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 State Health Officer of North Dakota; MARK J. HARDY, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; TYLER LANNOYE, in his official capacity as the President of the North Dakota Board of Pharmacy; WAYNE STENEHJEM, in his official capacity as the Attorney General of North Dakota
Defendants-Appellees.

On Appeal from the United States District Court for
the District of North Dakota, Southern Division

BRIEF OF THE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, NORTH DAKOTA PHARMACISTS ASSOCIATION, AND SIX OTHER STATE PHARMACY ASSOCIATIONS AS *AMICI CURIAE* SUPPORTING DEFENDANTS-APPELLEES AND AFFIRMANCE

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state as follows:

1. The National Community Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

2. The American Pharmacists Association (APhA) has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

3. The Arkansas Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

4. The Iowa Pharmacy Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

5. The Minnesota Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

6. The Missouri Pharmacy Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

7. The Nebraska Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

8. The North Dakota Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

9. The South Dakota Pharmacists Association has no parent corporation, and no publicly traded company owns ten percent or more of its stock.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are trade associations that represent pharmacists and pharmacy owners. The North Dakota laws that Appellant Pharmaceutical Care Management Association (PCMA) challenges as preempted under federal law—N.D. Cent. Code §§ 19-02.1-16.1 and 16.2—regulate how pharmacy benefit managers (PBMs) transact with pharmacies. *Amici* are comprised of members whom the North Dakota Legislative Assembly sought to protect.

The National Community Pharmacists Association (NCPA) was founded in 1898 and represents the interests of the owners, managers, and employees of more than 21,000 independent community pharmacies across the United States. NCPA's members employ over 250,000 individuals on a full or part-time basis and dispense approximately forty percent of the nation's retail prescriptions.[1]

The American Pharmacists Association (APhA) is the largest association of pharmacists in the United States and advances the interests of the entire pharmacy profession. Founded in 1852, APhA membership represents nearly 50,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care.

[1] All parties consent to the filing of this brief. No counsel for any party in this case authored this brief in whole or in part. No person or entity—other than *amici*, their members, or their counsel—made a monetary contribution specifically for the preparation or submission of this brief.

The remaining *amici* are State-level associations representing the interests of pharmacists from the seven states within the Eighth Circuit: Arkansas Pharmacists Association; Iowa Pharmacy Association; Minnesota Pharmacists Association; Missouri Pharmacy Association; Nebraska Pharmacists Association; North Dakota Pharmacists Association; and South Dakota Pharmacists Association.

Because their members deal daily with PBMs, *amici* can offer a unique perspective on the need for State-level regulation of PBMs. They can explain how PBMs operate as middlemen service providers between healthcare plans and pharmacies. They also can illustrate how PBMs leverage concentrated market power to the detriment of healthcare plans, pharmacies, and patients, and show how that conduct negatively impacts the availability of pharmacy services, particularly in rural areas.

In addition, *amici* can provide insight regarding the nature of PBMs and how they differ from third-party administrators who administer ERISA plans on behalf of employers. They can explain why PBMs cannot comply with the fiduciary duties that Congress imposed on plan administrators in 29 U.S.C. § 1002(21)(A), because PBMs' business model is contrary to the interests of ERISA plans and their beneficiaries. They also can provide insight into how this Court's interpretation of the preemptive force of ERISA and Medicare could affect (and, if

erroneously decided, severely limit) the States' exercise of their historic police powers to regulate health care.

ARGUMENT

I. States Have Compelling Reasons to Regulate PBMs.

PBMs operate as middlemen between health care plans and the pharmacies that their beneficiaries use. *Rutledge v. Pharm. Care Mgmt. Assoc.*, 141 S. Ct. 474, 478 (2020). They organize networks of pharmacies and develop drug formularies (lists of covered drugs) that they offer to manage for health plans, but ultimately it is the health plan, and not a PBM, that must decide who is eligible and what drugs to make available to beneficiaries.

