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

BRIEF OF THE AMERICAN DENTAL ASSOCIATION AND EIGHT HEALTH-CARE PROVIDER ASSOCIATIONS AS *AMICI* CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE¹

Amici curiae are associations that represent The health-care providers. American Association is the nation's largest and oldest dental association and leading advocate for oral health. Established in 1859, it has more than 159,000 members. The American Optometric Association, founded in 1898, is the leading authority on vision care representing more than 48,000 optometrists, optometry students, and other vision professionals. The American Association of Orthodontists was created in 1900 and represents approximately 19,000 orthodontist members who diagnose, prevent, and treat dental and facial irregularities to correctly align teeth and jaws. The American Academy of Pediatric Dentistry, founded in 1947, represents approximately 11,000 pediatric dentists and is the recognized authority on children's oral health. The Association of Dental Support Organizations, established in 1995, represents dental support organizations, which are companies that handle the business and operational aspects of a dental practice so that dentists and dental clinics can focus on patient care. The American Association of Oral and Maxillofacial Surgeons, originally founded as the American Society of Exodontists in 1918, represents more than 9,000 oral

¹ Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part and that no person other than *amici*, their members, or their counsel made any monetary contributions intended to fund the preparation or submission of this brief. All parties have been notified in writing pursuant to Rule 27.2 that the American Dental Association and other *amici* would be filing this brief.

and maxillofacial surgeons in the United States. The additional *amici* are associations that represent health-care providers in various other medical specialties.²

This Court's unanimous decision in *Rutledge v. Pharm. Care Mgmt. Assoc. (PCMA)*, 592 U.S. 80 (2020), brought much need clarity to decades of confusion regarding when § 514(a) of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1144(a), preempts state law. *Rutledge* focused preemption on state laws that "govern a *central* matter of *plan* administration." 592 U.S. at 87 (emphasis added). It also emphasized that "not every state law that affects an ERISA plan or causes some disuniformity in plan administration" triggers preemption. *Id*.

In the decision below, PCMA v. Mulready, 78 F. 4th 1183, 1199 (10th Cir. 2023), the Court of Appeals ignores *Rutledge* and resurrects effectively expansive, benefits-focused test for ERISA preemption that this Court rejected in the 1980s. Left undisturbed, the retrograde decision could create even more confusion than existed pre-Rutledge. It preempts broad categories of generally applicable health-care regulations. It calls into question whether Rutledge even applies to many ERISA preemption disputes. And it raises federalism and constitutional concerns by usurping states' traditional authority to regulate health care and insurance.

² Those *amici curiae* are American Academy of Oral & Maxillofacial Pathology, American Association of Endodontists, Academy of General Dentistry, and American Academy of Periodontology.

Amici curiae have a strong interest in having the scope of ERISA preemption defined clearly and limited appropriately to those subjects that Congress addressed within ERISA. Amici regularly advocate for states to enact and enforce laws that promote the interests of patients and health-care providers, often against abusive practices by insurance companies and other third-party payors. The issues in this case regarding the proper scope of ERISA preemption have implications far beyond state regulation of pharmacy benefit managers (PBMs). They raise a more fundamental question—whether states retain their traditional authority to enact and enforce laws governing health care and insurance. As associations that represent health-care providers, amici have a strong interest in preserving states' authority. Amici advocate in virtually every state for health-care laws that protect patients and providers.

For example, *amici* advocate for laws requiring third-party payors to honor assignments of benefits, including in states within the Tenth Circuit. *See, e.g.*, Colo. Rev. Stat. § 10-16-106.7; N.M. Stat. Ann. § 13-7-42; and Okla. Stat. tit. 36, § 6055(F). Such laws require payors to pay providers directly for health-care services provided to patients. Without this protection, many patients would forgo needed health care because they cannot afford to pay up-front for services.

