No. 18-2926

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,
Plaintiff-Appellant,
v.

NIZAR WEHBI, in his official capacity as the
interim State Health Officer of North Dakota, et al.,
Defendants-Appellees.

On Appeal from the United States District Court
for the District of North Dakota (No. 1:17-cv-141-DLH)

BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., AS *AMICUS CURIAE* IN SUPPORT OF APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Amicus curiae certifies that it has no outstanding shares or debt securities in the hands of the public, and it does not have a parent company. No publicly held corporation has a 10% or greater ownership in *amicus curiae*.

/s/ Adam G. Unikowsky

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All parties consent to the filing of this amicus brief.[1]

STATEMENT OF INTEREST

The National Association of Chain Drug Stores ("NACDS") is a non-profit, tax-exempt organization incorporated in Virginia. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and health care affordability.

NACDS and its members have a strong interest in this case. The North Dakota law at issue is one of numerous state laws that help protect the health and safety of their citizens by promoting the economic viability of their trusted community pharmacies. The unregulated reimbursement practices of pharmacy benefit managers (PBMs) have caused numerous pharmacies to close, leaving many communities without front-line health care providers. NACDS' members include pharmacies who depend on state laws like North Dakota's to ensure fair treatment. NACDS does not suggest that ERISA preemption is never, or even rarely, warranted; to the

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), *amicus* affirms that no party or counsel for a party authored this brief in whole or in part and that no person other than *amicus*, its members, or its counsel has made any monetary contributions intended to fund the preparation or submission of this brief.

contrary, NACDS relies on ERISA preemption to ensure that employee health care plans are subject to one regulatory scheme, rather than a different scheme in each state. But ERISA preemption has its limits, and North Dakota's statute falls outside those limits. ERISA does not disable states from protecting the interests of pharmacies and the communities they serve merely because the state law may have indirect economic effects on health care plans.

SUMMARY OF ARGUMENT

Rutledge v. Pharmaceutical Care Management Ass'n, 141 S. Ct. 474 (2020), makes clear that ERISA does not preempt North Dakota's statute. The statute does not make any reference to ERISA—to the contrary, it applies to *all* pharmacy benefit plans, regardless of whether they are ERISA plans. Nor does it have a meaningful connection to ERISA plans—rather, it regulates the economic relationship between pharmacy benefit managers (PBMs) and pharmacies, neither of which are ERISA plans. Under *Rutledge*, any indirect effect North Dakota's law will have on the relationship between PBMs and ERISA plans is insufficient to trigger ERISA preemption.

North Dakota's statute also serves sound policy interests unrelated to the goal of ERISA preemption. The statute is designed to mitigate a health care crisis: the rampant closure of pharmacies. Pharmacies not only dispense medications, but also

provide front-line health care like immunizations, tobacco cessation, hormonal contraceptive therapies, blood pressure testing, glucose testing, flu shots, and information to customers on a variety of health-related matters. When a pharmacy closes in a rural area, local residents may have no alternative health care provider nearby, leading to the risk of noncompliance with medication regimens and poor health outcomes. North Dakota's statute prevents PBMs from forcing pharmacies to lose money every time they fill a prescription, and therefore ensures that those pharmacies can keep their doors open to patients. That is a laudable legislative goal—and it in no way undercuts the core purpose of ERISA preemption, which is to protect ERISA plans from inconsistent state administrative burdens.

ARGUMENT

I. *Rutledge* establishes that the North Dakota law is not preempted.

In *Rutledge*, the Supreme Court held that ERISA did not preempt Arkansas's regulations of PBMs' business practices. The Supreme Court's reasoning establishes that ERISA also does not preempt North Dakota's regulations of PBMs' business practices.

A. In *Rutledge*, the Supreme Court held that states may regulate PBMs' billing practices, even if those practices indirectly effect ERISA plans.

