No. 18-2926

IN THE
UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

Pharmaceutical Care Management Association,

Appellant,

vs.

Nizar Wehbi et al.,

Appellees.

ON APPEAL FROM UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA

BRIEF OF AMICI CURIAE STATES OF MINNESOTA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, GEORGIA, HAWAII, ILLINOIS, INDIANA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, NEBRASKA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, OREGON, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, VIRGINIA, AND WASHINGTON, AND THE DISTRICT OF COLUMBIA, IN SUPPORT OF APPELLEES AND AFFIRMANCE

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STATEMENT UNDER FED. R. APP. P. 29(a)(4)(D)

The States of Minnesota, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, and Washington, and the District of Columbia, submit this brief as amici curiae to support the appellees. The states have an interest in preserving states' authority to regulate companies doing business in their states and in protecting their residents' access to healthcare and shielding them from abusive business practices. To advance these interests, nearly all states regulate pharmacy benefit managers. The sweeping approach to ERISA and Medicare preemption that Appellant advocates would severely impede states' abilities to protect their residents and potentially upend licensing and regulatory structures in nearly every state.

The states file this brief under Fed. R. App. P. 29(a)(2), which permits a state to file an amicus brief without the parties' consent or leave of the Court.

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States have an inherent interest in ensuring their residents can afford their lives. Consumers across America struggle to afford healthcare. A principal cause for their plight is the increasing, unsustainable cost of prescription drugs. States have sought to address these concerns in myriad ways, more recently by regulating a source of these increasing costs: pharmacy benefit managers (PBMs) and their business practices. PBMs are not health plans. They are intermediaries in the prescription-drug insurance market, a segment of the healthcare industry that has grown exponentially, largely without regulation and largely to the detriment of consumers, who have lost access to affordable means of filling their prescriptions. States have enacted laws to curb some of the worst abuses in the PBM industry and to protect consumers, independent pharmacies, and states.

Because regulation cuts into their profits and provides accountability, PBMs naturally resist these laws. In an effort to perpetuate the industry's abuses, Appellant Pharmaceutical Care Management Association (PCMA), a national trade association, has filed multiple lawsuits claiming ERISA or Medicare preempts various states' regulations. PCMA advocates for nearly boundless ERISA and Medicare preemption. As the appellees argue, this position is meritless and the Court should reject it.

ARGUMENT

PCMA claims ERISA and Medicare broadly preempt state PBM regulations. As recently reaffirmed by the Supreme Court, ERISA preemption applies only to laws that require insurance providers to structure benefit plans in specific ways, such as by requiring specific benefits or rules to determine beneficiary status. *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 480 (2020). Medicare preempts state laws only if a Medicare "standard" particularly addresses the subject of state regulation. *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018), *rev'd on other grounds*, *Rutledge*, 141 S. Ct. 474. Because the challenged North Dakota laws do not dictate plan benefits or conflict with a Medicare standard, they are not preempted.

I. REGULATING PBMS PROTECTS CONSUMERS AND CURBS ABUSES BY A MULTI-BILLION-DOLLAR INDUSTRY.

Prescription drugs are an inescapable and increasingly prevalent facet of modern healthcare. In 2017, about 58% of adults aged 18-64, and 86% of adults over 65, were prescribed medication in the preceding year.[1] In 2019, annual prescription-drug spending in the United States grew 5.7% to $369.7 billion.[2]

[1] Ctrs. for Disease Control & Prevention, U.S. Dep't of Health & Hum. Servs., *QuickStats*, 68 Morbidity & Mortality Wkly Rep. 97 (2019), https://perma.cc/YAT6-B3SZ.

[2] Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Fact Sheet*, https://perma.cc/8YES-JUPJ.

Healthcare spending is projected to continue increasing and comprise more of the GDP.[3]

While early PBMs in the 1970s played a limited role in the healthcare system, their role steadily expanded over the past fifty years to control nearly every aspect of health plans' pharmacy benefits.[4] The way a medication gets to a consumer is relatively straightforward: manufacturer → distributor → pharmacy → consumer. How that medication is paid for is anything but simple, in large part due to PBMs. PBMs implement complicated processes and requirements that maximize PBM profits at the expense of pharmacies and patients.

PBMs' growing role in healthcare was largely overlooked for decades, cultivated by the lack of transparency PBMs designed into the system.[5] Within the healthcare industry, PBMs became an interwoven web, imposing self-serving protections that reduced reimbursement rates to pharmacies, maximized rebates to PBMs, and imposed various confidentiality requirements. For example, before states began regulating, basic information like the amount PBMs reimbursed pharmacies for dispensing medications was often confidential.[6] PBMs thrived in

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[3] *Id.*

[4] Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., *Pharmacy Benefit Managers 101* 2 (Cal. Mar. 20, 2017), https://perma.cc/D4SL-PBB6.

[5] Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 Pharmacy & Therapeutics 206-08 (2015), https://perma.cc/G8RX-TP54.

[6] *Id.*

this opaque space in the healthcare industry so much that the PBM market is now estimated to be in the hundreds of billions of dollars annually. Coupled with many consumers' limited pharmacy choices, PBMs created a captive market that demanded regulation to safeguard the public's financial and physical health.

