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Honorable Rob Nosse
Chair, House Interim Committee
on Behavioral Health and Health Care
Oregon State Legislature
900 Court Street NE, H-472
Salem, Oregon 97301
Rep.RobNosse@oregonlegislature.gov

**Re: Legislation Regulating Pharmacy Benefit Managers**

Dear Representative Nosse:

I represent the Oregon State Pharmacy Association (OSPA). Founded in 1889, OSPA is a professional trade association representing pharmacists, pharmacy technicians, pharmacy students, and others who have an interest in advancing the practice of pharmacy through advocacy and education, and thereby improving the health of their fellow Oregonians.

OSPA has retained my services to provide guidance as the Oregon State Legislature considers legislation that regulates pharmacy benefit managers (PBMs). As I understand it, individuals and organizations aligned with the interests of PBMs have argued that the Employee Retirement Income Security Act of 1974 (ERISA) would preempt legislation that OSPA has supported to regulate PBMs. My letter is intended to dispel those claims, which are not founded on any legitimate understanding of ERISA.

I have substantial experience in this space. For more than ten years, I have worked on issues related to the regulation of PBMs. I have authored *amici curiae* briefs in three federal cases challenging State laws that regulate PBMs, including in *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. 80 (2020). And I served as a Special Assistant Attorney General to the State of North Dakota in successfully defending most of the provisions of two State laws from claims of preemption under ERISA and Medicare Part D in *Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956 (8th Cir. 2021).

As you will likely recall, OSPA has supported State legislation with two key features. The first would regulate the anticompetitive practices of some PBMs that strongarm pharmacies into accepting reimbursements for less than the pharmacies' cost to dispense medications. Under OSPA's proposal, PBMs must reimburse pharmacies no less than the average acquisition cost for a particular drug, and they must provide the pharmacy with a fee to cover the cost of dispensing the medication. The second provision would require PBMs to admit into their preferred pharmacy

networks any pharmacy willing to accept the standard terms and conditions for admission into such networks. Neither provision raises any concerns under ERISA.

**1. ERISA Does Not Preempt State Laws Regulating the Amount that PBMs Reimburse Pharmacies for Prescription Drugs.**

In *Rutledge*, the Supreme Court held that ERISA does not preempt an Arkansas law that "requires PBMs to reimburse pharmacies for prescription drugs" at an amount dictated by the State. 592 U.S. at 88. The Court noted that, because of this law, PBMs may pay more for drugs than they would otherwise, and they might pass this cost on to plans, "meaning that ERISA plans may pay more for prescription-drug benefits." *Id.* "But," the Supreme Court continued, "'cost uniformity was almost certainly not an object of pre-emption'" under ERISA. *Id.* (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 662 (1995)).

The legislation contemplated by OSPA fits squarely within this holding. Oregon can dictate the amount that PBMs reimburse pharmacies for the ingredient costs associated with medications, and it can dictate a minimum dispensing fee without running afoul of ERISA. Both provisions may well bear on the costs that ERISA plans ultimately pay for prescription drugs. But neither is an object of ERISA preemption. Indeed, the Arkansas law at issue in *Rutledge* operated in similar fashion. It essentially mandated that PBMs reimburse pharmacies at no less than their costs to acquire medication. *See id.* OSPA's proposal is no different.

**2. ERISA Does Not Preempt State Any-Willing-Pharmacy Laws.**

The Supreme Court also has held that ERISA does not preempt State any-willing-provider laws—though the reasoning to get there is slightly more complex. Regardless, it is clear Oregon has the authority to enact an any-willing-pharmacy provision and apply it to PBMs that happen to serve ERISA plans.

As the Supreme Court explained in *Rutledge*, ERISA is "primarily concerned with preempting laws that require [ERISA-plan sponsors] to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status." *Id.* at 87 (citations omitted). Thus, "[a]s a shorthand for these considerations," the Supreme Court has asked "whether a state law 'governs a central matter of plan administration or interferes with nationally uniform plan administration.'" *Id.* (quoting *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 320 (2016)).

A State law requiring PBMs to admit any willing pharmacy into their preferred pharmacy networks does not require ERISA plans to provide any specific benefits or bind plan administrators to any specific rules governing plan administration. Rather, such a law merely regulates the goods and services that PBMs can sell to ERISA and non-ERISA plans.

To understand why such a State law is not preempted, it is necessary to understand how PBMs operate. PBMs are not ERISA plans, and they are not ERISA plan administrators, either. PBMs are third-party service providers that sell ERISA and non-ERISA plans access to a network of pharmacies that the PBMs have created for dispensing medications to beneficiaries.