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). The Supreme Court has interpreted this phrase to require preemption of two categories of state laws. First,

ERISA preempts state laws that have "an impermissible connection with an ERISA plan." *Rutledge*, 141 S. Ct. at 480 (internal quotation marks omitted). That standard is satisfied when "a state law governs a central matter of plan administration or interferes with nationally uniform plan administration." *Id.* (internal quotation marks omitted). But "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.* "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." *Id.*

Second, ERISA preempts state laws if they "refer[] to ERISA." *Rutledge*, 141 S. Ct. at 481 (internal quotation marks omitted). "A law refers to ERISA if it acts immediately and exclusively upon ERISA plans or where the existence of ERISA plans is essential to the law's operation." *Id.* (internal quotation marks omitted). By contrast, if a state statute regulates a class of plans that "need not necessarily be ERISA plans," it does not make "reference to" ERISA for purposes of ERISA preemption. *Cal. Div. of Labor Standards Enf. v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997) (internal quotation marks omitted); *accord N.Y. State Conf. of Blue Cross & Blue Shields Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656 (1995) ("The surcharges are imposed upon patients and HMO's, regardless of whether the commercial coverage or membership, respectively, is ultimately secured by an

ERISA plan, private purchase, or otherwise, with the consequence that the surcharge statutes cannot be said to make 'reference to' ERISA plans in any manner.").

In *Rutledge*, the Supreme Court unanimously held that ERISA did not preempt an Arkansas statute closely similar to North Dakota's statute. Like North Dakota's statute, the Arkansas statute (known as Act 900) regulated PBMs, which "serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use." 141 S. Ct. at 478. Act 900 was enacted "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." *Id.* at 478-79. To remedy those concerns, Act 900 effectively "requires PBMs to reimburse Arkansas pharmacies at a price equal to or higher than that which the pharmacy paid to buy the drug from a wholesaler." *Id.* at 479.

Act 900 "accomplishes this result through three key enforcement mechanisms." *Id.* "First, the Act requires PBMs to tether reimbursement rates to pharmacies' acquisition costs by timely updating their MAC lists when drug wholesale prices increase." *Id.* "Second, PBMs must provide administrative appeal procedures for pharmacies to challenge MAC reimbursement prices that are below the pharmacies' acquisition costs." *Id.* "If a pharmacy could not have acquired the

drug at a lower price from its typical wholesaler, a PBM must increase its reimbursement rate to cover the pharmacy's acquisition cost." *Id.* "Third, and finally, the Act permits a pharmacy to decline to sell a drug to a beneficiary if the relevant PBM will reimburse the pharmacy at less than its acquisition cost." *Id.*

The Supreme Court ruled that ERISA did not preempt Act 900. First, the Court concluded that Act 900 does not "refer to" ERISA. "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 481. "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.*

Second, the Court concluded that Act 900 did not have an impermissible "connection to" ERISA plans. Rather, it merely "requires PBMs to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost." *Id.* Although the effect of Act 900 might be that "ERISA plans may pay more for prescription-drug benefits in Arkansas than in, say, Arizona," "cost uniformity was almost certainly not an object of pre-emption." *Id.* (internal quotation marks omitted).

B. *Rutledge* dictates the outcome of this case.

Rutledge establishes that North Dakota's law does not fall within either category of preemption. First, like Act 900, North Dakota's statute does not make

"reference to" ERISA. Instead, North Dakota's statute "regulates PBMs whether or not the plans they service fall within ERISA's coverage." *Id.*

Hence, *Rutledge* has now abrogated this Court's prior decision invalidating North Dakota's statute. Before *Rutledge*, this Court held that North Dakota's statute "is preempted due to its impermissible 'reference to' ERISA plans." *Pharm. Care Mgmt. Ass'n v. Tufte*, 968 F.3d 901, 904 (8th Cir. 2020), *summarily vacated sub nom. Wilke v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 1364 (2021). The Court reasoned that the statute's "references to 'third-party payers' and 'plan sponsors' impermissibly relate to ERISA benefit plans." *Id.* at 904-05. It noted that "a statute that implicitly regulates ERISA plans as part of its regulatory scheme is preempted by ERISA and cannot be saved merely because the reference also includes entities not covered by ERISA." *Id.* at 906. *Rutledge* has now repudiated that reasoning. Because North Dakota's statute "also includes entities not covered by ERISA," *id.*, *Rutledge* dictates that it does not "refer to" ERISA plans.

PCMA recognizes that this Court's prior reasoning is irreconcilable with *Rutledge*. PCMA Br. 20-21. Accordingly, PCMA switches gears. It now contends that North Dakota's statute has an impermissible "connection with" ERISA plans. PCMA Br. 22-32. PCMA is incorrect. All of PCMA's new arguments here already were considered and rejected by the Supreme Court in *Rutledge*.

