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,

Petitioners,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

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

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REPLY BRIEF FOR PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES ii
REPLY BRIEF 1
I. The Decision Below Conflicts With This Court's ERISA Precedent And Decisions Of Other Circuits Faithfully Applying It 3
A. The Decision Below Flouts *Rutledge* and the Cases on Which It Relied 3
B. The Decision Below Creates a Circuit Split 7
II. The Decision Below Creates A Circuit Split On The Scope Of Medicare Preemption 9
III. The Questions Presented Are Important, And This Is A Good Vehicle To Resolve Them 11
CONCLUSION 13

TABLE OF AUTHORITIES

Cases

Cal. Div. of Lab. Standards Enf't v. Dillingham, 519 U.S. 316 (1997) 1, 2, 3, 4

CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub, 82 F.3d 642 (5th Cir. 1996) 8

Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016) 6

Ky. Ass'n of Health Plans, Inc. v. Miller, 538 U.S. 329 (2003) 7

Ky. Ass'n of Health Plans, Inc. v. Nichols, 227 F.3d 352 (6th Cir. 2000) 7

Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli Hernández, 58 F.4th 5 (1st Cir. 2023) 9

Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985) 6

PCMA v. Wehbi, 18 F.4th 956 (8th Cir. 2021).................... 3, 4, 7, 9, 10

Rush Prudential HMO, Inc. v. Moran, 536 U.S. 355 (2002) 6

Rutledge v. PCMA, 592 U.S. 80 (2020) 1, 3, 4, 5, 6, 7

Statutes

36 Okla. Stat. §6960 (2019)..4

36 Okla. Stat. §6960 (2024)..5

36 Okla. Stat. §6962 10

42 U.S.C. §1395w-26 9

Ark. Code §17-92-507 5

Regulation

42 C.F.R. §423.505 .... 9, 10

Other Authority

Liz Essley Whyte, *Drug Middlemen Push Patients to Pricier Medicines, House Probe Finds*, Wall St. J. (July 23, 2024), https://tinyurl.com/yjnyszwa 11

REPLY BRIEF

This Court has long cautioned against stretching ERISA to preempt laws in "traditionally state-regulated" areas about which "ERISA has nothing to say." *Cal. Div. of Lab. Standards Enf't v. Dillingham*, 519 U.S. 316, 330 (1997). The court of appeals threw that caution to the wind, holding preempted a suite of recently enacted Oklahoma laws that regulate pharmacy benefit managers ("PBMs") to ensure that rural patients have meaningful access to pharmacies, even though pharmacy regulation is an area of traditional state concern and neither PBMs nor prescription-drug benefits are mentioned anywhere in ERISA. That sweeping view of ERISA preemption is inconsistent with this Court's precedents down the line, and the conflict with *Rutledge v. PCMA*, 592 U.S. 80 (2020), is especially stark. *Rutledge* made clear that plans' voluntary decisions to contract with PBMs do not somehow expand the scope of ERISA preemption, let alone cabin States' authority to regulate PBMs to preserve rural pharmacies from PBM-driven extinction. Yet the Tenth Circuit read ERISA so broadly and *Rutledge* so narrowly as to effectively grant PBMs the get-out-of-State-regulation-free card this Court unanimously denied them in *Rutledge*. Given that sharp conflict with *Rutledge*, it should come as no surprise that the decision below squarely conflicts with other cases faithfully following that precedent. Indeed, while PCMA tries to downplay the split, the Tenth Circuit openly admitted that it was parting company with the Eighth Circuit.

That is reason enough for this Court to intervene, but far from the only reason. The decision below landed on the wrong side of yet *another* split, this one on the scope of Medicare preemption. Once again, the Tenth Circuit "disagree[d] with" the Eighth Circuit, deriding that court's "fastidious approach," Pet.App.47-48, and instead aligning with the First Circuit, which has adopted a contrary and overbroad view of Medicare preemption.

