No. _____

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In 2019, the Oklahoma Legislature responded to a wave of pharmacy closures and patient complaints by enacting the Patient's Right to Pharmacy Choice Act. The Act imposes modest rules on pharmacy benefit managers ("PBMs"), middlemen that wield enormous power in the prescription-drug market and have favored national chains and mail-order pharmacies (which they often own) over local providers that have long been cornerstones of communities and subject to state regulation. While PBMs are not ERISA plans and do not contract exclusively with ERISA plans, they have attempted to wield ERISA's preemption clause as a de facto immunity from state regulation. This Court unanimously rejected that gambit in *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020), which upheld Arkansas' effort to curb PBM abuse. Yet the Tenth Circuit largely cast *Rutledge* aside in favor of decades-old lower-court decisions, reviving an expansive view of ERISA preemption far out of step with this Court's modern precedents. Adding insult to injury, the court held that Medicare Part D precludes States from regulating PBMs with respect to Part D plans at all except as to licensing and plan solvency—openly creating not one, but two, circuit splits in the process.

The questions presented are:

1. Whether ERISA preempts state laws that regulate 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.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are directly related to this case within the meaning of Rule 14.1(b)(iii):

- *Pharmaceutical Care Management Association v. Mulready*, No. 22-6074 (10th Cir.), judgment entered on Aug. 15, 2023;
- *Pharmaceutical Care Management Association v. Mulready*, No. 5:19-CV-00977-J (W.D. Ok.), judgment entered on April 4, 2022.

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PETITION FOR WRIT OF CERTIORARI

Pharmacies have long been cornerstones of local communities, large and small. In recent years, however, they and the countless patients they serve have come under increasing threat from once-obscure forces that have squeezed their margins and favored national chains: pharmacy benefit managers. PBMs are not healthcare providers or benefit plans; they are middlemen: "intermediaries between prescription-drug plans and the pharmacies that beneficiaries use." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 83-84 (2020). Because they contract with all manner of healthcare plans, from ERISA plans to Part D plans to private insurance and beyond, PBMs wield far more market power than any plan could wield on its own. While in theory that could yield savings for healthcare plans and beneficiaries, PBMs have no fiduciary duty to anyone beyond their own shareholders. As a result, prescription-drug prices remain high and keep rising—while the effects on local, and especially rural, pharmacies have been devastating. Many have been forced to shutter, relegating their patients to mail-order pharmacies or long drives to urban areas served by national chains (many of which the PBMs own). Patients have complained and States have acted.

Arkansas was one of the first to respond, and Oklahoma quickly followed suit, enacting the Patient's Right to Pharmacy Choice Act unanimously in 2019. Shortly after the PBMs' trade association ("PCMA") challenged the Act, this Court unanimously rejected PCMA's separate challenge to Arkansas' PBM law in *Rutledge*. *Rutledge* made clear that while ERISA's express preemption is broad, its target is

state laws that actually regulate ERISA plans. Efforts to regulate entities like PBMs that contract with ERISA plans along with many others and use the resulting market power to disrupt professions long subject to state control stand on very different footing.

Rutledge should have signaled to lower courts that state efforts to regulate PBMs are unlikely to be preempted by federal law. Some circuits, including the Eighth Circuit, which this Court unanimously reversed in *Rutledge*, have gotten the message. Unfortunately, the Tenth Circuit ignored this Court's clear message in the decision below, creating a clear conflict with both *Rutledge* and the Eighth Circuit's faithful application of *Rutledge* upholding North Dakota's effort to regulate PBMs. The Tenth Circuit then went further and created a separate circuit split with the Eighth Circuit over the scope of Medicare preemption. While the latter holding impacts only Part D plans, the combined effect of the Tenth Circuit's ERISA and Medicare holdings is to invalidate the heart of Oklahoma's effort to address some of the worst abuses of PBMs.

Oklahoma, Arkansas, and North Dakota are not alone in trying to curb PBMs from further distorting drug prices and devastating local pharmacists. All 50 States have enacted some form of PBM regulation, and a bipartisan coalition of 34 of them—including California, Florida, New York, and Texas—filed an *amicus* brief below supporting Oklahoma's law and state authority in this important area. ERISA itself does nothing to address problems that are distinct to PBMs, but not specific to ERISA plans. It thus makes no sense to create a regulatory vacuum that leaves

PBMs immune from any meaningful regulation. And it makes even less sense to allow North Dakota and Arkansas to address the problem while Oklahoma is hamstrung by a decision that conflicts with *Rutledge* and cases faithfully applying it. This Court should grant certiorari and reverse.

OPINIONS BELOW

The Tenth Circuit's opinion, 78 F.4th 1183, is reproduced at App.1-51. The district court's opinion, 598 F.Supp.3d 1200, is reproduced at App.54-70.

JURISDICTION

The Tenth Circuit issued its opinion on August 15, 2023, App.1, and denied a petition for rehearing on December 12, 2023, App.52-53. Justice Gorsuch granted an initial application to extend the filing deadline on March 4, 2024, and an additional extension on April 3, 2024, extending the filing deadline to May 10, 2024. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause, U.S. Const. art. VI, cl. 2, is reproduced at App.71. The relevant provisions of ERISA, 29 U.S.C. §1144, and the Medicare Act, 42 U.S.C. §§1395w-26(b)(3), 1395w-112(g), are reproduced at App.71-79. Oklahoma's Patient's Right to Pharmacy Choice Act is reproduced at App.79-98.

STATEMENT OF THE CASE

A. Legal and Factual Background

1. ERISA

Congress enacted the Employee Retirement Income Security Act of 1974, 88 Stat. 829, to "make the benefits promised by an employer more secure." *Rutledge*, 592 U.S. at 86; *see* 29 U.S.C. §1001. ERISA accomplishes that goal not "by requiring employers to provide any given set of minimum benefits," but by "control[ling] the administration of benefit plans." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 651 (1995); *see* 29 U.S.C. §1002(3) (defining "employee benefit plan"). Specifically, ERISA imposes various "reporting and disclosure mandates," "participation and vesting requirements," "funding standards," and "fiduciary responsibilities." *Travelers*, 514 U.S. at 651.

Congress included in ERISA an express-preemption provision "to ensure that plans and plan sponsors would be subject to a uniform body of benefits law." *Rutledge*, 592 U.S. at 86 (quoting *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142 (1990)). With this provision, Congress was focused on state interference with benefit plans and did not intend to disturb the States' traditional role in regulating the practice of medicine, healthcare providers, and insurance. Subject to specified exceptions, "the provisions of [ERISA] shall supersede any and all State laws insofar as they … relate to any employee benefit plan described in section 1003(a) of this title." 29 U.S.C. §1144(a); *see id.* §1003(a) (applying ERISA's provisions to nearly all "employee benefit plan[s]").