Although North Dakota's statute has many components, all of them share a common characteristic: they regulate the relationship between PBMs and pharmacies, while leaving ERISA plan administrators with leeway to structure their plans however they choose. Under *Rutledge*, such statutes are not preempted. Although North Dakota's regulation of PBMs may indirectly increase costs and cause operational efficiency for ERISA plans, *Rutledge* holds that those indirect effects are insufficient to establish ERISA preemption. 141 S. Ct. at 482 (no preemption when provisions "do not require plan administrators to structure their benefit plans in any particular manner, nor do they lead to anything more than potential operational inefficiencies").

PCMA's scattershot attacks on the various provisions of North Dakota's statute can be divided into three categories, each of which *Rutledge* directly addresses.

First, PCMA attempts to redefine *anything* a PBM does as "plan administration." Hence, it asserts that *any* regulation of PBMs' interactions with pharmacies constitute direct regulation of plan administration. For instance, PCMA claims that "[t]he design of a plan's network of providers for covered health benefits is a substantive element of the benefit." PCMA Br. 23. Based on this theory, it alleges that ERISA preempts portions of North Dakota's statute that "prohibit PBMs from requiring, as a condition of network participation, that pharmacies satisfy" certain

regulatory requirements. PCMA Br. 24. Likewise, PCMA challenges certain conflict-of-interest rules that apply *only* to PBMs—not to the plans themselves. PCMA Br. 29-30. PCMA insists that "it is of no moment" that the statute applies to the PBMs only, because in PCMA's view, all of the PBMs' interactions with pharmacies constitute plan administration subject to the exclusive regulatory authority of the federal government. PCMA Br. 31-32.

Rutledge rejected this argument. In *Rutledge*, PCMA "claim[ed] that Act 900 affects plan design by mandating a particular pricing methodology for pharmacy benefits." 141 S. Ct. at 482. In effect, PCMA defined its pricing methodology as an aspect of the ERISA plan, and then claimed that Act 900 was preempted because it regulated that methodology. The Supreme Court disagreed: "Requiring PBMs to reimburse pharmacies at or above their acquisition costs does not require plans to provide any particular benefit to any particular beneficiary in any particular way." *Id.* By the same token, North Dakota's challenged restrictions regulate PBMs' relationship with pharmacies. But under *Rutledge*, such restrictions do not constitute impermissible regulation of an ERISA plan when they do not require plans to provide any particular benefit to any particular beneficiary in any particular way.

Second, PCMA invokes the Supreme Court's statement that "reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform

system[,] of plan administration contemplated by ERISA." *Gobeille v. Liberty Mutual Ins. Co.*, 577 U.S. 312, 323 (2016). Based on *Gobeille*, PCMA insists that recordkeeping and disclosure obligations burdens imposed on PBMs should be deemed preempted because "states are forbidden from supplementing federal standards concerning recordkeeping and disclosure requirements with respect to benefit plans." PCMA Br. 28.

Again, *Rutledge* rejected this argument. In *Rutledge*, PCMA complained about a state-required appeal procedure in which pharmacies could challenge PBMs' reimbursement rates. According to PCMA, under Act 900, "plan administrators must comply with a particular process, subject to state-specific deadlines, and Act 900 dictates the substantive standard governing the resolution of an appeal." 141 S. Ct. at 482 (internal quotation marks and alterations omitted). But the Supreme Court held that the imposition of these burdens on PBMs was insufficient to establish preemption. It concluded that "Act 900's appeal procedure … does not govern central matters of plan administration." *Id.* As the Court observed, "any contract dispute implicating the cost of a medical benefit would involve similar demands and could lead to similar results." *Id.*

The same is true here. North Dakota's statute imposes administrative burdens on PBMs in connection with the pharmacy-PBM relationship: for instance, it "prohibits PBMs from redacting certain information in paperwork shared with

providers." PCMA Br. 28. But under *Rutledge*, the imposition of administrative burdens on PBMs "does not govern central matters of plan administration." 141 S. Ct. at 482.

Third, under the guise of a "field preemption" argument, PCMA insists that federal statutes and regulations "fully occupy the field of laws regulating employee benefit plans." PCMA Br. 34-35. Therefore, PCMA asserts, ERISA field-preempts laws regulating "transactions with interested third parties, including PBMs." *Id.* at 35.