Amici similarly advocate for laws that require third-party payors to honor prior authorizations. See, e.g., Colo. Rev. Stat. § 10-16-112.5; N.M. Stat. Ann. § 13-7-41(C); Okla. Stat. tit. 36, § 7303(B); Utah Code Ann. § 31A-22-650(2)(c). When payors issue a prior

authorization, providers and patients rely on that promise of payment. These laws prevent payors from later denying payment after the authorized service has been performed. Such laws protect patients from surprise bills they may not have the resources to pay and ensure that providers get paid for their services.

Amici also advocate for laws that prohibit payors from requiring patients to use designated laboratories. See, e.g., Kan. Stat. Ann. § 40-5903(b); 2023 Okla. H.B. 1979 (veto overridden May 30, 2024). Vision plans sometimes require patients to obtain lenses from laboratories owned by the plan's administrator or its affiliate. A study conducted by independent health economists found that such restrictions resulted in longer wait times, fewer options, and lower quality eyeglasses. See Avalon Health Economics https://avalonecon.com/wpcontent/uploads/2022/01/AOA-ADA-Non-Covered-Services-Final-Report.pdf.

As a fourth and final example, *amici* advocate for laws that limit the time for third-party payors to clawback payments to providers for health-care services provided to patients. *See*, *e.g.*, Colo. Rev. Stat. § 10-16-704(4.5); N.M. Stat. Ann. § 59A-23G-10(B). *Amici's* members have faced efforts by payors to reverse payments several years after they provided the relevant health-care service. These laws also protect patients from surprise bills and ensure providers get paid for their services.

Even outside of the Tenth Circuit, the decision below creates confusion that exacerbates hurdles that *amici* already face in advocating for patients and providers. State legislative attorneys have rejected or weakened health-care legislation for fear of ERISA preemption. Third-party payors use preemption to justify ignoring health-care laws. Insurance commissioners and state law enforcement agencies have expressed reluctance to enforce such laws based on a mistaken belief that ERISA preempts the laws from applying to plans.

This Court should grant review to restore clarity to the law regarding ERISA preemption, particularly given the issue's significance to federal-state comity.

SUMMARY OF ARGUMENT

I. Rutledge established a clear two-step approach for determining whether a state law has a "connection with" ERISA plans that triggers preemption. First, courts should ask whether the state law directly regulates "a central matter of plan administration," such as laws that require specific benefits or rules for determining beneficiary status. Id. at 86-87. Second, courts should ask whether a state law produces indirect economic effects that are so "acute" that they "force an ERISA plan to adopt a certain scheme of coverage." Id. At least three parts of the decision below contradict Rutledge, create substantial confusion regarding the scope of ERISA preemption, and therefore warrant review.

A. The decision below creates confusion by conflating regulation of ERISA benefit *plans* with regulation of *benefits*, and thereby expanding ERISA preemption far beyond "central matters of plan administration." *Rutledge*, 592 U.S. at 87. It holds that ERISA preempts every state law that has even a *de minimis* impact on "benefit design." *Mulready*, 78 F. 4th at 1198, 1201-02. Every health-care service can be

described as a "benefit," so every health-care law becomes a target for preemption.

The decision below substantially intrudes into the "the historic police powers of the State" to regulate "matters of health and safety." De Buono v. NYSA-ILA Med. & Clinical Servs. Fund, 520 U.S. 806, 814 (1997). Even basic licensing requirements would trigger preemption by excluding unlicensed individuals from the provider networks that a plan can choose. The Court of Appeals' holding that even a de minimis impact on "benefit design" triggers preemption, Mulready, 78 F.4th at 1203, precludes any limiting principle that could moderate the extreme outcomes that the decision produces.