"A state law *relates to* an ERISA plan" and is preempted under §1114(a) "if it has a connection with or reference to such a plan." *Rutledge*, 592 U.S. at 86 (emphasis added) (quoting *Egelhoff v. Egelhoff*, 532 U.S. 141, 147 (2001)). "Reference-to" preemption is straightforward: If a state law "acts immediately and exclusively upon ERISA plans" or "the existence of ERISA plans is essential to the law's operation," it is preempted. *Id.* at 88 (quoting *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 319-20 (2016)).[1]

"Connection-with" preemption has proven more complicated. This Court has found a state law impermissibly connected with ERISA plans if it requires plans to cover certain benefits, *see Gobeille*, 577 U.S. at 320; *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983), or binds plan administrators to specific rules for determining beneficiary status, *see Egelhoff*, 532 U.S. 141. But because ERISA is "primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways," *Rutledge*, 592 U.S. at 86-87, the Court has made clear that ERISA "does not pre-empt" state laws that regulate other actors in the healthcare economy and "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage," *id.* at 88. *See also, e.g.*, *Travelers*, 514 U.S. at 668.

2. Medicare Part D

The Medicare program provides federally subsidized health insurance to Americans aged 65 or

[1] PCMA "disclaim[ed] any reliance on reference-to preemption," App.16, so we focus on "connection with" preemption.

older and individuals with disabilities. Under Medicare Part D, which Congress added in 2003, all Medicare beneficiaries have access to prescription-drug coverage, "regardless of income, health status, or prescription drug usage." *What is Medicare Part D?*, U.S. Dep't of Health & Human Servs. (Feb. 12, 2014), https://shorturl.at/ruAVZ; *see* Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2071-76. Unlike traditional Medicare plans, which the government administers directly, Part D works via public-private partnerships. *See generally* 42 U.S.C. §1395w-115. The government contracts with private plan sponsors who administer the coverage and, "in turn, enter contracts with pharmacies (sometimes through [PBMs])" to dispense drugs to beneficiaries. *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 744-45 (2023); *see* App.4-5.

Those contracts are subject to various federal regulations. To ensure the uniformity and primacy of those regulations, Part D incorporates Medicare Part C's express-preemption provision. *See* 42 U.S.C. §1395w-112(g). Under that provision, "[t]he standards established under [Part D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D plans] … offered by [plan sponsors]." *Id.* §1395w-26(b)(3). The statute does not delimit the universe of those "standards," instead empowering the Secretary of Health and Human Services to "establish by regulation other standards." *Id.* §1395w-26(b)(1).

Part D preemption is limited in two important respects. First, it preempts only with respect to plans

operating under Part D. Second, it applies only to state laws that "supersede," *i.e.*, displace, federal standards. "Thus, [it] does not preempt all state laws as applied to Medicare Part D; rather, it preempts only those that occupy the same 'place'—that is, that regulate the same subject matter as—federal Medicare Part D standards." *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 971 (8th Cir. 2021).

3. PBMs and *Rutledge*

PBMs are "intermediaries" between pharmacies and benefit plans in the prescription-drug market. *Rutledge*, 592 U.S. at 83-84. Prescription drugs are ubiquitous in modern America, and their pricing and sourcing is notoriously complex, which has given rise to PBMs. While health-benefit plans could themselves perform the same basic functions as PBMs, they have largely (and voluntarily) chosen to outsource that role to PBMs. *See* CA10.App.67. The way PBMs perform their functions impact the availability and affordability of prescription drugs for ordinary citizens, whether they access those drugs through Part D, employer plans, or private insurance.

PBMs contract with pharmacies to establish networks (theoretically to help secure price concessions from pharmaceutical manufacturers) and separately contract with benefit plans to provide access to those networks and process claims submitted by in-network pharmacies for reimbursement on the plan's behalf. When a benefit-plan participant fills a prescription at an in-network pharmacy, the pharmacy files a claim with the PBM; the PBM processes the claim and notifies the pharmacy how much the patient's plan will cover and how much the

beneficiary owes out of pocket. The PBM will then reimburse the pharmacy per the terms of their contract and bill the plan according to their separate agreement. The difference between the price the PBM pays the pharmacy and the price it receives from the benefit plan is known as the "retail spread" (*i.e.*, the PBM's profit margin), and it can be substantial. *See* CA10.App.734-35; *Rutledge*, 592 U.S. at 84 ("A PBM's reimbursement from a plan often … exceeds [its] reimbursement to a pharmacy. That difference generates a profit for PBMs.").

Playing the role of intermediary has allowed PBMs to amass considerable influence over the accessibility and affordability of prescription drugs. Recent estimates suggest that PBMs administer prescription-drug benefits for a sizable majority of Americans and Oklahomans.[2] App.4-5, 19-20. Given that scale, PBMs affect the accessibility and affordability of drugs for virtually all individuals.

To be clear, PBMs are not benefit providers, and they do not act as fiduciaries of benefit plans or their beneficiaries. Indeed, they have opposed efforts to make them fiduciaries at every turn. PBMs are thus under no obligation to act in the best interests of either the plans with which they contract or the pharmacies they pool into networks. As even PCMA's own expert witness admitted below, PBMs are not just "looking to

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[2] Roughly a third of the 270-odd million Americans for whom PBMs administer drug benefits are enrolled in an ERISA plan. PCMA, *Pharmacy Benefit Managers (PBMs): Reducing Costs and Improving Quality* 5 (May 18, 2018), https://perma.cc/JS9D-BLSA.

make a profit on the commercial health plan sponsor," but "out to get your money" too. CA10.App.68.

PBMs have been wildly successful in strong-arming plans, pharmacies, and patients. The networks PBMs have assembled not only allow them to secure concessions from drugmakers, but give them enormous leverage over plans and pharmacies—which they have used to maximize their margins, driving down the prices they reimburse pharmacies while driving up the prices benefit plans must pay them. This too is undebatable. The White House found in 2018 that PBMs "exercise undue market power … against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves." CA10.App.315.

In recent years, PBMs have used their substantial market power in ways that have made it harder for patients, especially those in rural areas, to access prescription drugs. PBMs have bought up pharmacies and forced patients to switch to ones they own, even when that means relegating a customer to a mail-order pharmacy. CA10.App.112, 133-137, 149-150, 262. They regularly exclude smaller pharmacies from their preferred networks, effectively forcing patients to eschew their local pharmacy. CA10.App.134-135, 139, 149. And they have even gone so far as to "act[] as quasi-regulators," cutting off pharmacies with pharmacists who state authorities have disciplined but deemed eligible to work. CA10.App.153.

