Testimony of Robert T. Smith,
Partner, Katten Muchin Rosenman LLP, and
Former Special Assistant Attorney General of North Dakota,

Before the Committee on Industry, Business and Labor,
North Dakota House of Representatives:

The State's Authority to Regulate Pharmacy Benefit Managers in the Wake of *Rutledge* and *Wehbi*

February 11, 2025

Chairman Warrey, thank you for providing me with an opportunity to testify before the House Committee on Industry, Business and Labor about the State's authority to regulate pharmacy benefit managers following the U.S. Supreme Court's decision in *Rutledge v. PCMA*, 592 U.S. 80 (2020), and the U.S. Court of Appeals for the Eighth Circuit's more recent decision in *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021). As you know, *Rutledge* and *Wehbi* held that States may regulate PBMs even when those PBMs are serving plans subject to regulation by the federal Employee Retirement Income Security Act of 1974 (ERISA).

I am a partner at Katten Muchin Rosenman LLP in Washington, D.C., and a former special assistant attorney general for North Dakota, but I am appearing here solely in my individual capacity. Nothing I say here should be attributed to Katten or the Attorney General's Office. I also want to be clear that no one is compensating me for my time testifying here today. Nor did anyone compensate me for my time preparing to testify. I am here today at the invitation of the Chairman.

I have been involved in every major challenge to State PBM legislation for over a decade, including PCMA's challenges in *Gerhart* (852 F.3d 722 (8th Cir. 2017)),

Rutledge, *Wehbi*, and *Mulready* (78 F.4th 1183 (10th Cir. 2023), *pet. for cert. filed*, No. 23-1213 (U.S. filed May 15, 2024)). In some of those cases, I authored briefs on behalf of *amici curiae* defending the States' authority to regulate PBMs from challenges under ERISA and Medicare Part D. And in *Wehbi*, I led this State's successful defense of two North Dakota laws that regulate PBMs from challenges under ERISA. In that capacity, I twice argued in the Eighth Circuit, served as the principal author of the State's briefing at all levels of the federal judiciary, and successfully petitioned the Supreme Court to intervene when the Eighth Circuit reached the wrong result on the first go-round, and then helped the Eighth Circuit reach the right result on remand.

The results of these efforts—by many dedicated men and women in State AG offices across the country—is clear: The States possess robust authority to regulate PBMs even when those PBMs are serving plans subject to regulation under ERISA. You don't have to just take my word for it. The Supreme Court established as much in *Rutledge*, the Eighth Circuit extended those principles in *Wehbi*, and Texas Attorney General Ken Paxton recognized as much in a recent opinion letter about Texas's own efforts to rein in PBM abuses. *See* Tex. Att'y Gen. Op. No. KP-0480 (Feb. 5, 2025), https://www.texasattorneygeneral.gov/sites/default/files/opinionfiles/opinion/2025/kp-0480.pdf.

As I understand it, the Committee is currently contemplating legislation that would shift enforcement authority to the Commissioner of Insurance and make certain technical amendments to the definitions for a "covered entity" and a "pharmacy benefits manager."

I've divided my testimony into four parts: First, I will provide a brief overview of PBMs and State efforts to regulate those entities. Second, I discuss ERISA and the State's authority to regulate PBMs even when those PBMs are serving ERISA plans. Third, I will note how other States are handling enforcement authority and why it makes sense to charge the Insurance Commissioner and the Attorney General with authority to regulate PBMs. Finally, I explain why the Legislative Assembly should make certain technical amendments to the definitions for "covered entity" and "pharmacy benefits manager" contained in the North Dakota Century Code.

1. State Enforcement of PBM Laws

PBMs are powerful intermediaries who sit between patients and health plans. PBMs enter contracts with benefit plans and insurers to provide beneficiaries with access to prescription drugs. PBMs deliver this access by contracting separately with pharmacies to create networks where beneficiaries can fill their prescriptions. To be clear, PBMs are *not* health benefit plans. Rather, PBMs *sell* health benefit plans access to the pharmacy networks that PBMs create.

For many years, PBMs operated with impunity across the country, shielded by the false claim that any attempt by State governments to regulate their actions would yield to preemption by ERISA. PBMs originally were created to facilitate coverage determinations and quickly adjudicate prescription-drug claims at the pharmacy counter. Over time, PBMs developed an outsized role as the key financial middlemen in the prescription drug supply chain, establishing the prices that pharmacies would be paid, demanding kickbacks or rebates from drug manufacturers in exchange for

favorable formulary placement, and building pharmacy networks that determined which pharmacies could even participate in the marketplace.

