . . . impose some burdens on the administration of ERISA plans but nevertheless do not relate to them so as to trigger preemption (quotations omitted)); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 660 (1995) (holding that ERISA did not preempt law that influences "a plan's shopping decisions, but . . . does not affect the fact that any plan will shop for the best deal it can get").

The Tenth Circuit disregarded this precedent and *Rutledge II*'s specific holding that the consequences of

PBM regulations fall on PBMs, not the ERISA plans that voluntarily choose to use them. The Tenth Circuit addressed two types of PBM regulations: network regulations and pricing regulations. More specifically, it rejected Oklahoma's network requirements that PBMs: (1) maintain an adequate network; (2) grant any network-pharmacy (as opposed to only PBM-affiliated pharmacies) preferred status if the pharmacy meets the criteria for that status; and (3) not discriminate in network participation based on a pharmacy employee's probationary status with Oklahoma's licensing board; as well as Oklahoma's pricing regulation that PBMs (4) not use discounts to incentivize using particular in-network pharmacies. Okla. Stat. tit. 36, §§ 6961(A)(B), 6962(B)(4)-(5), 6963(E) (2023). But none of these requirements imposes any regulation on ERISA plans. Instead, they are all directed solely at PBMs. *Rutledge II* made clear that "the responsibility lies first with the PBM" for complying such regulations, which are therefore not preempted by ERISA. 592 U.S. at 91.

The Tenth Circuit also fundamentally ignored the Court's instruction on what types of regulations are subject to preemption. In *Rutledge II*, the Court reaffirmed that ERISA is "primarily concerned with pre-empting laws" that "determin[e] beneficiary status" or "requir[e] payment of specific benefits," the *who* and *what* of employee benefits. *Id.* at 86-87. The Tenth Circuit (correctly) did not hold that any of Oklahoma's PBM regulations implicated who received employee benefits. *See generally Mulready*, 78 F.4th at 1196-1204. But it took umbrage with both Oklahoma's network and pricing regulations, reasoning that both dictated particular benefits. *Id.* at 1199, 1203-04. This reasoning conflicts with *Rutledge II*.

With respect to Oklahoma's pricing regulation, it is quintessentially a "form of cost regulation" like those that the Court upheld in *Rutledge II*. 592 U.S. at 88. Oklahoma prohibits PBMs from "using any discounts in cost-sharing or a reduction in copay or the number of copays" to incentivize using particular, in-network pharmacies. Okla. Stat. tit. 36, § 6963(E). And this Court expressly held that "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans." 592 U.S. at 88. Oklahoma's law is precisely that; it regulates the rates at which PBMs cover claims. While this regulation may "alter incentives" insofar as it means PBMs cannot favor their own, PBM-affiliated pharmacies, *Rutledge II* makes clear that that alteration does not trigger preemption.

The Tenth Circuit disregarded this Court's *Rutledge II* instruction, going so far as to declare that state laws trigger preemption if they affect the "cost-sharing arrangements [under which] pharmacies participate in the network." *Mulready*, 78 F.4th at 1198. But this Court upheld such laws in *Rutledge II*. The regulation in that case certainly impacted the cost-sharing arrangements for pharmacy-network participation because it outlawed reimbursing pharmacies at below drug-acquisition costs. *Rutledge II*, 592 U.S. at 90. Although this Court held such laws are not preempted, the Tenth Circuit ignored that ruling here.

Turning to the network regulations, *Rutledge II* made clear that PBM regulations establishing floors for the cost of benefits that plans choose to provide are not preempted. 592 U.S. at 90. Oklahoma's network regulations operate in a similar manner with respect to networks: they ensure a base level of geographic coverage in Oklahoma,

prohibit PBMs from discriminating against non-affiliated pharmacies when those pharmacies can meet the PBM's established standards, and prohibit PBM discrimination based on probationary status. None of these requirements "bind plan administrators" (or PBMs for that matter because PBMs are not plans) to any "particular" choice. *Id.* at 87 (internal quotation marks omitted). Instead, the particulars of implementing their networks remain entirely in PBMs' hands.