PBMs' growth has come at the expense of community pharmacies, which have shuttered at an alarming rate. Rural pharmacies have been hit particularly hard, as PBMs typically prefer to deal

with large national pharmacy chains that are prevalent in metropolitan areas, but do not view rural outposts as attractive. *See, e.g.*, Edmer Lazaro et al., *Update on Rural Independently Owned Pharmacy Closures in the United States, 2003-2021*, Rural Pol'y Brief (Aug. 2022), https://shorturl.at/awNSZ.

Deluged with complaints from patients and pharmacies, States have taken action. *See, e.g.*, *Rutledge*, 592 U.S. at 84 (observing that Arkansas acted "in response to concerns that the reimbursement rates set by PBMs were often too low to cover pharmacies' costs, and that many pharmacies, particularly rural and independent ones, were at risk of losing money and closing"). Although PBMs spent years behind the scenes and below the radar, today, all 50 States regulate PBMs. *See* Jennifer Reck, *State Pharmacy Benefit Manager Legislation*, Nat'l Acad. for State Health Pol'y (Nov. 7, 2023), https://shorturl.at/crCU0; Br. for Cal. et al. as *Amici Curiae*, *Rutledge*, 2020 WL 1372774, at *14-21 (cataloging state approaches). Oklahoma is no exception. *See, e.g.*, 59 Okla. Stat. §§357-360 (2014).

State efforts to regulate PBMs reached this Court in *Rutledge*. Although the PBMs' principal trade association (PCMA)—the respondent here—sought to blunt state regulatory efforts by invoking ERISA, this Court unanimously rejected that effort. 592 U.S. 80. The Court recognized that although PBMs contract with the benefit plans directly regulated by ERISA, plans' voluntary decisions to rely on PBMs for prescription-drug benefits did not extend the scope of ERISA preemption, let alone diminish States' ability to regulate entities that are having a profound impact

on local conditions and the accessibility of prescription drugs for virtually all state citizens. *Id.* at 86-92.

B. Proceedings Below

1. Oklahoma's Pharmacy Choice Act

Against the backdrop of PBM consolidation and a wave of rural pharmacy closings, the Oklahoma Legislature unanimously enacted the Patient's Right to Pharmacy Choice Act in 2019 "to establish minimum and uniform access to a provider" and prohibit PBMs from restricting "a patient's right to choose a pharmacy provider." 36 Okla. Stat. §6959.

Four provisions are at issue here.

- The "Access Standards" prohibit PBMs from cutting off rural patients' access to in-network pharmacies. *Id.* §6961(A)-(B).
- The "Discount Prohibition" forbids PBMs from steering patients to favored pharmacies by offering discounts at those pharmacies and them alone. *Id.* §6963(E).
- The "Any Willing Provider Provision" requires PBMs to accept into their preferred-pharmacy networks all pharmacies willing to accept the network terms and conditions. *Id.* §6962(B)(4).
- The "Probation Prohibition" forbids a PBM from terminating its contract with a pharmacy based on a pharmacist's active probation status. *Id.* §6962(B)(5).

App.81-88. The Tenth Circuit referred to the first three collectively as "network restrictions." App.21. It

labeled the last provision an "integrity and quality restriction." *Id.*

2. PCMA files suit pre-*Rutledge*

Before the Act could take effect, PCMA sued, claiming that nearly all the Act's provisions are preempted. App.11. A few months later, this Court granted certiorari in *Rutledge* over PCMA's opposition. 140 S.Ct. 812 (2020) (mem.). PCMA nonetheless sought to enjoin the Act before this Court resolved *Rutledge*. The district court denied that motion in large measure, rejecting PCMA's sweeping ERISA claims across the board and rejecting most of PCMA's Medicare claims. Order, No. 5:19-cv-00977-J (W.D. Okla. July 9, 2020), Dkt.48.

PCMA then filed a motion for an emergency injunction in the Tenth Circuit to prevent the Act from taking effect, which was swiftly denied. Order, *PCMA v. Mulready*, No. 20-6107 (10th Cir. Aug. 17, 2020). PCMA voluntarily dismissed its interlocutory appeal, and the Act took effect.

After the Act took root and this Court issued its unanimous opinion in *Rutledge*, PCMA sought summary judgment below under ERISA and Medicare. Relying on *Rutledge*, the district court largely rejected PCMA's claims once again. PCMA argued that the challenged provisions all "directly affect[ed] the benefits a plan offer[ed] to plan members" and thus had an "impermissible connection with ERISA plans." App.58. The court held the opposite. While the challenged provisions "may alter the incentives and limit some of the options" available to benefit plans, none of them "force[s] ERISA plans to make any specific choices" with respect to what

coverage to offer. App.59. Thus, under *Rutledge*, none is impermissibly "connect[ed] with" an ERISA plan. App.58. As for Medicare, the court rejected PCMA's challenges to the Any Willing Provider Provision and the Probation Prohibition, but held that Part D preempted the Access Standards and Discount Prohibition. App.62-69.[3]

3. The Decision Below

The Tenth Circuit reversed in relevant part.

a. Starting with ERISA, the court grouped together three of the four challenged Act provisions (the Access Standards, Discount Prohibition, and Any Willing Provider Provision) under the banner of "network restrictions" and summarized them as follows. The Access Standards "dictate which pharmacies must be included in a PBM's network"; the Discount Prohibition requires "cost-sharing and copayments be the same for all network pharmacies"; and the Any Willing Provider Provision requires "those pharmacies [to] be invited to join the PBM's preferred network." App.25-26. As those summaries underscore, these provisions regulate only PBMs, not plans, and do not "forc[e] plans to adopt any particular scheme of substantive coverage." *See Rutledge*, 592 U.S. at 88. Nevertheless, the court relied on decades-old circuit-court cases to hold that the provisions were all impermissibly connected with ERISA plans merely because they operate to "winnow[] the PBM-network-

[3] The State "had conceded that Medicare Part D preempted the Discount Prohibition," App.13 n.4, and it chose not to cross-appeal, leaving unchallenged the district court's ruling that the Access Standards are preempted with respect to Part D plans.

design options" available to benefit plans, be they ERISA plans or not. App.27.