Through consolidation and aggressive business practices, three PBMs now control over 80% of prescription drug reimbursements in the United States. These three companies have vertically integrated operations that include retail, mail order, and specialty pharmacies in direct competition with the pharmacies for which they establish reimbursement rates. PBMs have aggressively steered high-dollar medications to mail-order specialty pharmacies they themselves own, which has put their own interests above the plans and patients that PBMs purport to serve.

As PBMs have consolidated their grip over the prescription drug marketplace, their anticompetitive business practices have caused more than 7,000 pharmacies to close their doors just since 2019, according to data from a study at the University of Pittsburgh.[1] At the same time, prescription drug costs have skyrocketed even after adjusting for inflation.[2]

Seeking to take action to correct this trend of increasing prescription drug costs and decreased access to community pharmacies, nearly every State has now enacted legislation that regulates PBMs. These laws include requirements that PBMs apply for and maintain a license, regulating the process and amount of PBM-pharmacy reimbursements, the composition and quality of the pharmacy networks that PBMs

[1] https://apnews.com/article/pharmacy-closure-drugstore-cvs-walgreens-rite-aid-91967f18c0c059415b98fcf67ad0f84e

[2] https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#Nominal%20and%20inflation-adjusted%20per%20capita%20spending%20on%20retail%20prescription%20drugs,%201960-2021

create to sell access to insurers and benefit plans, and conflict of interests and predatory practices that PBMs impose on pharmacies.

2. ERISA and State Laws Regulating PBMs

For many years, there was substantial uncertainty about whether States could regulate third-party service providers, like PBMs, when they were serving plans subject to regulation by ERISA. A federal statute, ERISA regulates private employer- and union-sponsored welfare benefit plans, including prescription drug plans. In one early case, the U.S. Court of Appeals for the Fifth Circuit, which includes Texas, Louisiana, and Mississippi, held that ERISA preempts State insurance laws because they might have a tangential effect on ERISA plans. S*ee Texas Pharm. Ass'n v. Prudential Ins. Co.*, 105 F.3d 1035 (5th Cir. 1997). As a result, many States decided to regulate PBMs only when they were serving non-ERISA plans.

The Supreme Court's decision in *Rutledge v. PCMA*, 592 U.S. 80 (2020), rejected the logic that underpins those earlier decisions. In *Rutledge*, the Supreme Court considered a challenge to an Arkansas law that regulates PBMs. Act 900, as Arkansas's law is known, regulates the amounts PBMs reimburse pharmacies for generic drugs; requires PBMs to provide a reasonable administrative appeal procedure, and to update and disclose their reimbursement lists to pharmacies; and allows pharmacies to decline to dispense drugs to beneficiaries when a PBM intends to reimburse the pharmacy less than the pharmacy's cost to acquire the drug. Ark. Code Ann. § 17-92-507. PCMA, a trade association representing the eleven largest

PBMs, claimed that ERISA preempts Act 900. A unanimous Supreme Court disagreed.

According to the Supreme Court, ERISA preempts State laws that have a "connection with" or "reference to" ERISA plans. *Rutledge*, 592 U.S. at 86. A State law has a "connection with" ERISA plans when it "governs a central matter of plan administration or interferes with national uniform plan administration." *Id.* at 87. A State law has a "reference to" ERISA plans if and only if it "acts immediately and exclusively upon ERISA plans" or "the existence of ERISA plans is essential to the law's operation." *Id.* at 88.

The Supreme Court held that Act 900 did not have a forbidden "connection with" ERISA plans. *Id.* at 87-88. In so holding, the Court emphasized 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. Rather, ERISA is "primarily concerned with preempting [State] laws that require providers 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 86-87. Thus, the Supreme Court has deemed preempted State laws that dictate eligibility or benefits contrary to the terms of an ERISA plan. *Egelhoff v. Egelhoff*, 532 U.S. 141, 147-48 (2001) (eligibility); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983) (benefits); *accord Rutledge*, 592 U.S. at 87. Act 900 does none of these things. The Court explained that the main part of Arkansas's law was a form of "cost regulation," which does not force ERISA plans "to adopt any particular

scheme of substantive coverage." *Id.* at 88. Similarly, the Court held the law's "enforcement mechanisms"—the appeal, update, and decline-to-dispense provisions—simply regulate the relationship between PBMs and third parties that sell access to the "medical benefit[s]" that plans ultimately provide to their beneficiaries. *Id.* at 89-90. The Court emphasized that State law has traditionally governed the relationship between plans and third parties who happen to sell goods and services to ERISA plans. *See id.*

The Court also held that Act 900 did not make a prohibited "reference to" ERISA plans. *Id.* at 88-89. "Act 900 does not act immediately and exclusively upon ERISA plans because it applies to PBMs whether or not they manage an ERISA plan." *Id.* at 88. And "ERISA plans are likewise not essential to Act 900's operation," because "Act 900 regulates PBMs whether or not the plans they service fall within ERISA's coverage." *Id.* at 89.