The issues on which the circuits are split are both timely and of critical importance. States, federal regulators, and consumers have all observed, with alarm, the increasing retail prices, decreasing consumer choice, and disappearance of rural pharmacies associated with the rise of PBMs. There is no basis for States in the Eighth Circuit to be able to address that widely recognized problem, while nearby States in the Tenth Circuit are powerless to take the same countermeasures. Moreover, while *Rutledge* and its antecedents strongly suggest that the decision below is wrong, if States really are powerless under current law to take sensible actions to counteract the rising power of PBMs and preserve the shrinking universe of rural pharmacies—even though ERISA does nothing to redress those problems—then Congress deserves to learn that news, so it can fix what "no sensible person could have intended." *Dillingham*, 519 U.S. at 335-36 (Scalia, J., concurring). Either way, certiorari is imperative.

I. The Decision Below Conflicts With This Court's ERISA Precedent And Decisions Of Other Circuits Faithfully Applying It.

A. The Decision Below Flouts *Rutledge* and the Cases on Which It Relied.

As this Court made clear in *Rutledge*, ERISA does not preempt state laws unless they "require providers to structure benefit plans in particular ways" or "requir[e] payment of specific benefits." 592 U.S. at 86-87. Oklahoma's PBM laws do neither, and thus are not preempted. Pet.20-25. In trying to defend the Tenth Circuit's contrary decision, PCMA distorts *Rutledge* and ignores the cases on which it relied.

PCMA does not dispute that "the practice of pharmacy is an area traditionally left to state regulation" or that HHS "has a 'general position of deferring to States for regulating the practice of pharmacy.'" Pet.23 (quoting *PCMA v. Wehbi*, 18 F.4th 956, 972 (8th Cir. 2021)). Nor does PCMA deny that—as this Court has long made clear—ERISA does not preempt laws in "traditionally state-regulated" areas about which "ERISA has nothing to say." *Dillingham*, 519 U.S. at 330. Instead, PCMA ignores those realities.

But those realities confirm that Oklahoma's PBM laws are not preempted. The Discount Prohibition prohibits PBMs from steering patients to pharmacies the PBMs own or otherwise favor; ERISA has nothing to say about anti-steering laws. Pet.21. The Access Standards regulate the quality of the networks to which PBMs sell access; nothing in ERISA insulates PBMs from state efforts to prevent them from driving rural and independent pharmacies out of business.

Pet.21-22. The Any Willing Provider Provision prevents PBMs from discriminating against *already-in-network* pharmacies; it "does not require a plan to accept any willing pharmacy into its pharmacy network" in the first instance. App.58; Pet.22. And the Probation Prohibition simply preserves the State's authority to determine how best to rehabilitate pharmacists who have violated state health-and-safety standards. Pet.22-23; *see Wehbi*, 18 F.4th at 972.

None of that comes within, or even anywhere near, ERISA's bailiwick. *See Dillingham*, 519 U.S. at 330 (detailing the "areas with which ERISA is expressly concerned"). To be sure, Oklahoma's provisions may "cause[] some disuniformity in plan administration," given different States' different PBM regulations. *Rutledge*, 592 U.S. at 87. But that is a product of the Framers' design, not something that renders sensible regulations of pharmacies and PBMs impermissibly connected with ERISA plans. The Tenth Circuit's contrary conclusion stretches ERISA preemption far beyond its breaking point, at the expense of the traditional authorities of States. Any erosion of that traditional authority requires action from Congress; simply contracting with ERISA plans is not enough to put PBMs beyond the States' reach.

Citing a portion of the Act's "PBM" definition that extends to "any 'person that performs pharmacy benefits management,'" PCMA claims that "the Act applies directly to plan sponsors that administer their own ERISA-covered benefits," not just to PBMs. BIO.12-13, 21 (quoting 36 Okla. Stat. §6960(3) (2019)). The Tenth Circuit did not see things that way, and for

good reason: The language PCMA cites goes downstream to those working for PBMs, not upstream to sweep in benefit plans—as evidenced by the statute's explicit limitation to those "perform[ing] pharmacy benefits management," a term inextricably intertwined with PBMs' unique role. Indeed, this argument is just a redux of one *Rutledge* rejected. Arkansas' Act 900 similarly defines "PBM" to mean "an entity that administers or manages a pharmacy benefits plan or program." Ark. Code §17-92-507(a)(7). Despite PCMA's assertion that Act 900 applied directly to plans, this Court correctly held that it "does not directly regulate health benefit plans at all, ERISA or otherwise." 592 U.S. at 88-89. The same is true here. And if there is any doubt on that score, the proper course is to honor the State's interpretation and avoid preemption, not strain to create a Supremacy Clause violation.[1]