Turning to the Probation Prohibition, the court did not seriously dispute that the provision had at most a de minimis effect on pharmacy-benefit design. Yet it thought that even such a trivial effect implicated "a central matter of plan administration" and held the provision preempted. App.34-36. In doing so, the Tenth Circuit expressly parted company with the Eighth Circuit, which held that "two North Dakota laws that resemble the Probation Prohibition" did not have an impermissible connection with ERISA plans. App.35. The Eighth Circuit rebuffed PCMA's challenges to the North Dakota laws because they "merely limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network" and thus constitute "regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects." *Wehbi*, 18 F.4th at 968; *see* App.35-36. The Tenth Circuit explicitly rejected that reasoning, holding the Probation Prohibition preempted because it "dictat[es] which pharmacies must be included in a plan's PBM network," even though it is merely a mechanism for upholding the State Pharmacy Board's disciplinary control over pharmacists. App.37.[4]

b. With respect to Medicare, the Tenth Circuit held "Part D preempt[ed] the [Any Willing Provider] Provision as applied to Part D plans." App.41. The court "agree[d] with PCMA" that Medicare's

[4] Finally, the Tenth Circuit held that "Oklahoma did not preserve a saving-clause argument," and thus declined to address ERISA's saving clause, 29 U.S.C. §1144(b). App.39.

preemption clause "is 'akin to field preemption' and precludes States from regulating Part D plans except for licensing and plan solvency." App.43. And "because" the Any Willing Provider Provision "is not a licensing law or law relating to plan solvency," the court was satisfied that it did not need to identify any "specific federal-state overlap." App.48-49.

In so holding, the court once again "disagree[d]" with the Eighth Circuit. App.46. The Eighth Circuit held in a "portion of [its] *Rutledge* opinion that [this] Court left intact" that Part D preemption turns on "whether Congress or CMS 'has established "standards" in the area regulated by the state law' and whether 'the state law acts "with respect to" those standards.'" *Id.* (quoting *PCMA v. Rutledge*, 891 F.3d 1109, 1113-14 (8th Cir. 2018)). The Tenth Circuit rejected that approach as supposedly inconsistent with the text of the express-preemption provision. *Id.*

The Tenth Circuit also split from *Wehbi*, which expanded on the Eighth Circuit's *Rutledge* opinion. *Wehbi* held that "Part D 'preempts only those [state laws] that … regulate the same subject matter as … federal Medicare Part D standards.'" App.47 (first alteration in original) (quoting *Wehbi*, 18 F.4th at 971). The Tenth Circuit again rejected "how *Wehbi* framed the issue," concluding that "requiring such a close match between federal and state standards" in the Part D inquiry "'slic[ed] the baloney [too] thin.'" App.47-48. In the Tenth Circuit's eyes, "allowing States to regulate Part D plans above what Part D already requires would 'detract[] from the integrated scheme of regulation created by Congress.'" App.48 (alteration in original). The court accordingly held,

contrary to *Wehbi*, that "a specific federal-state overlap is unnecessary." *Id.*

Finally, the court opined that "the result would be the same even under [the] narrower approach" adopted by the Eighth Circuit. App.49. The court read federal regulations requiring Part D plan sponsors to "agree to have a standard contract … whereby any willing pharmacy may access the standard contract and participate [in] a network" to speak directly to (and thus preempt) "how Part D plan sponsors must construct their networks." *Id. But see Wehbi*, 18 F.4th at 972-73 (holding the opposite about the same regulations).

REASONS FOR GRANTING THE PETITION

The decision below is irreconcilable with this Court's unanimous decision in *Rutledge* and conflicts with decisions of other circuits faithfully applying *Rutledge*. *Rutledge* recognizes that PBMs are not ERISA plans and that plans' voluntary decisions to contract with PBMs does not somehow expand the scope of ERISA preemption or restrict States' ability to address the disappearance of rural pharmacies and other negative manifestations of PBM market power. As a result, *Rutledge* held that ERISA preempts only those state "laws that require providers to structure benefit plans in particular ways" or "requir[e] payment of specific benefits." 592 U.S. at 86-87. And no Arkansas PBM regulation was preempted under this narrow standard.

None of the provisions at issue here comes close to mandating any benefit plan structure or the provision of any particular benefit, either. The Act does not operate on providers of benefit plans at all. Yet the

Tenth Circuit held all the challenged provisions preempted on the theory that ensuring patients have meaningful access to pharmacies by regulating PBMs somehow intrudes on a central matter of *plan* administration. App.23-24, 26-27, 31. That sweeping theory cannot be squared with *Rutledge* or with this Court's longstanding caution against stretching ERISA preemption to areas of "traditionally state-regulated substantive law … where ERISA has nothing to say." *Cal. Div. of Labor Standards Enf't v. Dillingham*, 519 U.S. 316, 330 (1997). Moreover, the decision below admittedly conflicts with a post-*Rutledge* decision of the Eighth Circuit rejecting PCMA's argument that "two North Dakota laws that resemble the Probation Prohibition" were impermissibly connected with ERISA. App.35.

Separately, the decision below creates a textbook circuit split on the scope of Medicare Part D preemption. The Tenth Circuit openly "disagree[d] with the … fastidious approach" to Part D preemption that the Eighth Circuit took, instead adopting a "sweeping" view of Medicare preemption. App.43, 47. In the Eighth Circuit, state laws are not preempted unless a Part D standard speaks directly to the issue regulated. The Eighth Circuit thus held that Medicare does not preempt state laws limiting the conditions that PBMs may place on pharmacies' participation in their preferred networks, because no federal Part D standard speaks directly to that issue. The Tenth Circuit held the opposite, finding the Any Willing Provider Provision here preempted as to Part D plans even though the court acknowledged that no federal Part D standard speaks directly to participation in PBMs' preferred networks.

Finally, the questions presented are important, and this is an excellent vehicle to resolve them. PBMs have had a profound and profoundly negative effect on pharmacies and the patients who rely on them. Unsurprisingly, Oklahoma is not alone in trying to address the problems created by the increasingly powerful, opaque, and self-dealing PBM industry. There is no reason to believe that Congress federalized an area of traditional state regulation through statutes that do not actually govern the topics or entities at hand. And there is even less reason to allow North Dakota to address the problem while tying the hands of Oklahoma. The Court should grant the petition and reverse on both issues.

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.