A. State Regulation Is Necessary Because PBMs Harm Pharmacies, Consumers, and States.

PBMs have exploited decades of lax or non-existent regulation to become a massive part of the prescription-medication industry. Because PBMs are essentially middlemen, their profits depend on reaping large fees and rebates while spending as little as possible to reimburse pharmacies for medications. This drives down reimbursement rates and increases drug prices, all while operating largely in the shadows. State regulation is necessary to curb PBM practices that harm pharmacies, consumers, and states.

1. PBMs harm pharmacies by lowering reimbursement rates and favoring certain pharmacies.

Local pharmacies are critical in providing healthcare to rural communities, and pharmacy closures have been particularly detrimental.[7] From 2003 to 2018, approximately 16% of independently owned rural pharmacies closed.[8] In major

[7] Abiodun Salako et al., RUPRI Ctr. for Rural Health Pol'y Analysis, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* (2018), https://perma.cc/9XKN-7TU2.
[8] *Id.*

metropolitan areas between 2007 and 2015, pharmacies were less likely to open and more likely to close in neighborhoods with majority Black or Hispanic/Latinx residents.[9] This trend in closures spans the rural-urban divide and is traceable to PBMs. PBMs' historically unregulated business model harmed pharmacies in two principal ways: by using PBMs' superior bargaining position to drive down reimbursements to pharmacies and by steering business—and offering preferable terms—to pharmacies affiliated with the PBM.

First, PBMs' reimbursement rates and practices harm independent pharmacies. PBMs profit from the "spread" between the amount they charge health plans for a drug and the amount they reimburse pharmacies.[10] PBMs reimburse pharmacies for multi-source drugs based on PBM-created maximum allowable cost (MAC) schedules, which PBMs often keep confidential, even from health plans.[11] The less the PBM reimburses the pharmacy, the higher the "spread" and the higher the profit for the PBM.

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[9] Jenny S. Guadamuz et al., *Fewer Pharmacies in Black and Hispanic/Latino Neighborhoods Compared with White or Diverse Neighborhoods, 2007-15,* 40 Health Affairs 802, 805 (2021).

[10] Elizabeth Seeley & Aaron Kesselheim, Commonwealth Fund, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead* (2019), https://perma.cc/4Q36-B5YE.

[11] *Id.*

Independent pharmacies identify low reimbursements and outdated MAC lists as a major financial concern.[12] Minnesota has seen more pharmacies close in the last decade than any state.[13] Local pharmacies must work with PBMs but have relatively little bargaining power.[14] Of the fifteen largest U.S. companies, three own or operate PBMs.[15] Consolidation in the PBM industry is also a longstanding concern.[16] All major health insurers now operate PBMs.[17] And all but the largest retail pharmacies receive only "take it or leave it" offers from PBMs.[18] This bargaining disparity invariably results in independent pharmacies accepting financially detrimental terms.

Second, PBMs steer business away from independent pharmacies and toward PBM-owned or -affiliated pharmacies. In addition to limiting consumers' choice and creating potential conflicts of interest, this reduces non-affiliated pharmacies' business. Again, a lack of regulation perpetuates the problems. For example, when Ohio pharmacists reported conflicts of interests because PBMs were requiring

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[12] Abiodun Salako et al., *Financial Issues Challenging Sustainability of Rural Pharmacies*, 2 Am. J. Med. Research 147, 153 (2017).
[13] Sarah D. Kerr, *Pharmacist's View: Independent Pharmacies Threatened by Middlemen*, Duluth News Trib., Apr. 26, 2021, https://perma.cc/NN4C-2DSG.
[14] *Id.*
[15] *Fortune 500 – 2020*, Fortune Mag. (2020), https://perma.cc/2CKZ-VQ93.
[16] Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 Val. U. L. Rev. 33, 36 (2007).
[17] Bruce Japsen, *Express Scripts Boosts Cigna as Employers Stick with Larger Insurer*, Forbes Mag. (Aug. 1, 2019), https://perma.cc/C2W3-7JC2.
[18] Garrett & Garis, *supra* note 16, at 46.

customers to obtain prescriptions from PBM-owned pharmacies, the state auditor could not fully investigate because data needed from PBMs were inaccessible.[19] PBMs also divert prescriptions to their own pharmacies by "prescription trolling:" after local pharmacists work with patients, their insurers, and their doctors to obtain prior authorization for expensive medications, PBMs can divert prescriptions to their own mail-order pharmacies.[20] Independent pharmacies are forced to accept terms that are likely to put them out of business, while the PBM prefers its affiliated pharmacies for expensive and mail-order medications. This is often done behind the veil of gag clauses that shield PBMs' business practices from sight. State regulation in this space is sorely needed because these pharmacy closures reduce access to medical care for state residents and impair public health.

2. PBMs' historically unregulated business practices harmed consumers by driving up drug costs.

PBMs contribute to the crisis of increasing medical costs nationwide. While medical spending has increased by approximately 17% since 2014, prescription-medication list prices have increased 33%.[21] One-third of consumers have skipped

[19] Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* 1, 13 (Aug. 16, 2018), https://perma.cc/V29P-DRA3.
[20] Hearing on HF 728 Before the H. Commerce Comm., 2019 Leg., 91st Sess. at 1:52:25 (Minn. 2019) (statement of Randy Schindelar), http://ww2.house.leg.state.mn.us/audio/mp3ls91/com022719.mp3.
[21] Tori Marsh, Good RX, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service* (Sept. 17, 2020), https://perma.cc/L2LR-C643.

filling a prescription and 10% have reported rationing their medications.[22] The rising cost of medications directly affects the most vulnerable Americans' ability to afford their lives and access medications prescribed to them.