PBMs generate profit in several ways. They charge health plans more for a beneficiary's drug purchase than they pay to the pharmacy, and "that difference generates a profit for PBMs." *Id.* In some cases, PBMs pay a pharmacy less than the pharmacy's cost to acquire the drug, a "negative reimbursement," creating a risk that "many pharmacies, particularly rural and independent ones," will lose money and close. *Id.* at 478-479. PBMs also charge pharmacies "performance-based" fees purportedly to incentivize pharmacies to perform better. They also profit from rebates that drug manufacturers pay to have their drugs placed and preferred on drug formularies. *See Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 298 (1st Cir. 2005).

The three largest PBMs or their owners—CVS Caremark (a subsidiary of CVS Health), OptumRX (a subsidiary of UnitedHealth Group), and Express Scripts (a subsidiary of Cigna)—are ranked four, five, and thirteen, respectively, on the Fortune 500 list of largest United States companies. *See Fortune 500*, Fortune (2021).[2] These PBMs claim to provide services for more than 268 million Americans—over 85% of all Americans with health insurance.[3]

PBMs also establish affiliated pharmacies to compete with the pharmacies in their network. The three largest PBMs own large mail-order pharmacies.[4] They own three of the four largest specialty pharmacies. *2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2020). CVS also owns one of the largest retail pharmacy chains in the country. *See U.S. National Pharmacy Market Summary*, IQVIA (July 2019).

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[2] https://fortune.com/fortune500/.

[3] *See CVS Health Announces $2.5 Million in New Funding to Help Build Healthier Communities in Ohio*, CVS Health, https://cvshealth.com/news-and-insights/press-releases/cvs-health-announces-25-million-in-new-funding-to-help-build (claiming to serve for "more than 102 million plan members"); *What's a Pharmacy Benefit Manager?*, Express Scripts, https://www.express-scripts.com/corporate/articles/whats-pharmacy-benefit-manager (claiming to serve "100 million people"); *Pharmacy benefit management solutions*, OptumRx, https://professionals.optumrx.com/services/pbm.html (claiming to serve "over 66 million members").

[4] *See CVS Caremark Mail Service Pharmacy*, https://www.caremark.com/manage-prescriptions/rx-delivery-by-mail.html; *Express Scripts Pharmacy Home Delivery Program*, https://www.express-scripts.com/rx; *OptumRX Mail Service Pharmacy*, https://www.optumrx.com/public/landing.

A. PBMs Wield Concentrated Market Power.

North Dakota Century Code § 19-02.1-16.1 (Section 16.1) and § 19-02.1-16.2 (Section 16.2), like similar laws enacted by other States, are designed to constrain how PBMs wield concentrated market power. One industry study found that three PBMs accounted for 77% of the market in 2020. *The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute (Mar. 2021).

PBMs use this power to maximize what health plans pay and minimize what pharmacies (not affiliated with the PBM) receive. The big three PBMs offer pharmacies a Hobson's choice—either accept the PBM's mandated contract terms or lose the many customers whose health plans contract with that PBM. Those terms typically grant PBMs unilateral authority to: set the reimbursement for generic drugs; require pharmacies to dispense prescriptions at a loss; limit which drugs a pharmacy may dispense; prohibit pharmacies from competing for mail order service; and even restrict what pharmacists tell their patients.

Pharmacies have no choice but to accept PBMs' take-it-or-leave-it terms. Over 97 percent of pharmacies in the United States are in an Express Scripts network. *In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655, 663 (S.D.N.Y. 2018). The GAO has found that most Prescription Services Administrative Organizations (PSAOs are cooperative networks for independent

pharmacies) "hav[e] little success in modifying certain contract terms" with PBMs given the "dominant market share of the largest PBMs." *Prescription Drugs: The Number, Role, and Ownership of Pharmacy Services Administrative Organizations*, GAO Report to the Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives at 17 (Jan. 2013), GAO-13-176. Recent "increasing consolidation of entities in the PBM market … has diminished the" already minimal "ability of PSAOs to negotiate with them." *Id.*