Because of their unique status, PBMs are not subject to any direct regulation under ERISA. To be sure, ERISA imposes duties on fiduciaries to ERISA plans. But PBMs are not fiduciaries under ERISA. A "fiduciary" exercises "discretionary authority," "control," or "responsibility" over the management or administration of a plan or its assets. 29 U.S.C. § 1002(21)(A). PBMs have absolved themselves of these responsibilities because they are incompatible with their business model. Whereas a fiduciary must act in the best interests of the plan, a PBM profits off the services it sells to ERISA and non-ERISA plans. Nor can a PBM serve as a plan "administrator" under ERISA. Such an "administrator" is a specifically designated fiduciary under ERISA, 29 U.S.C. § 1002(16)(A)—which comes with all the baggage of fiduciaries that PBMs have sought to avoid. For these reasons, the Pharmaceutical Care Management Association (PCMA), the largest trade association representing PBMs, has conceded repeatedly that PBMs are not fiduciaries under ERISA, and PBMs are therefore not plan administrators, either.

Critically, ERISA does not preempt State laws that regulate the goods and services that third parties happen to sell to ERISA plans. And that makes sense. Otherwise, ERISA would preempt State health and safety standards. To save costs, for example, an ERISA plan might wish to utilize the services of unlicensed healthcare professionals. Yet nothing in ERISA empowers benefit plans to override State laws regulating "medical-care quality standards," *Cal. Div. of Labor Stds. Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 329 (1997), and "general health care regulation," *Travelers*, 514 U.S. at 661. A law regulating the composition of a PBM's pharmacy networks is no different.

For these reasons, the Supreme Court rejected challenges to provisions of the Arkansas law at issue in *Rutledge* that dictate the "process" and "substantive

standard" that PBMs apply in adjudicating appeals by pharmacies, compel PBMs to reverse and rebill claims, and authorize pharmacies to decline to dispense drugs to beneficiaries if a PBM is going to reimburse the pharmacy less than the pharmacy's cost to acquire the drug. 592 U.S. at 90-91. Notably, PCMA argued the decline-to-dispense provision "effectively denies plan beneficiaries their benefits." *Id.* at 91. But the Supreme Court held the law did not regulate "plan design" in any impermissible way, emphasizing that "state-law mechanisms" govern the relationship between PBMs and pharmacies. *Id.* at 90-91.

The any-willing-pharmacy provision proposed by OSPA is not meaningfully different from the Arkansas law at issue in *Rutledge*. True, OSPA's proposal, like Arkansas's law, would limit the services "a plan might prefer that PBMs" are permitted to offer. *Id.* at 90. But by regulating the pharmacy networks that *PBMs sell* to plans, OSPA's proposal, like Arkansas's law, would "not require *plans* to provide any particular benefit to any particular beneficiary in any particular way." *Id.* Or as the federal government explained the point in its brief in *Rutledge*, a law like OSPA's "regulates PBM administration, not ERISA plan administration." U.S. *Amicus* Br. 15, *Rutledge v. PCMA*, No. 18-540 (U.S. Dec. 4, 2019), *available at* 2019 WL 6609430.

Moreover, even if OSPA's any-willing-pharmacy proposal could be said to raise concerns under ERISA, that provision would be saved from preemption under ERISA's insurance savings clause. That clause provides that ERISA does not preempt a "State law which regulates insurance." 29 U.S.C. §1144(b)(2).

Notably, in *Kentucky Association of Health Plans v. Miller*, the Supreme Court considered whether ERISA preempted a State any-willing-provider law. 538 U.S. 329 (2003). In the end, the Court did not need to resolve whether ERISA preempted such a law because it held that, even if preempted, such a law was saved from preemption under ERISA's insurance savings clause. *Id.* at 334-39.

*Miller* adopted a two-part test for determining whether a State law falls within the savings clause: "First, the state law must be specifically directed toward entities engaged in insurance,'" and second, "the law must substantially affect the risk pooling arrangement between the insurer and the insured." *Id.* at 342. OSPA's proposed any-willing-pharmacy provision would satisfy both elements.

The first *Miller* factor is satisfied: OSPA's proposal would amount to a law directed at insurance. It makes no difference that the proposal is directed at PBMs, and that PBMs provide services to both insuring and non-insuring entities. In *Miller*,

the Supreme Court held that Kentucky's any-willing-provided law was saved from preemption even though it "appl[ied] to . . . HMOs that do not act as insurers but instead provide only administrative services to self-insured plans," because "administering self-insured plans . . . suffices to bring them within the activity of insurance." *Id.* at 336 n.1. The same outcome would be compelled here. OSPA's proposal would regulate PBMs providing services on behalf of entities engaged in the activity of insurance, including "an insurer," "entities that accept risk," and "an employer who is self-insured." H.B. 3013, § 1, 82d Ore. Leg. Assembly, 2023 Reg. Sess. (C-Engrossed). As the Supreme Court recognized, such organizations "engage in the same sort of risk pooling arrangements as separate entities that provide benefits to an employee benefit plan." *Miller*, 538 U.S. at 336 n.1.