One contributing factor to rising drug costs is the increasingly large rebates that PBMs demand from drug manufacturers. A recent study found that increases in rebates to PBMs correlated to a nearly equal increase in list prices.[23] Consolidation of the PBM market is leading manufacturers to offer increasingly attractive rebates: with three PBMs controlling an estimated 80-90% the market, if one PBM excludes a drug then the manufacturer loses access to a relatively large market share.[24] For example, one PBM demanded drug manufacturers give two years' notice before lowering list prices.[25] This market control results in PBMs securing favorable terms from manufacturers and pharmacies and contributes to higher prices for prescription medications.

Another way PBMs enrich themselves at the expense of consumers and independent pharmacies is through "claw backs." Gag clauses often prohibit

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[22] *Id.*

[23] Neeraj Sood et al., USC Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., *The Association Between Drug Rebates and List Prices*, (Feb. 11, 2020), https://perma.cc/L7GA-SA86.

[24] *Id.*; ND Appx 36.

[25] *Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the* S. *Comm*. *on Finance*, 116th Cong. (2019) (statement of John M. Prince, CEO, OptumRX).

pharmacists from telling consumers a medication's actual cost. In some cases, the cash cost is less than a consumer's copay. PBMs nonetheless require pharmacies to collect the copay from the unwitting consumer. The PBM can then later claw back from the pharmacy the difference between the copay and the actual cost, keeping the difference.[26] For example, a pharmacist collected a $35 copay for an allergy spray, only to have the PBM claw back $30.[27] The consumer would have been better off paying the $5 cash price for the medication, but a PBM gag clause precluded the pharmacist from giving the consumer this information.[28] These types of practices also affect local pharmacies when the reimbursement to the pharmacy is below the acquisition cost. And claw backs inject uncertainty because PBMs can claw back money long after the pharmacy dispenses the prescription.[29]

While the sources of rising drug costs are complex, they should not be beyond the states' traditional police power of protecting the public. States have done the work to identify and regulate problematic facets of the PBM industry that have developed over years, and they play a critically important role in this sphere.

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[26] Julie Appleby, *Filling a Prescription? You Might Be Better Off Paying Cash*, CNN, June 23, 2016, https://perma.cc/M242-ADQL.
[27] *Id.*
[28] *Id.*
[29] Schindelar testimony, *supra* note 20, at 1:53:54.

B. State PBM Regulation Protects the Public from Anti-Competitive and Abusive Practices.

In response to these concerning trends, nearly all states have enacted PBM regulations.[30] Since 2017 forty-eight states have enacted 166 state laws regulating PBMs.[31] In January 2021, eighty-one PBM bills were pending in twenty-nine states.[32] Four categories of legislation are prevalent in state PBM regulations: (1) MAC lists; (2) reimbursements; (3) transparency; and (4) fiduciary duties.[33] State regulation in these and other areas limits the harms discussed above.

1. MAC-list regulations

MAC-list or reimbursement-list regulations ensure fairness and transparency in how drugs are listed. MAC lists are particularly important to PBMs because they essentially control pharmacies' reimbursement rates. All but a few states regulate MAC lists in some form.[34] One common requirement is that PBMs update MAC

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[30] Nat'l Conference of State Legislatures, *State Policy Options and Pharmacy Benefit Managers* (Mar. 17, 2021), https://perma.cc/JVG7-XW2V.
[31] Trish Riley, Nat'l Acad. State Health Pol'y, *Celebrating Five Years of State Action to Lower Drug Prices* (May 18, 2021), https://perma.cc/D9AS-KTR3.
[32] Nat'l Conference of State Legislatures, *Pharmacy Benefit Managers (PBM) and Options for State Legislatures Webinar* (Jan. 28, 2021), https://perma.cc/U9VV-V5TX.
[33] Other types of state regulations are not discussed here because they are neither relevant nor prevalent. For example, while not relevant to the laws before the court, some states require registration or licensure. *E.g.*, Minn. Stat. § 62W.03.
[34] Nat'l Conference of State Legislatures, *supra* note 30.

lists in a timely manner.[35] *See Rutledge*, 141 S. Ct. at 479 (upholding state law requiring PBMs to update MAC lists and allowing pharmacies to appeal MAC reimbursements).

To increase transparency, many states also require PBMs to disclose their MAC lists to pharmacies.[36] Minnesota is typical in this regard, requiring PBMs to "make the [MAC list] available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy." Minn. Stat. § 62W.08(a)(5) (2020). More states also allow pharmacies to appeal MAC prices.[37]