B. PBMs Leverage Concentrated Market Power to Force Pharmacies to Accept Financially Oppressive Practices.

PBMs profit by maximizing the difference between what they pay pharmacies for a drug and the inflated amount they charge a plan for that same transaction. For example, a PBM billed an Iowa county $198.22 for a drug for which it paid the pharmacy $5.73—a markup of more than 3,400%. *See* R. Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, Bloomberg (Sept. 11, 2018).[5] As a result, many States limit such practices. *Id.*

PBMs sometimes maximize the spread by paying negative reimbursements to pharmacies. *See* L. Sullivan, *Powerful, secretive middlemen affect drug prices*,

[5] https://www.bloomberg.com/graphics/2018-drug-spread-pricing/.

Columbus Dispatch (May 19, 2018);[6] *see also* R. Wang, *Stark pharmacies struggle amid PBM issues; CVS offered to buy stores*, Columbus Dispatch.[7] They also impose retroactive fees without warning weeks or months after the pharmacy dispenses a drug. According to the Centers for Medicare & Medicaid Services (CMS), the post-sale fees PBMs charge to pharmacies "grew more than 91,500 percent between 2010 and 2019." *Justification of Estimates for Appropriations Committees*, CMS, U.S. Department of Health and Human Services (HHS) at 242 (FY 2022).[8] No competitive market force justifies such an exponential growth in fees, which are a key reason for recent pharmacy closures. Xil Consulting, *Payers and PBMs Profit from Obscure Pharmacy Fees, While Seniors See No Relief in Prescription Costs* (Feb. 11, 2020).[9]

PBMs also reduce competition by steering patients to their affiliated pharmacies. *See* K. Thomas, *Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out*, N.Y. Times (Jan. 9, 2017).[10] As CMS has recognized, "[m]arket competition is best achieved when a wide variety of pharmacies are able

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[6] https://www.dispatch.com/news/20180519/powerful-secretive-middlemen-affect-drug-prices.
[7] https://stories.usatodaynetwork.com/sideeffects/stark-pharmacies-struggle-amid-pbm-issues-cvs-offered-buy-stores/site/dispatch.com/.
[8] https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf.
[9] https://ncpa.org/sites/default/files/2021-01/xil-consulting-dir-analysis.pdf.
[10] https://nyti.ms/2jmugmO.

to compete in the market for selective contracting with plan sponsors and PBMs," not when PBMs can simply direct patients to themselves. 83 Fed. Reg. at 62,176.

PBMs steer patients to affiliated pharmacies by prohibiting other pharmacies from distributing "specialty drugs," which traditionally were a small category of higher-cost drugs that require special handling. PBMs have been expanding the designation of "specialty drugs" to include non-specialty medications that have been on the market for a long time. D. Rowland, *Specialty drugs: The new arena for pharmacy benefit manager profits?*, Columbus Dispatch (Apr. 24, 2019).[11] By 2022, specialty drugs likely will account for 47% of total prescription dispensing revenues. A. Fein, *The Top 15 Specialty Pharmacies of 2017: PBMs and Payers Still Dominate*, Drug Channels Institute (Mar. 13, 2018).[12]

CMS has expressed concern that PBMs are using pharmacy contracts "in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies" and has nothing to do with patient health. *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 82 Fed. Reg. 56,336, 56,410 (Nov. 28, 2017). For example, PBMs force beneficiaries to obtain drugs from their affiliated mail-order pharmacies that could be obtained at a corner drug store, which can endanger the health of patients on medications affected by extreme

[11] https://www.dispatch.com/news/20190423/specialty-drugs-new-arena-for-pharmacy-benefit-manager-profits.
[12] https://www.drugchannels.net/2018/03/the-top-15-specialty-pharmacies-of-2017.html.

temperatures. A. Smith, *Extreme Temperatures May Pose Risks To Some Mail-Order Meds*, NPR (Jan. 7, 2019).[13] This danger is particularly acute in North Dakota. *See* Declaration of Mark J. Hardy at ¶ 13 (Mar. 7, 2018), N.D.Appx.26.