PCMA's last-ditch effort is to rewrite *Rutledge*. In PCMA's revision, all *Rutledge* held is that reimbursement-rate regulations are not preempted because they "do not 'bind plan administrators to any particular choice.'" BIO.3, 19 (citation omitted). In reality, *Rutledge* was clear that state laws are not preempted unless they "force an ERISA plan to adopt a certain scheme of substantive coverage," "require

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[1] That is doubly true given that the Oklahoma Legislature recently clarified that "[n]othing in the [Act's] definitions … shall be construed to deem … [a]n employer of its own self-funded health benefit plan" "to be a [PBM]," unless it actually engages in pharmacy benefits management. 36 Okla. Stat. §6960(B)(1) (2024). That anti-circumvention provision, which ensures that PBMs cannot evade the Act's requirements through obfuscation, does not sweep in a single ERISA plan in Oklahoma.

providers to structure benefit plans in particular ways," or "bind[] plan administrators to specific rules for determining beneficiary status." 592 U.S. at 86-87. Moreover, in language PCMA ignores, *Rutledge* declared that "the responsibility lies first with the PBM" for decisions the PBM makes, even if those decisions affect plans. *Id.* at 91. As much as PCMA tries to join itself at the hip to benefit plans, it cannot escape the reality that PBMs are not plans—and that plans are not the problem. Oklahoma's law does not mandate that *benefit plans* provide any specific benefits. Instead, in line with *Rutledge*, it mandates that PBMs take responsibility for, and refrain from, their own practices that are harming Oklahomans. ERISA says nothing about that subject and does not prevent Oklahoma's efforts to respond to local conditions and the concerns of its citizens.

No decision of this Court countenances a contrary result. PCMA does not defend the Tenth Circuit's erroneous view that this Court held preempted state laws that "regulate[d] only third parties," not plans, in *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724 (1985), and *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002). App.18-19; *see* Pet.25-26. Instead, PCMA claims that two other cases embraced that counterintuitive result. BIO.18. PCMA is no less wrong than the Tenth Circuit. "The state law" in *Gobeille v. Liberty Mutual Insurance Co.* "by its terms[] applies to health plans established by employers and regulated by … ERISA." 577 U.S. 312, 315 (2016). And Kentucky's laws in *Kentucky Association of Health Plans, Inc. v. Miller* prohibited "'benefit plan[s]'" from "exclud[ing] from [their]

network[s] a provider who is willing and able to meet [their] terms." 538 U.S. 329, 335 (2003).

Simply put, this Court has never held preempted a state law that regulates non-plan entities only, let alone one that regulates in an area of traditional state concern about which ERISA has nothing to say. This case presents an ideal opportunity to make clear once and for all that ERISA preemption is not some inversion of ordinary principles of federalism. Federal law preempts conflicting state law where federal law actually regulates. It does not create a vacuum where PBMs can run wild, unconstrained by ERISA or state regulation.

B. The Decision Below Creates a Circuit Split.

PCMA's efforts to deny what the Tenth Circuit itself admitted fail. The decision below conflicts with the Eighth Circuit's decision in *Wehbi*. Pet.22-25.