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[35] *See* Alaska Stat. § 21.27.945(a)(4); Ark. Code Ann. § 17-92-507(c)(2); Del. Code Ann. tit. 18, § 3323A(b)(3); Fla. Stat. § 641.314(2)(a); Ga. Code Ann. § 33-64-9(a)(1); 215 Ill. Comp. Stat. 5/513b1(b)(1); Ind. Code § 27-1-24.8-4; Kan. Stat. Ann. § 40-3830(d); Ky. Rev. Stat. Ann. § 304.17A-162(6); La. Stat. Ann. § 22:1864(B)(2); Me. Stat. tit. 24-A, § 4350(4)(C); Md. Code Ann., Ins. § 15-1628.1 (c)(l); Minn. Stat. § 62W.08(a)(2); Miss. Code Ann. § 73-21-155(2); Mo. Rev. Stat. § 376.388(3); Mont. Code Ann. § 33-22-172(2)(a); N.J. Stat. Ann. § 17B:27F-2(a)(2); N.M. Stat. Ann. § 59A-61-4(D)(2); N.C. Gen. Stat. § 58-56A-5(b); N.D. Cent. Code § 19-02.1-14.2(2)(b); Ohio Rev. Code Ann. § 3959.111(A)(1)(a); Okla. Stat. tit. 59, § 360(A)(1); Or. Rev. Stat. § 735.534(2)(f); 40 Pa. Cons. Stat. § 4532(a)(2); 27 R.I. Gen. Laws § 27-41-38.2(b)(1); S.C. Code Ann. § 38-71-2240(B)(2); Tex. Ins. Code Ann. § 1369.355(b); Vt. Stat. Ann. tit. 18, § 9473(c)(2); Wash. Rev. Code § 19.340.100(2)(1); Wis. Stat. § 632.865(2)(1); Wyo. Stat. Ann. § 26-52-104(d)(iv).

[36] Kan. Stat. Ann. § 40-3830(c); Me. Stat. tit. 24-A, § 4350(4)(B); Miss. Code Ann. § 73-21-156(3); Mont. Code Ann. § 33-22-172(2)(c); N.M. Stat. Ann. § 59A-61-4(D)(11); N.D. Cent. Code § 19-02.1-14.2(2)(c); N.J. Stat. Ann. § 17B:27F-2; Ohio Rev. Code Ann. § 3959.111(A)(1)(a); Okla. Stat. tit. 59, § 360(A)(1); S.C. Code Ann. § 38-71-2240(B)(3); Tenn. Code Ann. § 56-7-3107(b)(2); Tex. Ins. Code Ann. § 1369.356; Utah Code Ann. § 31A-46-303(5)(d); Vt. Stat. Ann. tit. 18, § 9473(c)(1).

[37] *See* Alaska Stat. § 21.27.950(a); Ariz. Rev. Stat. Ann. § 20-3331(A)(3); Cal. Bus. & Prof. Code § 4440(f); Colo. Rev. Stat. § 25-37-103.5(3); Del. Code Ann. tit. 18,

(Footnote Continued on Next Page.)

Some states regulate which drugs PBMs can place on MAC lists. For example, Missouri prohibits PBMs from including drugs unless therapeutically equivalent generics are available from multiple sources or wholesalers. Mo. Rev. Stat. § 376.388.[38] These regulations ensure that drugs on MAC lists are available and competitive.

2. Reimbursement regulations

Closely related to MAC-list regulations are reimbursement regulations. States commonly prohibit below-cost reimbursements to pharmacies or allow pharmacies

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§ 3324A; Ga. Code Ann. § 33-64-9(d); Haw. Rev. Stat. § 328-106(f); 215 Ill. Comp. Stat. 5/513b1(b)(4); Iowa Code § 510B.8(3); Kan. Stat. Ann. § 40-3830(1); Ky. Rev. Stat. Ann. § 304.17A-162(1)(b); La. Stat. Ann. § 22:1865(A); Me. Stat. tit. 24-A, § 4350(5); Md. Code Ann., Ins. § 15-1628.1(f); Minn. Stat. § 62W.08(c); Miss. Code Ann. § 73-21-156(4)(a); Mo. Rev. Stat. § 376.388(5); Mont. Code Ann. § 33-22-l73(1)(a); N.H. Rev. Stat. Ann. § 420-J:8(a)(2); N.J. Stat. Ann. § l7B:27F-4; N.M. Stat. Ann. § 59A-61-4(5); N.Y. Pub. Health Law § 280-a(2); N.D. Cent. Code § 19-02.l-14.2(2)(e); Ohio Rev. Code Ann. § 3959.111(A)(1)(b)(3); Okla. Stat. tit. 59, § 360(A)(4); Or. Rev. Stat. § 735.534(4); 40 Pa. Cons. Stat. § 4533(a); 27 R.I. Gen. Laws § 27-41-38.2(d); S.C. Code Ann. § 38-71-2240(B)(5), (C), (D); Tenn. Code Ann. § 56-7-3108(a); Tex. Ins. Code Ann. § 1369.357(a); Utah Code Ann. § 31A-46-303(5)(c); Vt. Stat. Ann. tit. 18, § 9473(c)(3); Wash. Rev. Code § 19.340.100(3); Wis. Stat. § 632.865(2)(b); Wyo. Stat. Ann. § 26-52-104(e).