PBMs' predatory conduct is driving competing pharmacies out of business while PBM-affiliated pharmacies prosper. In Ohio, for example, CVS Caremark drove hundreds of pharmacies out of business with low reimbursements, steering of patients to CVS pharmacies, and high post-transaction fees. *See* M. Schladen & D. Caruso, *Pharmacy 'deserts' appear in Ohio as stores close amid drug pricing debate*, Columbus Dispatch (July 7, 2019).[14] After CVS Caremark squeezed hundreds of small pharmacies to the brink of financial ruin, CVS's director of acquisitions sent a letter to independent pharmacies in Caremark's Ohio network offering to acquire them cheaply: "'I know what independents are experiencing right now: declining reimbursements, increasing costs…. Mounting challenges like these make selling your store to CVS Pharmacy an attractive and practical option.'" C. Candisky et al., *Three CVS actions raise concerns for some pharmacies, consumers*, Columbus Dispatch (Apr. 15, 2018).[15]

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[13] https://www.npr.org/sections/health-shots/2019/01/07/673806506/extreme-temperatures-may-pose-risks-to-some-mail-order-meds.
[14] https://stories.usatodaynetwork.com/sideeffects/stingy-pharmacy-reimbursements-leave-ohio-communities-on-the-brink/site/dispatch.com/.
[15] https://www.dispatch.com/news/20180415/three-cvs-actions-raise-concerns-for-some-pharmacies-consumers.

As a result of such pressure, 132 independent pharmacies, 78 small chain pharmacies, and 161 large chain pharmacies closed in Ohio from 2013 to 2018. *See Ohio's Medicaid Managed Care Pharmacy Services*, Auditor of State Report at 14 (August 16, 2018).[16] During relatively the same time period, CVS has "opened approximately 790 new and relocated locations and acquired approximately 1,810 locations" nationwide. CVS Health Corp., Annual Report (Form 10-K) at 7 (Feb. 18, 2020). The Ohio Medicaid Director stressed that the same predatory conduct "is impacting all 50 states." C. Candisky & M. Schladen, *CVS accused of using Medicaid rolls in Ohio to push out competition*, Columbus Dispatch (Mar. 12, 2018).[17] Even big companies are not spared. Walmart—the world's largest company—has attributed significant financial losses to unilaterally-imposed reduced reimbursement rates from PBMs. *See* Walmart, *Fortune 500*, Fortune (2021);[18] N. Layne, *Walmart has a drug problem*, Business Insider (Aug. 18, 2015).[19]

PBMs also reimburse affiliated pharmacies substantially more than they pay non-affiliated pharmacies. CVS Caremark, for example, paid CVS pharmacies

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[16] https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.
[17] https://www.dispatch.com/news/20180312/cvs-accused-of-using-medicaid-rolls-in-ohio-to-push-out-competition.
[18] https://fortune.com/company/walmart/fortune500/.
[19] https://www.businessinsider.com/r-wal-marts-drug-problem-pharmacy-business-drags-on-profit-2015-8.

forty-six percent more for generic drugs than it paid pharmacies at Walmart and Sam's Club. M. Schladen & C. Candisky, *CVS paid itself far more than some major competitors*, Columbus Dispatch (Jan. 20, 2019).[20] And CVS paid itself over *five times* as much as it reimbursed independent pharmacies in Arkansas for some medications. L. Lopez, *What CVS is doing to mom-and-pop pharmacies in the US will make your blood boil*, Business Insider (Mar. 30, 2018).[21]

Abusive PBM reimbursement practices have driven more than sixteen percent of independent rural pharmacies out of business. A. Salako et al., *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis (July 2018).[22] In North Dakota, ten rural zip codes have recently lost their only pharmacy. *Id.*