As PCMA acknowledges, however, the "Supreme Court has not expressly grounded its ERISA preemption cases on the doctrine of field preemption." PCMA Br. 33. Indeed, this acknowledgment is an understatement: *Rutledge* affirmatively repudiates PCMA's field preemption theory. *Rutledge* makes clear that ERISA does *not* preempt the field of state laws that regulate "interested third parties," including PBMs, even if those laws may indirectly affect the economic incentives of ERISA plans. In *Rutledge*, "PCMA argue[d] that Act 900's enforcement mechanisms interfere with nationally uniform plan administration by creating 'operational inefficiencies.'" 141 S. Ct. at 483. The Supreme Court disagreed: "ERISA does not pre-empt a state law that merely increases costs, however, even if plans decide to limit benefits or charge plan members higher rates as a result." *Id.* This holding is

irreconcilable with PCMA's theory that ERISA field-preempts direct state regulation of PBMs.

In sum, PCMA's arguments are indistinguishable from the arguments that *Rutledge* considered and rejected. Under a straightforward application of *Rutledge*, North Dakota's statute should stand.

II. North Dakota's statute achieves laudable policy goals unrelated to ERISA.

North Dakota's statute curbs several practices by PBMs that have harmed ERISA plans, pharmacies, and patients. One purpose of North Dakota's statute is to protect patient access to care by ensuring that PBMs' reimbursement rates cover pharmacies' costs of providing prescription medications. That purpose is entirely consistent with the purpose of ERISA preemption: protecting ERISA plans, which are neither PBMs nor pharmacies, from the burden of simultaneously complying with regulatory programs in every state.

North Dakota's statute addresses a genuine health care crisis: the rampant closure of pharmacies, especially in rural areas. In fact, independent data sources have reported that the number of retail pharmacies in the United States dropped by almost 2,000 over the past two years.[2] Moreover, several pharmacy chains have announced

[2] National Association of Chain Drug Stores, *The Pharmacy Reimbursement Crisis*, https://www.nacds.org/pdfs/pharmacy/2020/Pharmacy-Reimbursement-2020.pdf (showing that the number of U.S. retail pharmacies dropped from 58,706 in December 2017 to 56,788 in December 2019 according to IQVIA, an industry

plans to close hundreds of additional pharmacies.[3] Pharmacy closures have disproportionately affected rural areas. Six hundred thirty rural communities that had at least one pharmacy in March 2003 had no retail pharmacy in March 2018.[4]

Pharmacy closures are harmful to patients because pharmacies serve as front-line health care providers. In addition to providing medications, pharmacies offer immunizations, tobacco cessation, hormonal contraceptive therapy, blood pressure and glucose testing, flu shots, and information to customers on a variety of health-related matters. When a pharmacy closes in a rural area, the frequent result is that the rural area has no front-line health care provider at all. Thus, if a patient in such a rural area wishes to obtain medications or basic health care testing, the patient may have to drive an hour or more out of their way and take time out of work. If the

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group that collects pharmacy data, and that a net 995 pharmacy profiles closed in 2018 and a net 695 pharmacy profiles closed in 2019 according to the National Council for Prescription Drug Programs, a national group that assigns identification numbers to pharmacies for billing purposes).

[3] Christine Blank, *Chains Closing Stores, Opening Fewer*, Drug Topics (Aug. 7, 2019), https://www.drugtopics.com/view/chains-closing-stores-opening-fewer.

[4] Abiodun Salako et al., *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, Rural Policy Brief, RUPRI Ctr. for Rural Health Pol'y Analysis (Brief No. 2018-2, July 2018), https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

patient is unable or unwilling to do so, the patient may not comply with medication regimens or may not get tested, and poor health care outcomes may result.[5]

One of the reasons for the mass closure of pharmacies is that PBMs can reimburse pharmacies at low rates that do not cover the costs of purchasing and dispensing expensive prescription medications, causing the pharmacies to take a loss for dispensed prescriptions. Some background on PBMs' operating practices is necessary to understand why.

Pharmacies buy drugs from drug manufacturers and distributors. To make a profit, pharmacies must recoup those costs from the patients who purchase the drugs. But in most cases, the patients do not pay the full cost of the drugs; rather, they pay a co-pay, and the rest comes from a health care plan. But pharmacies ordinarily do not interact directly with health care plans. Rather, they interact with middlemen—PBMs.