[38] *See also* Cal. Bus. & Prof. Code § 4440(d); Colo. Rev. Stat.§ 25-37-103.5(2); Del. Code Ann. tit. 18, § 3323A(a); Ga. Code Ann. § 33-64-9(c); Haw. Rev. Stat. § 328-106(d); 215 Ill. Comp. Stat. 5/513b1(c); La. Stat. Ann. § 22:1864(A); Md. Code Ann., Ins. § 15-1628.l(e); Minn. Stat. § 62W.08(b); Miss. Code Ann. § 73-21-156(2); N.J. Stat. Ann. § 17B:27F-3(a); N.M. Stat. Ann. § 59A-61-4(C); N.C. Gen. Stat. § 58-56A-5(a); N.D. Cent. Code § 19-02.1-14.2(3); Okla. Stat. tit. 59, § 360(B); Or. Rev. Stat. § 735.534(2); 40 Pa. Cons. Stat. § 4531(a)(2); 27 R.I. Gen. Laws § 27-41-38.2(c); S.C. Code Ann. § 38-71-2240(A)(1); Tenn. Code Ann. § 56-7-3106(a); Wash. Rev. Code § 19.340.100(2)(a); Wyo. Stat. Ann. § 26-52-104(a).

to appeal reimbursement rates.[39] Some states allow pharmacies to refuse to dispense medication that will be reimbursed below cost.[40] Consistent with its past decisions, in *Rutledge* the Court upheld both types of provisions in Arkansas law. 141 S. Ct. at 479. When a pharmacy declines to dispense a drug, "the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement." *Id.* at 482. Another common provision is North Dakota's prohibition on clawing back reimbursements after claims are adjudicated. N.D. Cent. Code § 19-02.1-16.1(4). Many states regulate claw backs, while some states outright ban them.[41]

3. Transparency regulations

The need for transparency cannot seriously be questioned and states have led absent federal action. Efforts to remedy the lack of transparency in the PBM industry can take many forms but two are most common: (1) laws requiring disclosures from

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[39] *See* Alaska Stat. § 21.27.950(c); Colo. Rev. Stat. § 25-37-103.5(3)(d); Ga. Code Ann. § 33-64-9(e); Haw. Rev. Stat. § 328-106(f)(1)(A); Ky. Rev. Stat. Ann. § 304.l 7A-162(1)(b)(4); La. Stat. Ann. § 22:1865(A); Me. Stat. tit. 24-A, § 4350(6)(B); Md. Code Ann., Ins. § 15-1628.1(f)(4)(ii); Minn. Stat. § 62W.08(c)(3); Miss. Code Ann. § 73-21-156(4)(a); Mo. Rev. Stat. § 376.388(6); N.H. Rev. Stat. Ann. § 402-N:3(l)(b)(3)(B); N.M. Stat. Ann. § 59A-61-4(D)(8); N.D. Cent. Code Ann. § 19-02.l-14.2(2)(d), (f); Ohio Rev. Code Ann. § 3959.111(A)(3)(d); Okla. Stat. tit. 59 § 360(A)(5); Or. Rev. Stat. § 735.534(4); 2021 Tenn. Pub. Acts ch. 568, § 3; Utah Code Ann. § 31A-46-303(4); Wis. Stat. § 632.865(2)(b)(4); Wyo. Stat. Ann. § 26-52-104(f).

[40] *See* Ark. Code Ann. § l 7-92-507(e); La. Stat. Ann. § 22:1860.3(B)(l); Miss. Code Ann. § 73-21-155(5)(a); Mont. Code Ann. § 33-22-174(1).

[41] *See State Policy Options*, *supra* note 30 (reflecting twenty-two states regulate claw backs).

PBMs;[42] and (2) laws prohibiting gag clauses on pharmacies.[43] As U.S. Senator Chuck Grassley stated, "More transparency is needed. The current system is so opaque that it is easy to see why there are many questions about PBMs' motives and practices."[44] Such opacity inhibits plans' and consumers' ability to determine whose interests PBMs are furthering.

Here, North Dakota requires PBMs to make disclosures (N.D. Cent. Code §§19-02.1-16.2(2) and 16.1(10)), while allowing pharmacists to disclose information (N.D. Cent. Code § 16.1(5) and (7)). Minnesota similarly requires PBM disclosures to plan sponsors and the state.[45] Robust transparency regulations allow states to properly serve their regulatory function and give consumers data needed to make informed decisions.

4. Fiduciary duties

Absent legislation, courts have generally held that PBMs do not owe a fiduciary duty to the plan sponsors or participants except in limited circumstances. *E.g.*, *In re Express Scripts, Inc. PBM Litig.*, No. 4:05-MD-01672, 2008 WL 2952787, at *3 (E.D. Mo. July 30, 2008). The lack of a fiduciary duty has prevented

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[42] *Id.* (reflecting more than two-thirds of states require disclosures or prohibit gag clauses).
[43] *Id.*
[44] *Drug Pricing in America: A Prescription for Change, Part III: Hearing before the S. Comm.*, 116th Cong. (statement of Sen. Chuck Grassley).
[45] Minn. Dep't of Commerce, *Public Pharmacy Benefit Manager (PBM) Transparency Report* (Dec. 12, 2020), https://perma.cc/QC2C-UGYZ.

plan participants from even litigating whether PBMs contract with drug manufacturers "in ways that enrich [the PBM] to the detriment of the plan." *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 667, 692 (M.D. Tenn. 2007).

Some states, like Iowa and South Dakota, expressly impose a duty of good faith and fair dealing on PBMs.[46] While North Dakota prohibits PBMs from owning mail-order specialty pharmacies and patient-assistance programs (section 16.2(3)). other states require PBMs to disclose conflicts of interest.[47] States have properly taken the lead on preventing unfair practices, self-dealing, and conflicts of interest.