To summarize, *Rutledge* clarifies that States may regulate PBMs even when PMBs are serving ERISA plans, and ERISA preemption is concerned primarily with State laws only when they "requir[e] payment of specific benefits" or "bind[] plan administrators to specific rules for determining beneficiary status.'" *Id.* at 87. Typical State laws regulating PBMs do neither of these things.

In *PCMA v. Wehbi*, the Eighth Circuit extended the reasoning of *Rutledge* to apply to two North Dakota laws that regulated the accreditation standards that PBMs impose upon pharmacies, a PBM's ability to refer patients to PBM-affiliated pharmacies, and other aspects of how PBMs design the pharmacy networks to which

they charge health plans for access. 18 F.4th 956 (8th Cir. 2021). In that case, PCMA argued the laws impermissibly regulated "benefit design" by limiting the range of choices 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), 2021 WL 2022000. But the Eighth Circuit held that ERISA does not preempt these PBM-network provisions, emphasizing that they "do not 'requir[e] payment of specific benefits' or 'bind[] plan administrators to specific rules for determining beneficiary status.'" *Wehbi*, 18 F.4th at 968 (quoting *Rutledge*, 592 U.S. at 87).[3]

3. The Appropriate Entity to Enforce State PBM Laws

As a general matter, most States have charged their insurance commissioner or attorney general (or both) with authority to regulate PBMs. For example, Texas, Arkansas, Louisiana, and Tennessee have all regulated PBMs within their insurance codes and given far-reaching authority to their insurance commissioners. *See, e.g.*, Tex. Ins. Code §§ 1369.551–.555, §§ 1369.601–.610; Ark. Code § 23-92-505; La. Rev. Stat. § 22:1657; Okla. Stat. §§ 36-6958 – 36-6968; Tenn. Code Ann. § 56-7-3113.

North Dakota is somewhat unique in giving six different agencies or executive officials a role in regulating PBMs: the Attorney General, the Board of Pharmacy, the Department of Health and Human Services, the Insurance Commissioner, the Public Employees Retirement Board, and the State's Attorneys.

[3] To be clear, even where ERISA preempts a State law, that law is preempted "only insofar as [it] relate[s] to plans covered by ERISA." *Shaw*, 463 U.S. at 97 n.17. That means that ERISA does not preempt State laws as applied to non-ERISA plans, including government-sponsored plans.

In my opinion, the State might benefit from consolidating most of its enforcement powers with the Insurance Commissioner and the Attorney General. A few thoughts inform this opinion.

Although PBMs are not risk-bearing entities, the three largest PBMs are vertically integrated with large health insurance companies that do bear risk and are subject to traditional regulation by the insurance commissioner. When viewed in the appropriate context, PBMs are simply an extension of how many health insurers ultimately administer fully insured pharmacy benefits. And even when a PBM is acting as a third-party administrator on behalf of a self-insured plan, a PBM is providing the same services that it provides to fully insured plans. The insurance commissioner is best positioned to understand and regulate the plan- and beneficiary-facing sides of a PBM's business.

In addition, ERISA provides the States with more authority to regulate PBMs when the State is regulating insurance. Under ERISA's insurance savings clause, even when a State law makes an impermissible connection with ERISA plans, nothing in ERISA shall be "construed to exempt or relieve any person from any law of any State which regulates insurance." 29 U.S.C. § 1144(b)(2)(A). At the same time, under the so-called deemer clause, an ERISA plan "shall not be deemed to be an insurance company" subject to "any law of any State purporting to regulate insurance companies." *Id.* § 1144(b)(2)(A). According to the United States government, the net effect of these two provisions is to allow States to regulate PBMs under their insurance codes even when those PBMs are applying services to ERISA plans, but a

State cannot regulate ERISA plans directly. *See* Br. of United States as *Amicus Curiae* 17-20, *PCMA v. Mulready*, No. 22-6074 (10th Cir.) (filed Apr. 10, 2023), *available at* 2023 WL 2990378.

According to the Supreme Court, a State law need only be directed towards the insurance industry and affect the risk-pooling arrangement between an insurer and its insured to qualify under the savings clause. *Miller v. Ky. Ass'n of Health Plans, Inc.*, 538 U.S. 329, 334, 338 (2003). As a result, regulating PBMs under the insurance code does two things: It matches the reality that PBMs are often integrated with insurers and regulations of PBMs often affects the risk pooling arrangements of the insurance that is offered, and it further insulates State laws from claims of ERISA preemption.