B. The decision below creates confusion by dismissing this Court's decision in Rutledge as an inapposite "rate regulation case." Mulready, 78 F.4th at 1199-1200. Rather than beginning with Rutledge, the Court of Appeals based its decision on two pre-Rutledge decisions from other Circuits. See Mulready, 78 F.4th at 1197-98. It distinguished this Court's decisions leading up to Rutledge as "cases [that] dealt purely with cost or rate regulation" and that "offer little" of relevance here. Mulready, 78 F.4th at 1201. This categorical distinction allowed it to avoid examining several clear conflicts between the results below and this Court's analysis in Rutledge. Left undisturbed, $_{
m the}$ decision below could create substantial uncertainty regarding whether and how Rutledge and this Court's other recent precedents apply to a substantial portion of ERISA preemption disputes.

C. The decision below creates confusion by expanding ERISA preemption to encompass topics that ERISA does not address. *Mulready*, 78 F.4th at 1201. The Court of Appeals cited *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983) in support. Yet it overlooked this Court's statements in *Rutledge* and three other post-*Shaw* cases indicating that ERISA preemption should be limited to the topics that ERISA addresses. *See, e.g., Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 314, 330-31 (1997).

Expanding ERISA preemption beyond the bounds of ERISA's substance infringes on states' traditional authority and creates regulatory vacuums that impact citizens' health care. The regulation of insurance and health care quality are parts of the historic police powers reserved for the states. If states cannot enforce laws regarding how health care is delivered, no one can. Insurance companies and large employers will dictate how Americans receive health care with no government oversight accountability. or beneficiaries Congress enacted ERISA to protect will be vulnerable to abusive practices unconstrained by government oversight.

This Court should hold that ERISA preemption is limited to "the areas with which ERISA is expressly concerned—'reporting, disclosure, fiduciary responsibility, and the like." Dillingham, 519 U.S. at 330 (quoting N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 661 (1995)). Tying the scope of ERISA's preemption provision to the statute's explicit substantive reach still addresses Congress's and employers' legitimate

concern regarding the burdens of complying with fifty state laws governing *plan* administration. At the same time, it avoids creating regulatory vacuums regarding the delivery of health care and respects the traditional authority of states.

II. In addition to the conflict identified in the Petition, the decision below conflicts with the First Circuit's decision in *PCMA v. Rowe*, 429 F.3d 294 (2005). In *Rowe*, the First Circuit held PBMs are not ERISA fiduciaries, and therefore they cannot "exercise 'discretionary authority or control in the management and administration of the plan." *Id.* at 301 (quoting 29 U.S.C. § 1002(21)(A)). Thus, a state law that imposed certain administrative responsibilities on PBMs did not constitute regulation of plans that could trigger ERISA preemption. *Id.* at 302-03.

In contrast, the decision below held that "regulating PBMs functions as regulation of an ERISA plan" and that even a *de minimis* change to a PBM's "administrative burdens" triggers preemption. *Mulready*, 78 F.4th at 1202-03. As a result, the statute saved from preemption in *Rowe* would be struck down under *Mulready*.

This Court can resolve this conflict by ruling that the scope of ERISA's preemption provision is limited to those matters that the statute addresses. ERISA says nothing about the composition of provider networks. See Mulready, 78 F.4th at 1201. Such a ruling would affirm the analysis in Rowe and correct the overly broad application of ERISA preemption in the decision below.

ARGUMENT

I. The Decision Below Creates Confusion by Expanding ERISA Preemption Far Beyond the Bounds Set by This Court.

This Court should review the decision below to protect and restore the much-needed clarity this Court brought to ERISA preemption in *Rutledge*. Defining the proper scope of ERISA preemption has challenged even this Court, in large part because of the "unhelpful text" in 29 U.S.C. § 1144(a) and "the frustrating difficulty of defining its key term"—"relates to." *Travelers*, 514 U.S. at 656. This Court even characterized its own pre-*Travelers* decisions as unhelpful. *Id*. at 655.