II. ERISA DOES NOT PREEMPT STATE LAWS GOVERNING TRANSACTIONS BETWEEN PBMS AND PHARMACIES.

To protect consumers and address industry abuses, nearly every state regulates PBMs. To protect PBMs' profits, PCMA claims that ERISA broadly preempts these laws because they supposedly dictate plan benefits. The Court should reject this argument. As long recognized and recently reaffirmed by the Supreme Court, ERISA preempts only laws affecting the "who" and "what" of benefits. *Rutledge*, 141 S. Ct. at 480 (recognizing ERISA's primary concern of preempting laws that

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[46] Iowa Code § 510B.4(1); S.D. Codified Laws § 58-29E-3; *see also* Cal. Bus. & Prof. Code § 4441(c); La. Stat. Ann. § 40:2864(A); Minn. Stat. § 62W.04(a); Nev. Rev. Stat. § 683A.178(1).

[47] Cal. Bus. & Prof. Code § 4441(d); D.C. Code § 48- 832.01(b)(1)(C); 305 Ill. Comp. Stat. 5/5-36(d); Iowa Code § 510B.4(2); Minn. Stat. § 62W.04(b); Nev. Rev. Stat. § 683A.178(2); 27 R.I. Gen. Laws § 27-29.1-7; Vt. Stat. Ann. tit. 18, § 9472(c)(2).

"determine[e] beneficiary status" or require "specific benefits"). The North Dakota laws at issue largely regulate PBM-*pharmacy* relationships, *not* PBM-*beneficiary* or plan-beneficiary relationships. *See, e.g.*, N.D. Cent. Code §§ 19-02.1-16.1(2)-(3), (5), (7)-(11), -16.2(2)-(5) (2020). Only one challenged provision addresses PBM-beneficiary interactions—and that section is a cost regulation permitted under *Rutledge* and not challenged on appeal. N.D. Cent. Code. § 19-02.1-16.1(4) (2020) (prohibiting copays that exceed medications' costs). Because North Dakota's laws do not affect the structure of benefits plans, ERISA does not preempt them.

A. ERISA Did Not Modify the Presumption that Congress Does Not Intend to Supplant State Law.

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) (2018). Congress "unequivocally" did not intend to "modify the starting presumption that Congress does not intend to supplant state law." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 813 (1997). To assert otherwise, PCMA cites the Court's statement in *Puerto Rico v. Franklin California Tax-Free Trust* that, when a statute contains an express preemption clause, the Court focuses on the clause's plain language to determine congressional intent. 136 S. Ct. 1938, 1946 (2016). But this statement—from a non-ERISA case—reflects only the unremarkable proposition that laws within an express preemption clause's scope are preempted. It does not

alter the presumption that if something is *not* within a preemption clause's language—as that language has been interpreted by the Court—it is not preempted.

In *Puerto Rico*, because the Bankruptcy Code "unmistakably" made Puerto Rico a state for preemption purposes, it precluded Puerto Rico from enacting its own code. 136 S. Ct. at 1946. In the ERISA context, in contrast, the Court has repeatedly reinforced the presumption against preemption. *See, e.g.*, *De Buono*, 520 U.S. at 813; *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995).

B. ERISA Preempts Only State Laws Affecting Who Receives Benefits and Which Benefits They Receive.

A state law relates to an ERISA plan if it has a "connection with" or "reference to" a plan. *Travelers*, 514 U.S. at 656. PCMA concedes that *Rutledge* forecloses its "reference to" challenges.[48] This case, therefore, turns on the "connection with" prohibition. In assessing "connections," courts focus on ERISA's goal of avoiding subjecting benefit plans to conflicting state regulation. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98–99 (1983); *see also Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 10 (1987). As reflected by a long line of Supreme Court precedent, laws like North Dakota's do not have a connection to a ERISA plans sufficient to invoke preemption.

[48] Appellant's Br. 22. PCMA also correctly concedes that, even if ERISA or Medicare preempts a state law, the law is not invalidated as to non-ERISA or -Part-D plans. *Id.* at 19 n.1.

A "connection" for ERISA purposes must be more than a potential, incidental impact. For example, the Court rejected an ERISA-preemption challenge to a state law that required hospitals to collect surcharges from patients who did not have insurance from a particular provider. *Travelers*, 514 U.S. at 649. The Court recognized that providers would pass these costs on to the entities paying for the insurance, i.e., ERISA plans. *Id.* at 659. Nevertheless, the statute did not "bind plan administrators to any particular choice and thus function as a regulation of the ERISA plan itself." *Id.* Such "indirect influences" do not preclude a uniform interstate benefit package. *Id.* at 660.

When the Court has held ERISA preempts a law, it has emphasized the central concern ERISA's preemption clause aims to address: could plan administrators determine a beneficiary's benefits merely by looking at plan documents, or would the administrator need to be familiar with fifty states' laws? *Egelhoff v. Egelhoff*, 532 U.S. 141, 148-49 (2001). Using this standard, the Court struck down a statute that automatically revoked a spouse's beneficiary designation upon divorce. *Id.* at 143. Other types of state regulations that could implicate ERISA preemption are laws that conflict with ERISA's reporting, disclosure, and bookkeeping requirements regarding benefits because they are central to uniform systems of plan administration. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 323 (2016).

In *Rutledge*, the Court reaffirmed that ERISA does not preempt regulations that merely "alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." 141 S. Ct. at 480. In rejecting PCMA's arguments, the Court specifically noted that mandating PBM pricing methodologies does not "require plans to provide any particular *benefit* to any particular *beneficiary* in any particular way." *Id.* at 482 (emphases added). In short, the Court reiterated that ERISA preemption is concerned with the *what* and *who* of benefits. But if a statute affects only transactions ancillary to those questions, then it is not preempted.