North Dakota's statute, and others like it, address certain practices by PBMs that can drive pharmacies out of business. Presently, PBMs can reimburse pharmacies for dispensing drugs at rates that do not cover pharmacies' costs of purchasing

[5] Dima M. Qato, et al., *Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults*, JAMA Network Open 12 (Apr. 19, 2019), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730785 (finding "pharmacy closures are associated with persistent, clinically significant declines in adherence to cardiovascular medications among older adults in the United States.").

those drugs. As a result of these practices, pharmacies can and do receive reimbursements from the PBM that are less than the cost of obtaining the drug in the first place.

At least 38 states, including North Dakota, regulate PBMs' pricing practices to help ensure that pharmacy reimbursement covers the cost to provide patient services and care. North Dakota's law does not regulate PBMs in their capacity as claim-processors of claims submitted to health care plans. Nor does North Dakota's law impose any restrictions on PBMs' contracts with health care plans. Instead, North Dakota's statute curbs certain abusive practices engaged in by PBMs, including, among other things, practices that cause pharmacies to receive excessively low reimbursement. For instance, North Dakota's statute prohibits the imposition of certain fees by PBMs. *E.g.*, N.D. Cent. Code § 19-02.1-16.1(2), 19-02.1-16.1(3)(a)-(c). Likewise, PBMs are required to share information with pharmacies about the PBMs' pharmacy networks to ensure that pharmacies can make an informed financial decision on whether to contract with the PBMs. N.D. Cent. Code § 19-02.1-16.1(10).

These policy goals are entirely disconnected from the goal of ERISA preemption: ensuring that ERISA plans do not face burdensome administrative requirements. As this Court has explained, "[r]equiring ERISA administrators to master the relevant laws of 50 States and to contend with litigation would undermine

the congressional goal of minimizing the administrative and financial burdens on plan administrators — burdens ultimately borne by the beneficiaries." *Gobeille*, 577 U.S. at 321 (quotation marks and alterations omitted). In the absence of ERISA preemption, the already-complex process of processing claims would become a nightmare: "A plan would be required to keep certain records in some States but not in others; to make certain benefits available in some States but not in others; to process claims in a certain way in some States but not in others; and to comply with certain fiduciary standards in some States but not in others." *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987). ERISA preemption ensures that employees' health care spending goes to health care, rather than administrators and lawyers.

Applying ERISA's preemption provision to North Dakota's statute would be like fitting a square peg in a round hole. North Dakota's statute does not increase administrative burdens on ERISA plans, either in intent or in effect. Rather, it regulates the economic relationship between two parties, neither of which are ERISA plans: PBMs and pharmacies. North Dakota's statute does impose certain administrative requirements on PBMs, but these requirements have nothing to do with the ERISA plans with which the PBMs contract. The whole premise of PBMs' business model is that their reimbursement rates are *different* from the amount they charge ERISA plans. PBMs are in an arm's length relationship with ERISA plans and make

money off of those plans. Curbing PBMs' practices that harm pharmacies and ERISA plans does not constitute a regulation of ERISA plans.

In reality, PCMA is not seeking centralized *federal* regulation; it is seeking *no* regulation. The federal government regulates ERISA plans in myriad ways. The purpose of ERISA preemption is to ensure that ERISA plans have one, rather than fifty-one, regulators. But the federal government does not regulate PBMs under ERISA, because PBMs are not ERISA plans. Thus, under PCMA's theory, PBMs fall within a strange sweet spot—not enough like ERISA plans to be subject to federal regulation, but sufficiently "related" to ERISA plans to be free from state regulation. The Court should not adopt that unlikely interpretation.

CONCLUSION

The judgment of the district court should be affirmed.

Dated: June 30, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5), the type style requirements of Fed. R. App. P. 32(a)(6), and the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because it is proportionally spaced, has a typeface of 14 point Times New Roman, and contains 3,732 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This brief complies with Circuit Rule 28A(h) because the files have been scanned for viruses and are virus-free.

/s/ Adam G. Unikowsky
Adam G. Unikowsky

CERTIFICATE OF SERVICE

I, hereby certify that on June 30, 2021 I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court Of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Adam G. Unikowsky
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