The effect of the Tenth Circuit's decision is to invite uncertainty as to this Court's holdings in *Rutledge II*. The Court made clear that compliance with PBM regulations "lies first" with PBMs, not plans, clearly recognizing that such regulations do not "bind plans" and therefore are not preempted. The Court also reiterated its prior holdings that regulations that did not direct particular benefits to particular people were not preempted. But the Tenth Circuit's disregard of these holdings throws states into doubt as to whether the Court meant what it said in *Rutledge II*. Review by this Court is therefore necessary to ensure that states continue to be able to enforce needed consumer protections and prevent the blatant abuses that PBMs would otherwise engage in.

C. The Tenth Circuit Decision Ignores States' Traditional Police Powers.

Apart from its divergence with *Rutledge II*, the Tenth Circuit's decision also disregarded states' well-established police powers to protect the health and safety of their constituents. As sovereigns, amici states have broad general police powers to enact regulations to protect their constituents. *See Munn v. Illinois*, 94 U.S. 113, 124-25 (1876).

ERISA did not shed states of these powers. On the contrary, the Court has repeatedly recognized amici states' traditional police powers as a basis for caution when determining ERISA's preemptive scope. For example, outside of the PBM context, the Court has recognized that it would be "unsettling" to interpret ERISA's preemption clause to preempt "traditionally state-regulated substantive law in those areas where ERISA has nothing to say." *Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 330 (1997) (citing *Travelers*, 514 U.S. at 665). Although that case applied to state regulations of apprenticeship programs, it is readily analogized to pharmacy benefits. There the Court held that:

> No apprenticeship program is required by California law to meet California's standards. If a contractor chooses to hire apprentices for a public works project, it need not hire them from an approved program (although if it does not, it must pay these apprentices journeyman wages). So, apprenticeship programs that have not gained CAC approval may still supply public works contractors with apprentices. Unapproved apprenticeship programs also may supply apprentices to private contractors. The effect of [the state regulation] on ERISA apprenticeship programs, therefore, is merely to provide some measure of economic incentive to comport with the State's requirements, at least to the extent that those programs seek to provide apprentices who can work on public works projects at a lower wage.

Id. at 332 (citations omitted). Applied to PBMs, "No [pharmacy-benefit] program is required by [Oklahoma] to meet [Oklahoma's] standards. . . . [Pharmacy-benefit] programs that have not [used a PBM] may still supply [non-compliant pharmacy benefits] . . . . The effect of [PBM regulations] on ERISA [pharmacy-benefit] programs, therefore, is merely to provide some measure of economic incentive to comport with the State's requirements." And within the context of state laws implicating medical benefits, parties bear a "considerable burden" to overcome the presumption against preemption with respect to state health and safety regulations. *De Buono*, 520 U.S. at 814; *see also Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365 (2002) (noting ERISA preemption must be "tempered" in light of states' historical police powers); *Travelers*, 514 U.S. at 655.

The Tenth Circuit disregarded these cautionary instructions. Indeed, its only acknowledgement of states' traditional regulatory authority appeared in a single parenthetical to a single citation in a single footnote. *Mulready*, 78 F.4th at 1206 n.22. This failure to even address states' traditional police powers further demonstrates the fundamentally flawed reasoning of the Tenth Circuit's decision. As discussed in Section I, PBM regulations play an important role in states' efforts to protect the health and safety of their citizens by increasing access to reasonably priced prescriptions. Those efforts fall squarely within the traditional categories of state regulation, but they have been disrupted by the Tenth Circuit's decision. The Court should accordingly grant review to restore the appropriate balance between those state interests and ERISA preemption.

CONCLUSION

The Court should grant the petition for a writ of certiorari on both questions presented. States' authority to regulate PBMs presents important questions and the Tenth Circuit's decision creates conflicts with decisions of both this Court and the Eighth Circuit.

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