1. ERISA preempts "State laws insofar as they … relate to any employee benefit plan" covered by the statute. 29 U.S.C. §1144(a). This Court has long held that a state law "relates to an ERISA plan" and is preempted under §1144(a) "if it has a connection with … such a plan." *Rutledge*, 592 U.S. at 86 (quoting *Egelhoff*, 532 U.S. at 147). To be sure, a wide swath of healthcare matters traditionally regulated by States have some connection with benefit plans. But this Court has rejected the sort of "uncritical literalism" that would yield preemption all the way down, *Travelers*, 514 U.S. at 656, as "matters of health and safety" are traditionally within the bailiwick of the States to regulate, *De Buono v. NYSA-ILA Med. &*

Clinical Servs. Fund, 520 U.S. 806, 814 (1997), and this Court has "never assumed lightly that Congress has derogated state regulation," *Travelers*, 514 U.S at 654. The Court has thus specifically cautioned against stretching ERISA to preempt laws in "traditionally state-regulated" areas about which "ERISA has nothing to say," *Dillingham*, 519 U.S. at 330—which is exactly the situation here.

Rutledge further clarified the narrow scope of so-called "connection with" preemption when it comes to state efforts to regulate entities like PBMs that interact with benefit plans (among others), but are not plans, or even fiduciaries to plans. At issue there was an Arkansas law that requires PBMs to reimburse pharmacies at a price no lower than what "a pharmaceutical wholesaler charges" and authorizes pharmacies to decline to dispense a drug if PBM reimbursements are "less than the pharmacy['s] acquisition cost." Ark. Code Ann. §17-92-507(a)(6), (e) (Supp. 2017). PCMA argued that, given plans' reliance on PBMs, the Arkansas statute "interferes with central matters of plan administration" on the theory that "allowing pharmacies to decline to dispense a prescription" when PBM reimbursement rates are too low "effectively denies plan beneficiaries their benefits." *Rutledge*, 592 U.S. at 91.

This Court unanimously disagreed. Arkansas' law "requires PBMs to compensate pharmacies at or above their acquisition costs." *Id.* And as this Court made clear, "[w]hen a pharmacy declines to dispense a prescription, *the responsibility lies first with the PBM* for offering the pharmacy a below-acquisition reimbursement." *Id.* (emphasis added). PBMs'

market power thus does not prevent States from holding them accountable for their own behavior.

In rejecting PCMA's sweeping theory of "connection with" preemption, *Rutledge* went out of its way to underscore that "not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Id.* at 87. State laws are not preempted via "connection with" ERISA plans unless they "require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits," "bind[] plan administrators to specific rules for determining beneficiary status," or "force an ERISA plan to adopt a certain scheme of substantive coverage." *Id.* at 86-87. Any other rule would blur the line between the benefit plans that are the focus of federal concern and the broader healthcare system that remains subject to state and local regulation. The former cannot radically expand the scope of federal preemption—and shrink the scope of States' authority to address quintessentially local concerns—simply by entering into service agreements with non-fiduciary third parties like PBMs. Section 1144(a) thus leaves States free to enact state-specific laws that "alter incentives" for ERISA plans, provided they do not mandate specific benefits. *Id.* at 87-88.

2. In light of *Rutledge*, it should have been clear that Oklahoma's Act is in no way impermissibly connected with ERISA. For one thing, neither prescription-drug benefits nor PBMs are mentioned in ERISA. For another, the Act "does not require plans to provide any particular benefit to any particular beneficiary in any particular way." *Id.* at 90. Not one

of the challenged provisions requires benefit plans to do anything; "the responsibility" to comply with the Act's terms "lies" exclusively "with the PBM[s]." *Id.* at 91. And as even the Tenth Circuit acknowledged, "PBMs are not plans, nor fiduciaries to plans," and "plans need not contract with PBMs." App.17.

The Tenth Circuit nonetheless held the Act's network provisions impermissibly connected with ERISA plans "because a pharmacy network's scope (which pharmacies are included) and differentiation (under what cost-sharing arrangements those pharmacies participate in the network)[] are key benefit designs for an ERISA plan." App.26. That addresses the wrong question, as virtually any PBM regulation (including those in *Rutledge*) will indirectly affect benefit designs. The relevant question is whether any of the challenged provisions mandate any "particular benefit" or "bind plan administrators to any particular choice." *Rutledge*, 592 U.S. at 87, 90. The answer here is clearly no.

First, the Discount Prohibition simply ensures a wide variety of pharmacies and protects patient choice by prohibiting PBMs from using incentives to steer Oklahomans to the pharmacies the PBMs own or otherwise favor. *See* 36 Okla. Stat. §6963(E). And it is well established that "ERISA is unconcerned" with anti-steering laws. *See Dillingham*, 519 U.S. at 327. Second, the Access Standards merely regulate the quality of the networks to which PBMs sell access, ensuring that Oklahomans have meaningful access to an in-network pharmacy, rather than stranding rural Oklahomans in pharmacy deserts. *See* 36 Okla. Stat. §6961(A)-(B). PBMs may prefer to construct their

networks free from such state efforts, but nothing in ERISA remotely insulates them from sensible state efforts to protect rural and independent pharmacies from extinction. Third, the Any Willing Provider Provision just prevents PBMs from arbitrarily discriminating against already-in-network pharmacies seeking to obtain preferred status. 36 Okla. Stat. §6962(B)(4). It leaves PBMs free to establish whatever conditions of preferred-pharmacy status they please and "does not require a plan to accept any willing pharmacy into its pharmacy network" in the first instance. App.58.

Of course, the network provisions take options off the table for PBMs and limit the options PBMs can offer plans. But nothing in this Court's caselaw supports the Tenth Circuit's holding that taking one option off the table for PBMs is tantamount to forcing plans into a particular benefit structure. Nor is such a holding logical. Nothing in Oklahoma's law forces plans to contract with PBMs (or regulates plans at all). And, to state what should be obvious, the mere fact that PBMs have arisen as a market force by contracting with plans does not imbue them with power to expand the scope of federal preemption or eliminate States' traditional authority to ensure the widespread availability of pharmacies. *Contra* App.20.

B. The Decision Below Openly Creates a Circuit Split.

The Tenth Circuit made a similar leap of (il)logic for the Probation Prohibition. The upshot of that provision is that "PBMs could not oppose pharmacies employing pharmacists on probation" with the State

Pharmacy Board. App.38. The Tenth Circuit took from this that the provision somehow "dictat[es] which pharmacies must be included in a plan's PBM network." App.37. In reality, however, the provision simply preserves the State's traditional authority to license pharmacists within the State and determine how best to sanction and rehabilitate individuals in that field who have transgressed. CA10.App.153-54. Telling a PBM it cannot override a State's decisions about how best to regulate the practice of pharmacy—whether through active probation and rehabilitation (the State Board's choice) or a career death sentence (PBMs' approach)—in no way dictates the terms of "a *plan's* PBM network." *Contra* App.37 (emphasis added).