C. PBMs' Exploitation of Concentrated Market Power Harms Healthcare Plans and Beneficiaries.

PBMs exploit inherent conflicts of interest to generate profit at the expense of health care plans and beneficiaries beyond merely maximizing the spread between what PBMs receive from plans and pay to pharmacies. PBMs create drug formularies—lists of covered drugs—for health care plans to adopt. Drug

[20] https://www.dispatch.com/news/20190120/cvs-paid-itself-far-more-than-some-major-competitors-report-says.
[21] https://www.businessinsider.com/cvs-squeezing-us-mom-and-pop-pharmacies-out-of-business-2018-3.
[22] https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

companies offer PBMs rebates to include their drugs on those formularies, and they link the size of the rebate to the cost of the drug to incentivize PBMs to give priority to more expensive drugs. *See* Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale L. & Pol'y Rev. 360, 362 (2020). HHS described these rebates as "creat[ing] a perverse incentive that rewards manufacturers for increasing their list price, while subjecting consumers to higher out-of-pocket costs." *Fraud and Abuse; Removal of Safe Harbor Protection*, 85 Fed. Reg. 76,666, 76,667 (Nov. 30, 2020); *see also* 84 Fed. Reg. at 2341 ("A manufacturer choosing to lower the list price of a drug would be reducing … the size of the rebate…. This could result in a drug being removed from the formulary or being placed in a less-preferred formulary tier. As a result, the current system works to the disadvantage of beneficiaries….").

PBMs also encourage drug price increases to get bigger rebates. "Drug makers assert that they are pressured to increase drug list prices out of fear that, if they do not, PBMs will retaliate by dropping their drugs from the formularies." 38 Yale L. & Pol'y Rev. at 362. PBMs typically do not disclose these rebates, or their spread, to health plans. *See id.* at 376; K. Eban, *Painful prescription*, Fortune (Oct. 10, 2013).[23] PBMs even contract for "the ability to switch out an originally

[23] https://fortune.com/2013/10/10/painful-prescription/.

prescribed drug in favor of another drug within the same therapeutic class that has more favorable rebate terms." 38 Yale L. & Pol'y Rev. at 377. "PBMs have paid [eight-figure] settlements … to resolve allegations that they switched patients to higher-cost drugs on the formulary in order to realize higher rebates." *Id*.

Rebates have steadily increased in recent years, with PBMs taking the lion's share. Between 2012 and 2016, "over half of the increase in list price purchases was paid to PBMs as higher rebates," meaning that "although drug list prices are increasing, drug makers are keeping a decreasing share of the revenue while PBMs are keeping an increasing share." *Id.* at 378. According to one recent study of publicly reported data from six major pharmaceutical manufacturers, the list price of brand name drugs increased by an average of 2.9% in 2020, while the amount that manufacturers kept after paying rebates and other deductions fell by 3.1%. *See* A. Fein, *Gross to Net Bubble Update: Net Prices Drop Again at Six Top Drug Makers*, Drug Channels (Apr. 14, 2021).[24] The manufacturers paid, on average, 51.9% of their list prices as rebates and other deductions. *Id.* Another study found that PBM rebates, at $143 billion in 2019, add nearly 30 cents per dollar to the price consumers pay for prescriptions.[25]

[24] https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html#more.

[25] Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines, IQVIA (Aug. 2020) https://www.iqvia.com/-

PBMs' response to the opioid epidemic illustrates how they leverage market power to the detriment of health care plans and beneficiaries. Buprenorphine-Naloxone is a life-saving drug that "can quickly restore normal breathing and save the life of a person who is overdosing on opioids." *Naloxone for Opioid Overdose: Life-Saving Science*, National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services.[26] Pharmaceutical manufacturers dropped the drug's price to make it more affordable. "From 2016 Q1 to 2018 Q4, [the] average acquisition cost [at which pharmacies purchased] Buprenorphine-Naloxone 8-2 mg SL tablet fell by 60%." HPC Datapoints, Massachusetts Health Policy Commission at 4-5 (June 5, 2019).[27] Over the same time period, "the MassHealth MCO price increased by 13%" because PBMs responded to the price drop by increasing their spread. *Id.* PBMs "now realize larger revenues than most drug manufacturers even though they engage in almost no innovation, bear little risk, and, unless they own a mail-order or specialty pharmacy, do not even take possession of drugs." 38 Yale L. & Pol'y Rev. 360 at 372.