Wehbi involved two North Dakota laws that "limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network." 18 F.4th at 968. The Eighth Circuit held that such laws do not regulate a central matter of plan administration because "they do not 'requir[e] payment of specific benefits' or 'bind[] plan administrators to specific rules for determining beneficiary status.'" *Id.* (alterations in original) (quoting *Rutledge*, 592 U.S. at 87). The Tenth Circuit held the opposite vis-à-vis the Probation Prohibition, explicitly rejecting *Wehbi* in favor of (a misreading of) two pre-*Rutledge* decisions from other circuits. App.35-38 (citing *Ky. Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352, 363 (6th Cir. 2000); *CIGNA*

Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub, 82 F.3d 642, 648 (5th Cir. 1996)); *see* Pet.27-28.

PCMA, which lost *Wehbi* unanimously, criticizes the Eighth Circuit's reasoning and tries to cabin *Wehbi* to its facts. BIO.22-25. But there is nothing "materially different" about the North Dakota laws there and the Act here. *Contra* BIO.23. Even the Tenth Circuit recognized that, just like the laws in *Wehbi*, Oklahoma's Probation Prohibition restricts PBMs' ability to impose pharmacist-accreditation standards beyond what the State requires. App.35-38.

PCMA notes that "*Wehbi* did not assess the North Dakota law's 'effects on the structure of the provider network and connected effect on plan design.'" BIO.24 (quoting App.36). But that just underscores the split. *Wehbi* declined to undertake that inquiry because it deemed any such effect legally irrelevant.

PCMA claims this is a poor vehicle to resolve the split because the Tenth Circuit found an argument based on ERISA's savings clause forfeited. BIO.26. But the savings clause is not some separate claim or defense, just an additional argument that ERISA does not preempt Oklahoma's law. Pet.28. Regardless, PCMA admits that the savings-clause issue was fully presented below, BIO.26, which suffices to preserve it for this Court's review. And as the federal government recognized below, there is a clean circuit split on the Probation Prohibition, which does not implicate the savings clause. *See* Pet.28 n.6.

PCMA's protestations that the circuit conflict is "shallow" are belied by its own assertion that the decision below sided with pre-*Rutledge* "cases from the Fifth and Sixth Circuits." BIO.22. Moreover, PBMs

are having a devastating effect on rural pharmacies, and the Eighth and Tenth Circuits contain a sizable chunk of the Nation's rural areas. It makes no sense to force Oklahoma and its fellow Tenth Circuit States to endure what their neighboring States can redress. Whether the split is 1-1 or 3-1, and whether urban residents on the coasts are spared some PBM-driven market distortions, certiorari is amply justified.

II. The Decision Below Creates A Circuit Split On The Scope Of Medicare Preemption.

This is the rare case involving not just one circuit split, but two. In the Eighth Circuit, a state law is preempted under 42 U.S.C. §1395w-26(b)(3) as applied to Part D plans "only if" it "regulate[s] the same subject matter as a federal Medicare Part D standard." *Wehbi*, 18 F.4th at 972; *see* Pet.15-16. In the Tenth Circuit, by contrast, "a specific federal-state overlap is unnecessary" for Part D preemption. App.48; *see also Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli Hernández*, 58 F.4th 5 (1st Cir. 2023) (adopting same broad approach for Part C preemption); Pet.33. Indeed, the Tenth Circuit not only derided the Eighth Circuit's "approach" to Medicare preemption as overly "fastidious," App.47, but read 42 C.F.R. §423.505(b)(18) to preempt state-law efforts to cabin the conditions that PBMs may impose on pharmacies, App.49-50, after *Wehbi* read the very same provision as "indicat[ing] an intent to leave to the states the specifics of what plans and PBMs may or may not demand of pharmacies," 18 F.4th at 972-73. *See* Pet.15-16, 33. That is a clear circuit split.

PCMA's attempt to deny that reality fails. According to PCMA (which, again, lost *Wehbi* 3-0), *Wehbi* holds that "a state law is preempted when it 'adds' *in any way* 'to a federal regulatory scheme that was designed to be comprehensive.'" BIO.27 (emphasis added) (quoting *Wehbi*, 18 F.4th at 970). That certainly was PCMA's position in *Wehbi*—but the Eighth Circuit just as certainly "disagree[d]" with it. 18 F.4th at 972; *see* Pet.30-31. In fact, as the decision below recognized, the Eighth Circuit rejected that argument in a "portion of [its] *Rutledge* opinion that [this] Court left intact." App.46.