Indeed, the Tenth Circuit's condemnation of the Probation Prohibition exemplifies how its overbroad conception of "connected-with" preemption obliterates sensible lines between uniquely federal interests and areas of traditional state and local concern. The proper approach to sanctioning and rehabilitating state-regulated pharmacists is not remotely the sort of thing one would expect to be "an object of pre-emption." *Travelers*, 514 U.S. at 646. On the contrary, "the practice of pharmacy is an area traditionally left to state regulation." *Wehbi*, 18 F.4th at 972. Indeed, "the Department of Health and Human Services has a 'general position of deferring to States for regulating the practice of pharmacy.'" *Id.* (citation omitted). It is well within a State's traditional authority to prevent third parties from circumventing its control over pharmacist licensing and discipline. And nothing in ERISA's protection of health-plan administration

entitles third-party PBMs to wrest that authority away from the States.

It is thus no great surprise that, in holding the Probation Prohibition preempted, the Tenth Circuit created a square circuit conflict. The Eighth Circuit held in *Wehbi* that ERISA did not preempt "two North Dakota laws that resemble the Probation Prohibition." App.35; *see Wehbi*, 18 F.4th at 968-69. The two North Dakota laws prohibit PBMs from conditioning a pharmacy's participation in their networks on satisfying "accreditation standards or recertification requirements … more stringent than, or in addition to[,] … state requirements for licensure." N.D. Code §§19-02.1-16.1(11), -16.2(4). Like the Probation Prohibition, those laws "limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network." *Wehbi*, 18 F.4th at 968. But unlike the Tenth Circuit, which viewed all state laws that restrict the network-participation conditions a PBM may impose as impermissibly "connected with" ERISA plans, App.35-38, the Eighth Circuit held that these provisions "constitute, at most, regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects." *Wehbi*, 18 F.4th at 969 (quoting *Gobeille*, 577 U.S. at 320).

In reaching that conclusion, the Eighth Circuit did not deny that the laws may "'cause[] some disuniformity in plan administration' by requiring PBMs to maintain different accreditation requirements in different states." *Id.* at 968 (alteration in original) (quoting *Rutledge*, 592 U.S. at 87). Nor did it deny that the laws' effect is that PBMs

could not oppose pharmacies employing pharmacists that satisfied the State's licensing requirements but fell short of the PBM's own higher standards. But it held that "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 exact opposite here. Indeed, the Tenth Circuit was explicit that it was rejecting the Eighth Circuit's reasoning and reaching a contrary result. App.38. Only this Court can resolve that square circuit split.

C. This Case Provides the Court With an Opportunity to Clarify That ERISA Does Not Preempt State Laws That Regulate Matters ERISA Does Not Address.

Beyond shirking *Rutledge* and opening up a circuit split, the decision below flouts this Court's ERISA cases in a more fundamental respect. As explained, Oklahoma's Act does not regulate plans at all; it regulates only PBMs—and only with respect to their dealings with pharmacies (not plans). Yet this Court has *never* expanded the scope of ERISA preemption in a comparable manner to preempt state laws that do not regulate benefit plans. *See Rutledge*, 592 U.S. at 96 (Thomas, J., concurring).

The Tenth Circuit incorrectly thought otherwise. According to the court, *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724 (1985), and *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002), each held impermissibly "connected with" ERISA a state law that "regulate[d] only third parties," not plans. App.18-19. But that is demonstrably

incorrect—as even the decision below inadvertently demonstrated. Both laws directly regulated insurers, including ERISA plans, and thus plainly regulated ERISA plans directly, albeit not exclusively. At issue in *Metropolitan Life* was "a Massachusetts law that required health insurers to provide mental-health benefits to state residents." App.18; *see* 471 U.S. at 734, 739. That is as direct a regulation of plans as it gets. And the Illinois law in *Rush* similarly "forced" "ERISA plans that chose to 'purchase medical coverage' through HMOs" to "comply with" an Illinois-specific "review process" for "certain benefit denials." App.19 (quoting *Rush*, 536 U.S. at 365). It once again regulated ERISA plans directly, if not exclusively.

The Act here is fundamentally different. Unlike the laws in those cases—which were saved from preemption under ERISA's saving clause in all events, *see* App.18-19 nn.7-8—the Act does not regulate plans at all or require plans to do anything. It simply requires PBMs not to unduly cabin access to in-network pharmacies, steer patients away from local pharmacies through discounts, or block from their networks pharmacies willing to accept their terms. At most, the Act regulates entities with whom ERISA plans—and others—contract.[5] To extend ERISA

[5] It bears emphasis that PBMs derive their immense market power—and ability to overpower plans, pharmacies, and patients—not just from contracts with ERISA plans, but arrangements with other insurers and national pharmacy chains. *See* n.2, *supra*. Thus, whatever hard questions might be posed by regulating entities that contract with ERISA plans alone, Oklahoma's Act is not (and state PBM laws more generally are not) some clever gambit to regulate ERISA plans indirectly,

preemption to PBM regulations like these would essentially allow private parties to expand the reach of federal preemption and whittle away the traditional authorities of States. There is no precedent of this Court that sanctions such preemption by contract.

Nor is there any circuit-court precedent for finding such a law preempted. The Tenth Circuit gave pride of place in its ERISA-preemption analysis not to *Rutledge*, which it treated as a mere impediment to be overcome, but to two pre-*Rutledge* circuit-court decisions: *Kentucky Association of Health Plans, Inc. v. Nichols*, 227 F.3d 352 (6th Cir. 2000), and *CIGNA Healthplan of Louisiana, Inc. v. Louisiana ex rel. Ieyoub*, 82 F.3d 642 (5th Cir. 1996). That inversion alone signals the need for this Court's intervention. But the Tenth Circuit misunderstood those cases in all events. In *Nichols*, as this Court explained in the course of reviewing other aspects of the decision, Kentucky's laws applied *directly to plans*: They barred "'benefit plan[s]'" from "exclud[ing] from [their] network[s] a provider who is willing and able to meet [their] terms." *Ky. Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 335 (2003) (citing Ky. Rev. Stat. Ann. §§304.17A-171). The Louisiana law in *CIGNA* was similar: It prohibited certain benefit plans from excluding any licensed physician willing and able to "agree to the[ir] terms and conditions." 82 F.3d at 645 (quoting La. Rev. Stat. Ann. §40:2202(5)(c) (1984)). Indeed, the law there expressly "refer[red] to ERISA-qualified plans." *Id.* at 647.

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but an effort to limit PBMs' abuse of market power derived from contracting with a wide variety of market participants.

Neither *Nichols* nor *CIGNA* supports the decision below. Nor does anything in this Court's caselaw. The Tenth Circuit's decision to allow preemption via private contracting stands alone and merits this Court's review and correction.