The second *Miller* factor is also satisfied. Indeed, *Miller* involved an any-willing-provider provision similar to OSPA's proposal. And yet, after assuming but not deciding that such a provision was preempted by ERISA, the Supreme Court held that an any-willing-provider law satisfied the second factor of the savings clause: "By expanding the number of providers from whom an insured may receive health services, [the State] laws alter the scope of the permissible bargains between insurers and the insured" and, as a result, substantially affect "the type of risk pooling arrangements that insurers may offer." *Id.* at 338-39.

The upshot is that, even if a court were to hold that ERISA preempts OSPA's proposed any-willing-pharmacy provision, that provision would fall within ERISA's savings clause. Thus, Oregon could continue to apply the provision to third-party PBMs. At the same time, under the "deemer" clause, the State could not apply any such provision directly to any self-insured ERISA plan. *See* 29 U.S.C. § 1144(b)(2)(B). But the deemer clause is limited to plans subject to regulation under ERISA. *See id.* As the federal government has explained, because third-party PBMs are not subject to such regulation, they cannot avail themselves of the deemer clause. *See* U.S. *Amicus* Br. 20-22, *PCMA v. Mulready*, No. 22-6074 (10th Cir. Apr. 10, 2023).

To be sure, the U.S. Court of Appeals for the Tenth Circuit took a different approach in *PCMA v. Mulready*, 78 F.4th 1183 (10th Cir. 2023). It held that an Oklahoma law that included an any-willing-pharmacy provision was preempted by ERISA. *Id.* at 1196-99. But there is no reason to believe that the Ninth Circuit (the federal court of appeals that covers Oregon) would follow *Mulready*'s logic. For one thing, the Tenth Circuit held that Oklahoma's law was not limited to PBMs, but rather also applied to ERISA plans. *See id.* at 1194-96. OSPA's proposal does not operate in similar fashion. For another thing, the Tenth Circuit read *Rutledge* as

limited to only to cost regulations. *Id.* at 1199-12000. But as noted above, *Rutledge* also involved a provision that authorized pharmacies to decline to dispense, which effectively regulated PBM-pharmacy networks. And yet, the Supreme Court held that ERISA did not preempt this provision. Finally, the Tenth Circuit did not consider the application of the insurance savings clause, because it deemed Oklahoma to have waived that argument, *id.* at 1204-05—a mistake that Oregon would not repeat.

For some of these reasons, the Eighth Circuit took a different approach in *Wehbi*. There, the Eighth Circuit rejected PCMA's challenge to a North Dakota law that regulates the accreditation requirements that PBMs impose on pharmacies as a condition for participating in a PBM's pharmacy network. 18 F.4th at 968. In that case, PCMA argued the law impermissibly regulated "benefit design" by limiting the range of choices that plans can make in their interactions with PBMs and pharmacies. PCMA Replacement Br. 22-27, 31, *PCMA v. Wehbi*, No. 18-2926 (8th Cir. May 11, 2021), *available at* 2021 WL 2022000. But the Eighth Circuit held that ERISA does not preempt these PBM-network provisions, emphasizing that they "do not require[e] payment of specific benefits' or 'bind[ ] plan administrators to specific rules for determining beneficiary status.'" *Wehbi*, 18 F.4th at 968 (quoting *Rutledge*, 141 S. Ct. at 480).

Not surprisingly, the Tenth Circuit's approach in *Mulready* has been widely criticized. Oklahoma has petitioned the Supreme Court to review that decision. Pet. for Writ of Certiorari, *Mulready v. PCMA*, No. 23-1213 (U.S. May 10, 2024). And thirty-one other States (including Oregon) and the District of Columbia submitted an *amici curiae* brief pointing out the flaws in the Tenth Circuit's approach. Br. of Minn., *et al.*, as *Amici Curiae*, *Mulready v. PCMA*, No. 23-1213 (U.S. June 10, 2024).

Thus, nothing in *Mulready* should serve as an impediment to Oregon enacting robust PBM regulations. *Mulready*'s logic is flawed. It is not binding within the Ninth Circuit. And it did not consider the full range of arguments that can be used to defend laws like the one proposed by OSPA.

Respectfully submitted,

Robert T. Smith