All that said, there are still benefits to providing the Attorney General with some authority over PBMs. Among other things, PBMs enter business transactions with pharmacies, pharmaceutical manufacturers, other businesses, and governments. As a result, there also is a role for the Attorney General in ensuring that PBMs do not engage in abusive business practices with these entities.

4. The Need for Technical Amendments

As I understand it, the proposed legislation before this Committee would make technical amendments to the definitions for "covered entity" and "pharmacy benefit manager." Among other things, the Committee has proposed striking exemptions from these definitions for self-funded plans subject to regulation under ERISA. The Committee is right to pursue these changes.

Unfortunately and somewhat counter-intuitively, the Eighth Circuit has twice held that where a State law includes an express exemption for self-funded plans, ERISA will preempt that State law in all of its applications—even as applied to fully insured ERISA plans—because such a provision bears an express reference to ERISA. *See Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr., Inc.*, 154 F.3d 812, 822-26 (8th Cir. 1998); *see also PCMA v. Gerhart*, 852 F.3d 722, 728-29 (8th Cir. 2017), *abrogated on other grounds by Rutledge v. PCMA*, 592 U.S. 80 (2020). Although the Supreme Court has since rejected other aspects of the Eighth Circuit's ERISA jurisprudence, it has not reviewed the Eighth Circuit's express-reference holding in *Prudential* or *Gerhart*.

As a result, there is a substantial risk that the Eighth Circuit would strike down North Dakota's PBM laws in their entirety as applied to ERISA plans if North Dakota continues to exempt self-funded plans subject to regulation under ERISA. It is therefore critical that the legislature remove the express reference to self-funded ERISA plans from the North Dakota Century Code.

That said, I understand that the Insurance Commissioner has expressed some uneasiness about regulating self-funded ERISA plans directly to the extent that they are self-administering their own pharmacy benefits. Some of this uneasiness may be traced back to an early view of the scope of ERISA preemption—a view that the Supreme Court has since refuted.

Nevertheless, there is an easy solution for this concern. The Committee can modify the definition of "pharmacy benefit manager" to clarify that it applies only to

persons or entities that perform pharmacy benefit management, as a third party, under a contract or other financial arrangement with a covered entity. Doing so would address the Commissioner's apparent concern about regulating self-funded plans that administer their own pharmacy benefits while avoiding the Eighth Circuit's line of decisions that prohibits States from including an express exemption for self-funded ERISA plans.

In addition, changing the definition as proposed could further insulate North Dakota's laws from legal challenge. Although the Eighth Circuit has held that the regulation of a PBM is effectively the regulation of an ERISA plan when a PBM is serving an ERISA plan, *see Wehbi*, 18 F.4th at 966-67, the Supreme Court has not blessed this approach—and there are reasons to believe the Supreme Court might decline to do so. In *Rutledge*, for example, the Supreme Court explained that State law governs a plan's relationship with third-party service providers, and PBMs should not be viewed as an exception to this rule. 592 U.S. at 90-91. Similarly, in *Metropolitan Life Insurance Co. v. Massachusetts*, the Supreme Court clarified that that "laws that regulate only the insurer, or the way in which it may sell insurance, do not 'relate to' benefit plans" under ERISA and are therefore not preempted by that law. 471 U.S. 724, 741 (1985). Because an insurer is a third party that sells a service to ERISA plans, it is possible to view this language to extend to laws that regulate only PBMs. Moreover, the Trump Administration previously supported this distinction in *Rutledge*, explaining that Arkansas's law did not trigger concerns under ERISA because it "regulates PBM administration, not ERISA plan administration."

Br. of United States as *Amicus Curiae* 15, *Rutledge v. PCMA*, No. 18-540 (U.S. Dec. 4, 2019), *available at* 2019 WL 6609430.

As a result, the Committee might consider changing the definition of "pharmacy benefit manager" to read:

> "Pharmacy benefit manager" means a person who performs pharmacy benefits management, as a third party, under a contract or other financial arrangement with a covered entity. The term does not include a health benefit plan that manages its own pharmacy benefits.

* * * * *

In the wake of *Rutledge*, there is growing consensus that States should exercise their authority to regulate PBMs—regardless of the type of plan that the PBM is serving. Even before the Supreme Court decided *Rutledge*, the federal government, forty-six States, and the District of Columbia filed briefs with the Supreme Court arguing that States have robust authority to regulate PBMs.

As a result, there has been a recent surge of State-level regulation of PBMs, and the push for such regulation has straddled the political divide. Red States and Blue States—from Arkansas to California, and everywhere in between—have enacted or are considering legislation to further regulate PBMs. North Dakota should continue to lead the charge by making common-sense tweaks to its existing law.

I am happy to answer any of the Committee's questions.