Finally, even if "regulating PBMs functions as a regulation of an ERISA plan itself," App.31, the challenged provisions are still saved from preemption under 29 U.S.C. §1144(b)(2)(A), as the United States contended below.[6] The Tenth Circuit did not hold otherwise; it just held that Oklahoma had somehow forfeited reliance on the saving clause. App.38-40. That was wrong as matter of fact and law. Not only did Oklahoma raise the saving clause, *e.g.*, CA10.Okla.Br.35 n.7; CA10.App.696 n.5; CA10.Supp.App.200 n.2, but the clause—which is in the same section as the express-preemption clause—is not some distinct issue, just an additional argument for why PCMA did not carry its "burden of proving preemption," *Wehbi*, 18 F.4th at 967. *See, e.g.*, *Yee v. City of Escondido*, 503 U.S. 519, 534 (1992). Thus, while Oklahoma's effort to combat the unique problems caused by PBMs' abuse of the kind of market power that no ERISA plan could wield on its own is not preempted on the front end, it would be saved from preemption on the back end in all events.

* * *

[6] The United States agreed with Oklahoma that, consistent with the Eighth Circuit decision in *Wehbi*, the Probation Prohibition is not preempted wholly apart from the saving clause. *See* CA10.US.Amicus.Br.9-11.

The decision below flouts *Rutledge* and is irreconcilable with this Court's ERISA caselaw. It openly creates a circuit split on whether state laws that prevent PBMs from usurping States' control over pharmacy licensing have an impermissible connection with ERISA plans. And it turns core federalism principles upside down. Indeed, the Tenth Circuit's conclusion that PBMs' power means that "regulating PBMs functions as a regulation of an ERISA plan itself," App.31, not only transforms PBMs into a sovereign unto themselves, but stretches ERISA preemption to a degree this Court has acknowledged would be "unsettling" to say the least. *Dillingham*, 519 U.S. at 330-31. The Court should grant the first question presented.

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

Under 42 U.S.C. §1395w-26(b)(3), which is made applicable to Medicare Part D via 42 U.S.C. §1395w-112(g), "[t]he standards established under [Part D] shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Medicare] plans which are offered by [Medicare] organizations under this part." The circuits are divided on the scope of preemption under this provision.

1. In the Eighth Circuit, state laws "are expressly preempted" as applied to Part D plans pursuant to §1395w-26(b)(3) "only if" they "regulate the same subject matter as a federal Medicare Part D standard." *Wehbi*, 18 F.4th at 972. Because §1395w-26(b)(3) speaks in terms of "superseding" state law and the verb "[t]o 'supersede' means to 'displace,'" *id.* at 971;

see also Rutledge, 592 U.S. at 93 (Thomas, J., concurring), the Eighth Circuit reads §1395w-26(b)(3) to expressly preempt state laws as applied to Part D plans only to the extent that a federal Part D standard "occup[ies] the same 'place'"—that is, speaks directly to the issue the State is regulating. *Wehbi*, 18 F.4th at 971.

At issue in *Wehbi* were a suite of North Dakota laws that broadly regulated PBMs' activities in the State. *See id.* at 964-65. The laws prohibited PBMs from, *inter alia*, barring pharmacists from telling patients they could save money by paying out of pocket or choosing "a more affordable alternative drug," N.D. Code §19-0.1-16.1(7); requiring pharmacies to satisfy "more stringent" accreditation requirements than the State itself "require[d] for licensure," *id.* §§19-0.1-16.1(11); 19-0.1-16.2(4); operating mail-order specialty pharmacies that they owned, *id.* §19-0.1-16.2(3); and withholding information showing the difference between the amount they reimburse pharmacies and the amount they charge a plan, *id.* §19-0.1-16.2(2). PCMA sued (as it does reflexively when a State regulates PBMs), arguing that Medicare preempted North Dakota's statutes as applied to Part D plans. *Wehbi*, 18 F.4th at 964, 972. Relevant here, PCMA argued that the laws were preempted "to the extent that they limit the conditions that PBMs may place on pharmacies' participation in their networks." *Id.* at 972. According to PCMA, 42 C.F.R. §423.505(b)(18)—which prohibits PBMs from imposing "unreasonable or irrelevant conditions" on "pharmacies' participation in [their] networks"—preempts "state laws that limit the conditions that PBMs may place on pharmacies' participation in their networks." 18 F.4th at 972.

The Eighth Circuit "disagree[d]." *Id.* "[T]he practice of pharmacy is an area traditionally left to state regulation." *Id.* Against that backdrop, "the highly general language of the regulation—requiring only that plans 'have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may … participate as a network pharmacy'"—was nowhere near enough to "claim[] this area for federal control pursuant to Medicare Part D's express preemption provision." *Id.* at 972-93. "On the contrary," the court viewed "the highly general language of the regulation" as a strong "indicat[ion of] an intent to leave to the states the specifics of what plans and PBMs may or may not demand of pharmacies." *Id.* at 973.

PCMA further argued that "miscellaneous federal Medicare Part D standards … preempt[] a subset of the challenged provisions." *Id.* at 974. The court "agree[d] with PCMA on some but not all of its claims." *Id.* Relevant here, PCMA argued that Section 16.2(3), "which addresses certain conflicts of interest that PBMs might have," was preempted "because some [Part D] regulations also address potential conflicts of interest." *Id.* at 976; *see* 42 C.F.R. §423.504(b)(4)(vi)(G). The Eighth Circuit rejected that claim because the Part D standards PCMA invoked "address different kinds of conflicts" than the state law. *Wehbi*, 18 F.4th at 976.

2. The Tenth Circuit did not mince words below in breaking with the Eighth Circuit. It derided *Wehbi* as adopting an overly "fastidious approach" to Part D preemption, concluding that "requiring such a close match between federal and state standards … 'slic[ed]

the baloney [too] thin.'" App.47. As an "example" of its "disagree[ment]," the Tenth Circuit balked at *Wehbi*'s analysis of the conflict-of-interest claim, deeming the "distinctions" the Eighth Circuit drew too "narrow[]." *Id.* In the Tenth Circuit's eyes, "a specific federal-state overlap is unnecessary" for Part D preemption, because "allowing States to regulate Part D plans above what Part D already requires would 'detract[] from the integrated scheme of regulation created by Congress.'" App.48 (alteration in original)).