/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf?_=1623260814916.

[26] https://www.drugabuse.gov/publications/naloxone-opioid-overdose-life-saving-science.

[27] https://www.mass.gov/doc/datapoints-issue-12-printable-version/download.

D. PCMA Seeks a Regulatory Vacuum for PBMs.

PBMs consistently have resisted regulation, including taking contradictory positions before federal regulators and this Court. When the Department of Labor considered a federal regulation that would require ERISA plan fiduciaries to obtain information from a PBM about how it calculates drugs prices and fees, PBMs argued that existing state laws made any such regulation unnecessary. *See PBM Compensation and Fee Disclosure*, Advisory Council on Employee Welfare and Pension Benefit Plans, U.S. Department of Labor at 18 (Nov. 2014).[28] Yet in this case and others, PCMA argues that ERISA preempts those same state laws. *See, e.g.*, *Rutledge*, 141 S. Ct. at 479. The combined effect of those contradictory positions is to forestall any regulation that limits how PBMs leverage concentrated market power to the detriment of plans, patients, and pharmacies.

II. PBMs Are Not ERISA Plans or Third-Party Plan Administrators.

PCMA and its supporting *amici* argue that this Court should treat North Dakota's regulation of PBMs as regulation of the ERISA plans they serve. PCMA argues that the district court erred by considering how "the laws here apply only to PBMs and 'do[] not impose any requirements on ERISA plans themselves.'" PCMA Br. at 31. The Chamber of Commerce (CoC) argues that it does not "matter" that the North Dakota laws impose regulations on PBMs rather than

[28] https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure.pdf.

ERISA plans. CoC Br. at 17. The Health Insurance Plans (HIP) argue that "PBMs are a type of specialized TPA that manage prescription drug benefits for ERISA Plans." HIP Br. at 12. They then argue that regulations of third-party administrators (TPAs) are regulations of ERISA Plans because TPAs provide "functions and services [that] relate to components of plan design and administration." *Id.* at 16.

Contrary to these arguments, PBMs are neither ERISA plans nor TPAs that administer such plans. They are mere service providers who negotiate at arms-length with ERISA plans. Under ERISA, PBMs cannot exercise any discretion regarding the administration or management of an ERISA Plan because they are not plan fiduciaries.

Congress specified in 29 U.S.C. § 1002(21)(A) that any person who exercises discretion in the administration or management of a plan must assume the fiduciary duties that a plan owes to its beneficiaries. Section 1002(21)(A) states in pertinent part:

> a person is a fiduciary with respect to a plan to the extent (i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, … or (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan.

As a result, a PBM cannot exercise *any* discretion in plan administration without

becoming a plan fiduciary.

Courts have near universally held that PBMs are not ERISA fiduciaries when they manage a plan's prescription drug benefit. *See, e.g.*, *Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 473 (7th Cir. 2007); *Rowe*, 429 F.3d at 300; *Doe 1 v. Express Scripts, Inc.*, 837 F. App'x 44, 49 (2d Cir. 2020); *In re United Health Grp. PBM Litig.*, No. 16-cv-3352, 2017 WL 6512222, at *9-10 (D. Minn. Dec. 19, 2017); *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 677 (M.D. Tenn. 2007).