Perhaps that is why PCMA goes to such lengths to argue that this issue is not actually presented. *See* BIO.27, 31. But those obfuscation efforts go nowhere. While the Any Willing Provider provision "does not dictate the conditions that a plan may place on network participation," BIO.27, it plainly limits the conditions PBMs may impose on preferred-network participation by prohibiting them from using predatory pricing to drive pharmacies out of business. 36 Okla. Stat. §6962(B)(4); *see* Pet.13, 22, 32; App.58; *see also* Spec.Pharmacy.Br.6-7. And while the Tenth Circuit claimed, without explanation, that "the result would be the same even under [the] narrower approach" adopted by the Eighth Circuit, App.49; *see* BIO.31-32, neither that court nor PCMA has any explanation for how that could be true when the two circuits reached diametrically opposed conclusions on the preemptive effect of 42 C.F.R. §423.505(b)(18). *Compare Wehbi*, 18 F.4th at 972-73, *with* App.49-50; *see also* Pet.33. PCMA simply ignores that reality, but its ostrich defense cannot make the split go away.

III. The Questions Presented Are Important, And This Is A Good Vehicle To Resolve Them.

While the dual splits and refusal to give *Rutledge* its due more than justify certiorari, the importance of the issues presented cannot be overstated. "PBMs have now caused more than 1,200 pharmacies to close, with the worst effects in rural communities, including in Oklahoma." Am.Pharmacies.Br.16; *see also* PatientRights.Br.12-18. The consequences are harrowing for local communities nationwide, and they can be even more devastating for vulnerable patients who depend on lifesaving (but not widely prescribed) medicines many PBM-backed pharmacies do not offer. *See* Spec.Pharmacy.Br.21. Beyond all that, the broader effects of PBMs on prices and consumer choice have drawn the attention of state and federal regulators alike. *See* Liz Essley Whyte, *Drug Middlemen Push Patients to Pricier Medicines, House Probe Finds*, Wall St. J. (July 23, 2024), https://tinyurl.com/yjnyszwa.

There is no need to wait for further percolation, while PCMA continues to sue every State that enacts commonsense PBM regulations. *See* BIO.25. Further percolation will not ameliorate the splits, given the Tenth Circuit's considered rejection of the Eighth Circuit's approach on both issues. And there is no reason to tolerate a split between two neighboring circuits with substantial rural populations on an issue that disproportionately affects rural communities.

That is particularly true given the serious deleterious consequences the decision below is *already* having even beyond the Great Plains and Midwest. As Oklahoma's amici detail, regulators from "States *in*

other circuits" have informed stakeholders "that the Tenth Circuit's decision serves as an immediate deterrent to enforcement action" against PBMs. Amer.Pharmacies.Br.16; *see* Spec.Pharmacy.Br.18. It is little wonder, then, that 31 States red and blue have filed a brief urging the Court to take up this case. *See* States.Br.; *see also* Spec.Pharmacy.Br.20 & n.17.

Finally, PCMA's supposed vehicle objections are illusory. As noted, any forfeiture concerns are misplaced, as even PCMA admits that the savings-clause issue was presented below, BIO.26; *see* Pet.28. PCMA criticizes *Wehbi* as thinly reasoned, BIO.16, 25, but no losing plaintiff views the adverse precedent it procured as a magnum opus. PCMA bizarrely tries to cast doubt on whether the Medicare-preemption issue is actually presented, BIO.27, but it cannot bring itself to make that argument in full voice, likely because it is frivolous. *See* p.10, *supra*. And the fact that "*Rutledge* was decided only a few terms ago," BIO.16, makes the need for this Court's timely intervention regrettable, but no less urgent. Indeed, the fact that multiple States used the authority *Rutledge* made clear was available to them to address the pressing problems created by the growth of PBMs, and only some of those laws have been allowed to take effect, underscores the need for this Court's review.

CONCLUSION

The Court should grant the petition.

Respectfully submitted,

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