That discord in approach led to concrete conflict in application. As explained, Oklahoma's Any Willing Provider Provision requires PBMs to allow "into their preferred networks" "all Oklahoma pharmacies that are willing to accept [their] terms." *Id.*; *see* 36 Okla. Stat. §6962(B)(4). Under the Eighth Circuit's rule, the key question would be whether the Part D regulations "deal[ing] with standard networks" occupy the same place as "the Act's AWP Provision," which "concerns preferred networks." App.48. The Tenth Circuit rejected that approach out of hand. In its view, the Any Willing Provider Provision "regulates 'with respect to [Part D plans]'" and thus is preempted under §1395w-26(b)(3) simply because "it establishes a rule that governs PBM pharmacy networks for Part D plans." App.49 (alteration in original).

The decision below thus held that *any* state law that restricts the universe of conditions PBMs may place on pharmacies' participation in their networks is preempted, viewing all such regulations as necessarily "'function[ing] as a regulation of a[] [Part D] plan itself.'" App.48 (first alteration added). That is the exact opposite of what the Eighth Circuit held.

To be sure, the Tenth Circuit declared in the alternative that it would find no preemption even "under [*Wehbi*'s] narrower approach." App.49. But that does not change that the broader approach—which conflicts with *Wehbi*—is the law of the circuit moving forward. In all events, the Tenth Circuit's alternative holding was no less contrary to *Wehbi*. As noted, *Wehbi* read the "highly general language" in 42 C.F.R. §423.505(b)(18) to "indicate[] 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. In stark contrast, the Tenth Circuit read *the same regulation* as demonstrating that "CMS has established guidelines about how Part D plan sponsors must construct their networks" and thus sufficiently close to the Any Willing Provider Provision to "preempt it." App.49-50.

3. Like the Tenth Circuit, the First Circuit has adopted a "sweep[ing]" view of Medicare preemption under 42 U.S.C. §1395w-26(b)(3). *Medicaid & Medicare Advantage Prods. Ass'n of P.R., Inc. v. Emanuelli Hernandez*, 58 F.4th 5, 12 (1st Cir. 2023). Unlike the decision below and *Wehbi*, *Emanuelli Hernandez* was a Part C case. *Id.* at 8-10. But, as explained, Part D's preemption provision *is* Part C's preemption provision. And in a decision that the Tenth Circuit echoed below, *see* App.44-45, *Emanuelli Hernandez* rejected as "legally unavailing" the view that preemption under §1395w-26(b)(3) "require[s] the existence of a federal 'standard' that specifically 'addresses the subject of the state regulation.'" 58 F.4th at 13. In other words, it rejected the Eighth Circuit's approach in *Wehbi*.

To be sure, the First Circuit "agree[d] with the Eighth Circuit" that it should not apply "the presumption against preemption in interpreting [§1395w-26(b)(3)]" and that the term "'standards'" in that provision "should be understood simply to mean 'statutory provision[s] or … regulation[s] promulgated under [Medicare] and published in the Code of Federal Regulations.'" *Id.* at 11-12, 13 n.6 (quoting *Wehbi*, 18 F.4th at 971). But that was where the agreement ended. Like the decision below, but in sharp contrast to how *Wehbi* approached the issue, the First Circuit held that "requiring the existence of a standard" on the exact issue a State seeks to regulate "would largely eviscerate the effect of the expansive preemption clause." *Id.* at 14.

* * *

Had this case arisen in the Eighth Circuit, it would have come out the other way. Likewise, had *Wehbi* arisen in the Tenth Circuit (or, in all likelihood, the First Circuit), it would have come out the other way. That split merits this Court's intervention. The Court should grant the second question presented.

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

The rise of PBMs has led to the decimation of local pharmacies, especially in rural areas, to the detriment of countless patients. That is an obvious concern for local citizens and state legislators. Indeed, that concern has prompted legislatures in all 50 States to regulate PBMs in some form. Here, the issues were sufficiently acute that the Oklahoma Legislature addressed the problem through legislation that was not just bipartisan, but unanimous.

Even federal regulators have recognized the threat to cornerstones of local communities. "Few small businesses are as essential to communities as independent pharmacies—especially in rural communities across America." Lina M. Khan, Chair, Fed. Trade Comm'n, *Remarks by Chair Lina M. Khan As Prepared for Delivery for White House Roundtable on PBMs*, at 2 (Mar. 4, 2024), https://shorturl.at/yBQRS. Yet while countless residents "trust[] their local pharmacist for high-quality and personalized care," the walls are closing in; "independent pharmacists … [a]re being squeezed and run out of business" by the "coercive contractual terms and punishing fees imposed by PBMs." *Id.*

PBMs derive part of their market power from contracting with ERISA plans, but their market power (and the resulting devastation of local and rural pharmacies) is hardly a unique product of ERISA or a specific byproduct of ERISA plans. Hence nothing in ERISA meaningfully restricts PBMs or does anything to protect local and rural pharmacies. Indeed, PBMs were not even a glimmer in Congress' eye when it enacted ERISA, *see* CA10.App.132, so that statute does nothing to address the problems created by PBMs' increasingly self-dealing and monopolistic practices. And to the extent Part D regulations address PBMs, they merely recognize the problem without providing a solution even for Part D plans, let alone the rest of the market.

Thus, what the PBMs seek (through PCMA's various lawsuits) is not to have to deal with one, rather than 50, regulators. They seek a vacuum—with no distinct federal oversight and functional

immunity from regulation by States who have the traditional authority over pharmacies and field their citizens' complaints about the shuttering of local institutions. That dynamic explains not just the unanimous vote in the Oklahoma Legislature but why a diverse coalition of 34 States filed an *amicus* brief below urging the court to reject PCMA's position. While the manifestations of the problem may differ in urban and rural areas, PBMs have profoundly distorted the operations of local pharmacies in both. As the *amici* States explained, PBMs "contribute to the crisis of increasing medical costs nationwide," "harm[ing] consumers" who rely on life-saving medicines day in, day out. CA10.States.*Amici*.Br.8. State-level regulation designed to quell the local-level problems PBMs create are a vital part of the cure.

The real-world problems PBMs pose for everyday Americans and the small local businesses that serve them are difficult to overstate. Nothing in ERISA or Part D equips the federal government to address this problem. Thus, the Tenth Circuit's decision paves the way for the continued demise of local pharmacies in the name of federal statutes that do nothing to address the problem. There is no justification for creating that regulatory vacuum, and even less justification for allowing North Dakota and Arkansas to tackle the problem while Oklahoma is sidelined. Congress did not create a one-sized-fits-all solution to this problem in ERISA. And if ERISA's preemption clause really does create a regulatory vacuum, then this Court should make that reality clear so Congress can redress a result that "no sensible person could have intended." *Dillingham*, 519 U.S. at 335-36 (Scalia, J.,

concurring). Either way, the case for this Court's intervention is clear.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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