C. *Rutledge* Is Not Limited to Cost Regulations.

Despite nearly forty years of the Court holding that ERISA does not preempt state laws unless they affect the who or what of benefits, PCMA attempts to limit *Rutledge*'s holding to cost regulations. PCMA is wrong. *Rutledge* reaffirmed that regulations that do not "for[ce] plans to adopt any particular scheme of substantive coverage" are not preempted. 141 S. Ct. at 480.

In arguing otherwise, PCMA relies on the Court's statement that ERISA preempts laws requiring providers to structure benefit plans in particular ways. *Id.* But after noting this uncontroversial point, the Court discussed how to determine when a law has such requirements. *See id.* at 480-81. Nothing in that discussion suggests that only cost regulations are permissible. Although *Rutledge* considered a cost regulation, the Court held—consistent with its precedent—that a law is not

preempted if it does not force plans to adopt particular coverage. *Id.* Indeed, *Rutledge* rejected PCMA's argument that requiring reimbursement at or above drug-acquisition costs effectively denied beneficiaries benefits. The Court noted that the requirement did not alter the *plan's* benefits; rather, any denial resulted from relations between the PBM and the pharmacy. *Id.* at 482. This confirms that, far from *Rutledge* excluding only cost regulations from preemption, statutes that only alter PBM-pharmacy relations—but have no direct effects on plans or beneficiaries—are likewise not preempted.

D. North Dakota's Laws Do Not Affect the Who or What of Beneficiaries' Benefits.

Despite the limits on ERISA's preemptive scope that were reaffirmed in *Rutledge*, PCMA argues that North Dakota's (and essentially all states') PBM regulations are preempted. PCMA is wrong; because none of North Dakota's statutes alter substantive coverage, they are not preempted.

PCMA first challenges sections 16.1(3), (8), (9), (11) and 16.2(4) as altering "network design." None of these sections dictate who get benefits or what benefits they receive. Sections 16.1(3), (11), and 16.2(4) curtail PBMs' ability to impose accreditation or performance-metric requirements on pharmacies beyond those imposed by unbiased third parties. This does not alter the who or what of benefits. Likewise, sections 16.1(8) and (9) stop PBMs from prohibiting pharmacies from mailing prescriptions or charging a shipping fee for doing so. These provisions do

not require plans to cover shipping as a benefit; instead, they merely provide that, if a particular drug from a particular pharmacy is already covered, PBMs cannot stop pharmacies from mailing that drug (and charging a shipping fee) if the patient so desires.

PCMA next challenges sections 16.1(4), (8), (9), and 16.2(5) as affecting "covered drugs and cost sharing." But none of these sections alter drug coverage or costs (except as cost regulations permitted by *Rutledge*). As already discussed, sections 16.1(8) and (9) address only pharmacies' ability to ship drugs, but do not alter benefits. Likewise, section 16.2(5) permits pharmacies to dispense all drugs permitted by their license. This does not mandate coverage, it merely provides PBMs cannot prohibit a pharmacy from dispensing a drug that is *already* covered by a plan. Finally, Section 16.1(4) prohibits PBMs from charging copays that exceed a medication's cost. As in *Rutledge*, this section affects PBM-patient transactions. "ERISA does not pre-empt state rate regulations that merely increase costs . . . ." *Id.* at 480. This is all section 16.1(4) does—it increases PBMs' costs (or rather, decreases entirely unearned profits) by preventing PBMs from charging, for example, $35 for a $5 drug and pocketing the difference.

Next, PCMA, challenges the disclosure requirements of sections 16.1(4), (5), (7), (10), and 16.2(2). Sections 16.1(5) and (7) impose no disclosure requirements on PBMs; they merely prevent PBMs from imposing gag clauses on others. And

section 16.2(2) requires PBMs to disclose information to "plan sponsor contracted payor[s]." But such disclosures are, in effect, disclosures *to ERISA plans*. A disclosure requirement *to* plans cannot be a requirement imposed *on* plans, and therefore cannot implicate ERISA preemption.

This leaves PCMA's disclosure challenges to sections 16.1(4) and 16.1(10). PCMA contests the prohibition on "redacting the adjudicated cost" in section 16.1(4). But as used therein, "redact" means "*reduce* the adjudicated cost;" it does not require any disclosures. (N.D. Appx 30-31.) Section 16.1(10) requires PBMs to provide pharmacies with "the processor control number, bank identification number, and group number for each pharmacy network" the PBM establishes or administers. PCMA relies on *Gobeille* to assert preemption. But *Gobeille* did not hold that ERISA preempts *all* state disclosure requirements. Instead, the Court considered whether disclosure requirements were "central to, and an essential part of, the uniform system of plan administration contemplated by ERISA." *Gobeille*, 577 U.S. at 323. Not all disclosure requirements implicate those concerns.

This leads to a major problem with PCMA's sweeping preemption approach. In contrast to the information sought in *Gobeille* (member eligibility, medical claims, and pharmacy claims), the information required by section 16.1(10) is not "central to uniform plan administration." Instead, North Dakota only requires reporting financial information about PBM pharmacy networks, which is PBM-

business information, *not* plan information. This information is, at best, ancillary to plan administration and therefore the disclosure requirement is not preempted.