Rutledge should have ended that confusion. It identified "ERISA's objectives 'as a guide to the scope of the state law that Congress understood would survive'." Rultedge, 592 U.S. at 86 (quoting Dillingham, 519 U.S. at 325). It then articulated a clear two-part test for determining whether a state law has an impermissible "connection with" an ERISA plan. First, state laws that interfere with "a central matter of plan administration" trigger preemption. Id. at 87 (emphasis added). It gave examples, such as laws "requiring payment of specific benefits" and imposing "specific rules for determining beneficiary status." Id.3 Second. state laws indirectly affecting

³ In *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 323 (2016), this Court added that "reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration."

administration can trigger ERISA preemption, but only if they meet a rigorous standard: "acute, albeit indirect, economic effects of the state law force an ERISA plan to adopt a certain scheme of substantive coverage." *Id.* (quoting *Gobielle*, 577 U.S. at 320).

This Court also made clear that state laws can affect an ERISA plan without triggering ERISA preemption:

Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law merely affects costs.

Id. (citing *Travelers*, 514 U.S. at 659-660). It also reiterated that a state law does not trigger preemption merely because it "might 'affect a plan's shopping decisions." *Id.*

This Court illustrated how these principles apply in upholding Arkansas' Act 900. It upheld the requirement that a PBM reimburse a pharmacy at least the wholesale price for a drug, holding that state laws "that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of coverage" do not trigger preemption. Id. at 88 (citing Travelers, 514 U.S. at 668). It also upheld Act 900's enforcement mechanism requiring PBMs to establish an appeal mechanism for pharmacies to challenge whether a reimbursement rate is below wholesale price, holding that the requirement at most created "operational inefficiencies" for PBMs that "merely increases costs" for ERISA plans. Id. at 91. The Court expressly noted that a contrary result "would pre-empt any suits

under state law that could affect the price or provision of benefits." *Id.* at 90.

The decision below threatens to undermine the clarity that this Court brought to this long-muddled area of law in *Rutledge*. Three aspects of the decision below conflict with *Rutledge* and this Court's other post-*Travelers* decisions. The fundamental issue at stake—whether states retain their traditional authority to enact and enforce laws in the areas of health care and insurance—warrants review.

A. The Decision Below Creates Confusion by Conflating Regulation of Benefits with Regulation of ERISA Plans.

The Court of Appeals' principal error was conflating state laws that regulate benefits—i.e., how healthcare is provided and paid for—with state laws that regulate benefit plan administration. See Mulready, 78 F.4th at 1198. It held that any state law that restricts how a plan provides benefits triggers ERISA preemption because it "forbids an element of ... benefit design." Id. It reasoned that "forbidding something is itself a requirement that the PBM do the opposite of what is forbidden." Id. at n.11. It then exacerbated its error by holding that even de minimis interference with how a plan can choose to deliver benefits, such as "eliminating the choice of one method of structuring benefits," triggers preemption. Id. at 1198, 1202-1203.

The Court of Appeals' benefit-focused test preempts even the most basic state health-care regulation. Every license requirement "eliminat[es] the choice of one method of structuring benefits" by excluding unlicensed individuals from provider networks. See id. Every standard of care limits the ability of "plans, which want to save money," to provide sub-standard "benefits." Id. at 1199. Expanding ERISA preemption beyond plan administration to include any regulation of benefits makes every state health-care regulation a target for preemption.

At base, the Court of Appeals resurrected an expansive version of ERISA preemption focused on benefits that this Court rejected in Fort Halifax Packing Co. v. Coyne, 482 U.S. 1, 18 (1987). "The argument that ERISA pre-empts state laws relating to certain employee benefits, rather than to employee benefit *plans*, is refuted by the express language of the statute, the purposes of the preemption provision, and the regulatory focus of ERISA as a whole." Id. (emphasis in original). This Court noted that "ERISA's pre-emption provision" "does not refer to state laws relating to 'employee benefits,' but to state laws relating to 'employee benefit plans." Id. at 7 (emphasis original). If preemption applied "expansively" to invalidate state laws that regulate how benefits are provided, "the word 'plan' [would] in effect be read out of the statute." Id. at 8. Such a reading would far exceed Congress's goal of affording "employers the advantages of a uniform set of administrative procedures." *Id.* at 12.

This Court has continued to reject benefit-focused interpretations of ERISA preemption. In *Travelers*, this Court refused "to read the pre-emption provision as displacing all state laws affecting costs and charges on the theory that they indirectly relate to ERISA plans that purchase insurance policies or HMO

memberships that would cover such services" because it "would effectively read the limiting language in § 514(a) out of the statute" and "displace general healthcare regulation." *Id.* at 1679-80. In *Dillingham*, this Court held that "if ERISA were concerned with any state action—such as medical care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's preemptive reach, and the words 'relate to' would limit nothing." 519 U.S. at 329 (emphasis added). In Rutledge, this Court rejected a similarly overbroad interpretation that "would pre-empt any suits under state law that could affect the price or provision of benefits." 592 U.S. at 90 (emphasis added).

This Court should grant review to clarify that state regulation of how health care is delivered is not direct regulation of plan administration. See Travelers, 514 U.S. at 660-661 (rejecting argument that "general health care regulation" and "quality control" constitute direct regulation of ERISA plans). Laws that merely regulate how health care is provided should be evaluated "for their indirect economic effects" on plans. 592 U.S. at 87. Such laws trigger preemption only if those effects are "acute" and "force an ERISA plan to adopt a certain scheme of substantive coverage." Id. (quoting, 577 U.S. at 320); see also Travelers, 514 U.S. at 664 (characterizing the standard as leaving plans with a "Hobson's choice").

B. The Decision Below Creates Confusion by Distinguishing *Rutledge* as an Inapposite Rate Regulation Case.

The Court of Appeals also erred by effectively ignoring *Rutledge*. Instead of applying *Rutledge* as the foundation of its analysis, it relied on two pre-*Rutledge* cases from other Courts of Appeals. See Mulready, 78 F.4th at 1197-98 (basing decision on CIGNA Healthplan of La., Inc. v. La. ex rel. Ieyoub, 82 F.3d 642 (5th Cir. 1996); and Ky. Ass'n of Health Plans v. Nichols, 227 F.3d 352 (6th Cir. 2000)). The Court of Appeals below addressed Rutledge in substance only after discussing how it reached its decision, and only then to explain why "Rutledge does not change our conclusion." Mulready, 78 F.4th at 1199-1200.

Specifically, the Court of Appeals dismissed *Rutledge* as a "rate-regulation" case. *See id.* at 1200. It explained that "[u]nlike Arkansas's reimbursement-rate regulations, Oklahoma's network restrictions do more than increase costs." *Mulready*, 78 F.4th at 1200. "They home in on PBM pharmacy networks ... [a]nd they impede PBMs from offering plans some of the most fundamental network designs." *Id.*

The Court of Appeals similarly eschewed this Court's decisions in *Travelers*, *Dillingham*, and *De Buono*. It held that "all three cases dealt purely with cost or rate regulations, not regulations pertaining to employee benefits or benefit design." *Mulready*, 78 F.4th at 1201. As a result, *Mulready* calls into question whether the clarifications this Court has provided in *Rutledge* and its progenitors even apply to a substantial portion of ERISA preemption cases.

The Court of Appeals' disregard for Rutledge and this Court's other more recent ERISA preemption cases allowed it to avoid reconciling its decision with those cases. For example, it held that ERISA preempts Oklahoma's "Discount Prohibition"—which "requires that cost-sharing and copayments be the same for all network pharmacies." Mulready, 78 F.4th at 1198. Yet it never explains why a statute that prohibits rate discrimination is any less a "rate regulation" than a statute that requires rate discrimination, like the statute at issue in Travelers, 514 U.S. at 660-661. Indeed, applying the Tenth Circuit's own reasoning that "forbidding something is itself a requirement that the PBM do the opposite of what is forbidden," Mulready, 78 F.4th at 1198 n.11, it should have found the two provisions to be alike for purposes of preemption.