Finally, PCMA challenges sections 16.2(2) and (3), which address self-dealing. As with each other challenged section, however, these sections do not alter the who or what of plan benefits. As previously discussed, section 16.2(2) is a disclosure requirement from PBMs to plans. And section 16.2(3) does not alter coverage. It merely ensures that PBMs cannot self-deal when doing so would violate fiduciary duties.

III. MEDICARE PREEMPTS ONLY STATE LAWS THAT CONFLICT WITH A MEDICARE STANDARD.

PCMA also asserts that Medicare Part D preempts North Dakota's PBM laws. Unlike ERISA preemption, Medicare preemption is a much more particularized inquiry depending on the state law and the relevant Medicare standards. Nevertheless, PCMA makes two overarching arguments on Medicare preemption that are so sweeping—and incorrect—that they must be addressed by the amici states.

Medicare's preemption clause states, "[t]he standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [prescription-drug] plans." 42 U.S.C. § 1395w-26(b)(3) (2018) (Medicare Part C preemption provision); *see also id.* § 1395w-112(g) (2018) (adopting Part C's preemption provision for Part D

prescription-drug plans). If no conflicting Medicare standard on a subject exists, then nothing preempts a state law. *Rutledge*, 891 F.3d at 1113; *see also Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148-49 (9th Cir. 2010).

PCMA's preemption analysis conflicts with the plain language of the law and aims to eradicate states' traditional police powers. First, PCMA suggests virtually all state regulation of PBM-pharmacy contracts is preempted because Medicare requires that plans permit participation of "any pharmacy that meets the terms and conditions under the plan" and that plan contracts have "reasonable and relevant terms and conditions of participation." 42 U.S.C. § 1395w-104(b)(1)(A) (2018); 42 C.F.R. § 423.505(b)(18) (2020). But the Centers for Medicare & Medicaid Services (CMS), the federal agency responsible for administering Medicare, has considered and rejected this position. During a rulemaking process, for example, CMS responded to concerns about a North Dakota PBM law by stating CMS "continue[s] to believe state pharmacy practice acts represent a reasonably consistent minimum practice." *Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-For Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, 83 Fed. Reg. 16,440, 16,598 (Apr. 16, 2018).

If CMS's standards preempted such laws, CMS would have said so; but it did not. PCMA argues CMS addressed only state standards as regulatory floors, not

PBMs' ability to impose additional requirements. But this misses a necessary premise underlying CMS's position—if some state regulation is permissible, then the any-willing-pharmacy and reasonable-and-relevant requirements do not generally preempt state laws regulation of PBM-pharmacy relations. Otherwise, even regulatory-floor laws would be preempted.

Such a broad view of Medicare preemption also belies the historic balance between Medicare and adjacent state regulations. *Cf. Med. Soc'y of State of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992) (recognizing that regulating public health and medical-care costs "are virtual paradigms of matters traditionally within the police powers of the state"). Indeed, states sometimes lead the way, with federal laws eventually catching up. For example, Congress amended Medicare in 1997 to require marketing-material review. Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 285-86 (1997). Before 1997, some states had laws to prevent fraudulent solicitations, deceptive advertising, and misrepresentations in the enrollment process. *See, e.g.*, *Solorzano v. Superior Court*, 13 Cal. Rptr. 2d 161, 167-70 (Cal. Ct. App. 1992). While the federal law then preempted conflicting state laws in this area, states were the leaders. *E.g.*, *Uhm*, 620 F.3d at 1157. Here, the lack of CMS standards necessarily means that PCMA's preemption claims fail. Although CMS could theoretically promulgate standards that may, in some

circumstances, preempt states' PBM regulations, unless CMS does so, states are free to continue protecting their consumers by prohibiting unscrupulous actions.

Second, PCMA asserts preemption because Medicare prohibits states from interfering in negotiations between pharmacies and PBMs. Although this Court endorsed this view in *Rutledge*, 891 F.3d at 1113, respectfully, the argument has no basis in Medicare's text, which prohibits only "the Secretary [of Health and Human Services]" from interfering in negotiations or requiring particular formularies or price structures. 42 U.S.C. § 1395w-111(i) (2018). And even if it applied to the states, it applies only to "negotiations or disputes involving payment related contractual terms." 83 Fed. Reg. at 16,590. It does not apply to regulations that "promote competition," "increas[e] the transparency of prices," or "minimiz[e] barriers to entry." *Id.* North Dakota's PBM regulations, and many state regulations, squarely fall into these categories, and as a result, they are not preempted.

CONCLUSION

PBMs market abuses have caused numerous harms, which states are attempting to curtail by placing reasonable restrictions on PBM-pharmacy contracts that increase transparency, discourage rent-seeking behavior, and reduce self-dealing. State laws to this effect do not alter substantive coverage of ERISA plans, and therefore they are not preempted. PCMA's arguments in favor of broad

Medicare preemption of state laws are similarly misplaced. Accordingly, the Court should affirm the district court.

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CERTIFICATE OF COMPLIANCE
WITH FED. R. APP. P. 32

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(A)(4)(G) and (5) because this brief contains 6,302 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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The undersigned, on behalf of the party filing and serving this brief, certifies that the brief has been scanned for viruses and that the brief is virus-free.

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I certify that I caused this document to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system on July 1, 2021. All participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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