Similarly, when the Court of Appeals analyzed the effects of the Oklahoma statute's pharmacy density requirements on ERISA plans (as opposed to the effect on PBMs), it articulated the impact in terms of cost, stating that "adding pharmacies costs plans money." Mulready, 78 F.4th at 1199. When it addressed how the Oklahoma statute limited how PBMs can restrict access to preferred networks and restrict authorization for pharmacies to dispense specialty drugs, it held: "This rule hurts the cooperative relationship between plans, which want to save money, and preferred pharmacies, which want the increased business that preferred status affords." Id. (emphasis added). The Court of Appeals never wrestled with how those cost-based effects on plans should be treated given this Court's holding that "not every state law that affects an ERISA plan ... has an

impermissible connection That is especially so if a law merely affects costs." *Rutledge*, 592 U.S. at 87; *see also Dillingham Constr.*, 519 U.S. at 333 (holding that economic effects do not trigger preemption unless they are "tantamount to compulsion").

Finally, the Court of Appeals below never reconciled its conclusion that any *de minimis* effect on the provision of benefits triggers preemption with this Court's ruling in *Rutledge*, 592 U.S. at 90-91, upholding Act 900's enforcement mechanism. That mechanism did more than just indirectly impose costs. It required PBMs to create a new administrative process. Under the flawed analysis in *Mulready*, there are no distinctions between PBMs and plans, and any administrative burden beyond pure cost, however *de minimis*, triggers preemption. *See* 78 F.4th at 1203 ("[f]inding no footing for a *de minimis* test for plan administration"). Yet the Court of Appeals never addressed this patent conflict.

These examples illustrate how the decision below can cause confusion regarding whether and how *Rutledge* applies in ERISA preemption cases. Review is warranted to eliminate that confusion, particularly given the important issues of federal-state comity at stake.

C. The Decision Below Creates Confusion by Applying ERISA Preemption to Subjects that ERISA Does Not Address.

The Court of Appeals also contributed to confusion by holding that ERISA preempted the "network restrictions" in Oklahoma's statute even though ERISA does not address provider networks. See Mulready, 78 F.4th at 1201. In support, it cited

Shaw for the proposition that "ERISA preemption is more comprehensive than targeting 'only state laws dealing with the subject matters covered by ERISA—reporting, disclosure, fiduciary responsibility, and the like." *Id.* (quoting *Shaw*, 463 U.S. at 98).

The Court of Appeals misplaced reliance on this language from *Shaw* (a decision this Court called "unhelpful" in *Travelers*, 514 U.S. at 655), because it overlooked this Court's more recent precedents. This Court has indicated in *Rutledge* and three other post-*Shaw* cases that ERISA preemption should be limited to those topics within the statute's substantive scope. Specifically, this Court should expressly confirm that when *Rutledge* held that ERISA preemption is focused on "central matters of plan administration," it was referring to those subject matters that ERISA explicitly addresses. *See* 592 U.S. at 87.

Four years after *Shaw*, this Court held in *Fort* Halifax, 482 U.S. at 19, that "[i]f a State creates no prospect of conflict with a federal statute, there is no warrant for disabling it from attempting to address uniquely local social and economic problems." In Travelers, 514 U.S. at 661, this Court addressed the same language from *Shaw* and held that "nothing in the language of the Act or the context of its passage indicates that Congress chose to displace general health care regulation." Two years later, this Court held in *Dillingham* that "[a] reading of § 514(a) resulting in the pre-emption of traditionally stateregulated substantive law in those areas where ERISA has nothing to say would be 'unsettling." 519 U.S. at 330-31 (citing *Travelers*, 514 U.S. at 665). Finally, this Court in *Rutledge* supported its holding that ERISA did not preempt Arkansas's Act 900 by noting that "PCMA does not suggest that Act 900's enforcement mechanisms overlap with 'fundamental components of ERISA's regulation of plan administration." 592 U.S. at 90 n.2 (quoting *Gobeille*, 577 U.S. at 323).

This case presents an opportunity for this Court to clearly hold what it strongly implied in *Rutledge*, *Fort Halifax*, *Travelers*, *Dillingham*—ERISA's preemptive scope should be limited to the activities that ERISA regulates. Those activities include "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *Fort Halifax*, 482 U.S. at 9.

Paring ERISA's preemption with its substantive scope gives operational effect to this Court's holding in *Rutledge* focusing preemption on "central matter[s] of plan administration." 592 U.S. at 87 (emphasis added). It shows due regard in our system of federalism for "the historic police powers of the State," which "include the regulation of matters of health and safety." De Buono, 520 U.S. at 814. It also adequately addresses Congress's and employers' legitimate concerns about the burdens associated with a state law that "interferes with nationally uniform plan administration." Rutledge, 592 U.S. at 87. Laws "requiring payment of specific benefits" and "binding plan administrators to specific rules for determining beneficiary status" would still be preempted. Id.

Such a limitation also tracks this Court's analysis in *Gobeille* holding that ERISA preempts state laws that either duplicate or deviate from ERISA's reporting requirements because "reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA." See 577 U.S. (documenting ERISA's "extensive" disclosure, "reporting, and recordkeeping requirements" in 29 U.S.C. §§ 1021(a)(1), 1021(b), 1022, 1023(b)(1), 1023(b)(3), 1024(a), 1024(b)(1), 1024(b)(3), 1026(a), 1027, 1133(1), 1135, 1143(a)(1), and 1143(a)(3)). At the same time, it alleviates constitutional concerns about "pre-empting 'substantial areas of traditional state power." Id. at 329 (Thomas, J., concurring). It also "honor[s] Congress' evident call for an expansive preemption principle without invalidating state regulations falling outside ERISA's domain." Id. at 337 (Ginsberg, J., dissenting) (emphasis added).

In contrast, expanding ERISA preemption to topics that ERISA does not address creates a regulatory vacuum regarding important issues of health and safety. If states cannot enforce laws regarding *how* health care is provided and paid for, no one can. These issues are reserved for the states as part of their historic police powers. *De Buono*, 520 U.S. at 814.

This Court in *Rutledge*, 592 U.S. at 86, instructed that "the scope of the state law that Congress understood would survive" should be a guide to determining the scope of ERISA preemption. Congress enacted ERISA to "protect ... the interests of participants in employee benefit plans and their beneficiaries' by setting out substantive regulatory

requirements for employee benefit plans and to 'provid[e] for appropriate remedies, sanctions, and ready access to the Federal courts." *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 208 (2004) (quoting 29 U.S.C. § 1001(b)).

The regulatory vacuum created by the decision below on vital issues regarding how health care is delivered—issues on which ERISA itself has nothing to say—would render those beneficiaries vulnerable to abusive practices. Insurance companies and large employers would dictate what health care citizens government receive with no oversight accountability. There is no evidence that Congress understood that it was usurping traditional state power to regulate health care, much less creating an untouchable regulatory vacuum in such an important area of the law. As this Court held in Travelers, "nothing in the language of the Act or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." 514 U.S. at 661.

II. The Decision Below Also Conflicts with a Decision by the First Circuit Regarding Whether State Regulation of PBMs Should Be Treated as Regulation of ERISA Plans.

As the Petition highlights and the Court of Appeals acknowledged, the decision below conflicts with the Eighth Circuit's decision in *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021). See Pet. at 22-24; *Mulready*, 78 F.4th at 1202-03. The decision below, by "overlooking" a "PBM-plan distinction," also conflicts with the First Circuit's decision in *PCMA v. Rowe*, 429 F.3d 294 (2005).

In *Rowe*, the First Circuit held that PBMs are not ERISA fiduciaries because they "do not exercise 'discretionary authority or control in the management and administration of a plan." *Id.* at 301 (quoting 29 U.S.C. § 1002(21)(A)). The Maine statute at issue in that case "plac[ed] fiduciary duties and administrative burdens on PBMs," such as requiring PBMs to "divulge[e] the terms of contracts with pharmaceutical manufacturers." *Id.* at 303. The First Circuit rejected PCMA's argument in that case that the Maine statute "attempts to regulate plans' relationships with PBMs when PBMs perform administrative functions for such plans." *Id.*

The decision below conflicts with *Rowe*. *Mulready* holds that "regulating PBMs 'function[s] as a regulation of an ERISA plan itself" and that any restriction on plan administration, however *de minimis*, triggers ERISA preemption. 78 F.4th at 1201-03. As a result, the Maine statute upheld in *Rowe* would be preempted by ERISA under *Mulready*.

This Court should take the opportunity to clarify whether and to what extent state regulation of PBMs functions as regulation of ERISA plans. Whether PBMs should be treated as plans bears directly on the scope of activities that ERISA preemption covers. Specifically, this Court should clarify that because PBMs are not ERISA fiduciaries and thus cannot exercise discretion regarding central matters of plan administration, regulation of PBMs (including regulation of how they create provider networks), does not automatically trigger ERISA preemption.

The First Circuit correctly found that PBMs are not ERISA fiduciaries. Courts have near-universally held that PBMs are not ERISA fiduciaries when they manage a plan's prescription drug benefit. See, e.g., Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc., 474 F.3d 463, 473 (7th Cir. 2007); Rowe, 429 F.3d at 300; Doe 1 v. Express Scripts, Inc., 837 F. App'x 44, 49 (2d Cir. 2020); In re United Health Grp. PBM Litig., No. 16-cv-3352, 2017 WL 6512222, at *9-10 (D. Minn. Dec. 19, 2017); Moeckel v. Caremark, Inc., 622 F. Supp. 2d 663, 677 (M.D. Tenn. 2007). PCMA has taken the position that PBMs are not ERISA fiduciaries to plans. Rowe, 429 F.3d at 300 n.3. As a result, a PBM cannot exercise any discretion regarding any central matter of plan administration. 29 U.S.C. § 1002(21)(A).

PBMs undeniably exercise discretion when they construct provider networks by deciding who is in, who is out, and on what terms. However, a service provider to an ERISA plan does not become a fiduciary "merely because it administers orexercises discretionary authority over its own ... business." Pegram v. Herdrich, 530 U.S. 211, 223 (2000). PBMs have invoked this doctrine successfully to argue that they merely pre-package options, and that an ERISA plan exercises all relevant discretion when it selects from those options in an arms-length transaction with the PBM. See, e.g., Moeckel, 622 F. Supp. 2d at 677; Am. Drug Stores, Inc. v. Harvard Pilgrim Health Care, Inc., 973 F. Supp. 60, 68 (D. Mass. 1997).

PBMs should not be able to have it both ways. Their creation of provider networks cannot be a "central matter of plan administration" for ERISA preemption without triggering ERISA's fiduciary obligations and the associated liabilities. See 29 U.S.C.

§§ 1109(a), 1132(a)(2). A ruling by this Court that ERISA preemption has the same scope as its substantive provisions will resolve this issue. As the Court of Appeals noted, ERISA does not contain provisions regarding the composition of provider networks. *Mulready*, 78 F.4th at 1201. Under such a ruling, network restrictions do not interfere with "central matters of plan administration." *Rutledge*, 592 U.S. at 87. Rather, such state laws merely "affect a plan's shopping decisions," while leaving the plan free to "shop for the best deal it can get." *Id*.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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