PCMA disavows that PBMs exercise any discretion in plan administration. "Unlike plan sponsors, PBMs do not exercise independent discretion … and are not plan fiduciaries." PCMA Br. at 9. PBMs undeniably exercise discretion when they construct the pharmacy networks by deciding who is in, who is out, and on what terms. However, the Supreme Court has held that an ERISA service provider does not become a fiduciary "merely because it administers or exercises discretionary authority over its own … business." *Pegram v. Herdrich*, 530 U.S. 211, 223 (2000). PBMs have successfully invoked this doctrine to argue that they merely pre-package options, and that an ERISA plan exercises all relevant discretion when it selects from those options in an arms-length transaction with the PBM. *See, e.g.*, *Moeckel*, 622 F. Supp. 2d at 677; *Am. Drug Stores, Inc. v. Harvard Pilgrim Health Care, Inc.*, 973 F. Supp. 60, 68 (D. Mass. 1997).

PCMA must take this position because ERISA requires plan fiduciaries to act solely in the interests of the plan's participants and beneficiaries. *See* 29 U.S.C. § 1104(a)(1). PBMs make money by maximizing the spread between what they charge a healthcare plan and what they pay the dispensing pharmacy for each drug transaction. *Rutledge*, 141 S. Ct. at 478. They also engage in other activities that benefit "PBMs financially to the detriment of health benefit providers." *Rowe*, 429 F.3d at 298 (discussing examples). As a result, PBMs cannot exercise *any* discretion in the administration of an ERISA Plan without breaching the fiduciary duties that Congress imposed in 29 U.S.C. § 1002(21)(A). PBMs cannot be TPAs for the same reason.[29] Thus the arguments by *amici* supporting PCMA about how state regulation of *bona fide* TPAs could disrupt uniform plan design and administration have no bearing on this case. *See* CoC Br. at 17-20; HIP Br. at 9-12 and 16-20.

III. ERISA Does Not Preempt the North Dakota Laws.

Sections 16.1 and 16.2 do not have an impermissible "connection with" ERISA plans for purposes of ERISA preemption because they primarily regulate the relationship between PBMs and pharmacies. They do not govern matters of

[29] The Chamber of Commerce's attempt to cast PBMs as ERISA plan "agents" fails for the same reason. *See* CoC Br. at 21. "The relation of an agent to his principal 'is universally recognized as being fiduciary in nature.'" *International Env't Mgmt., Inc. v. United Corp. Servs., Inc.*, 858 F.3d 1121, 1125 (8th Cir. 2017).

plan administration. Earlier in this litigation, PCMA conceded that Sections 16.1 and 16.2 do "not increase coverage or benefits" "under any ERISA plan," and they "in large part, only define the relationship between pharmacies and PBMs or third party payers." Mem. in Support of PCMA's Mot. for Summ. J. 21, *Pharm. Care Mgmt. Ass'n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D.) (No. 1:17-cv-141), Dkt. No. 33-1 (2018 WL 9561645).

Because PBMs cannot be ERISA fiduciaries, they cannot engage in *any* of the plan administration activities that Congress sought to protect from state interference. Those activities include "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987).

PCMA therefore is wrong when it argues that "[i]t does not change matters that Sections 16.1 and 16.2 apply most immediately to PBMs rather than plan sponsors themselves." PCMA Br. at 16. As the United States correctly argued as *amicus* in *Rutledge*, state regulation is not preempted where it "imposes obligations on PBMs, not plans." Br. for U.S. as *Amicus Curiae*, *Rutledge*, 2020 WL 1190622, at 27 (U.S. Mar. 2, 2020). CoC attacks this argument, noting that the government acknowledged in oral argument that "ERISA preemption 'focuses on *what* is being

regulated'—*i.e.* 'plan administration'—rather than 'who.'" CoC Br. at 19. In the case of PBMs, the "who" being regulated limits the "what." Regulation of PBMs cannot regulate plan administration, because PBMs as non-fiduciaries cannot administer plans.

Because PCMA and its *amici* cannot show how laws that regulate PBMs interfere with administration of ERISA *plans*, they employ a bit of sleight-of-hand to argue that Sections 16.1 and 16.2 regulate the administration of plan *benefits*. *See, e.g.*, PCMA Br. at 8; HIP Br. at 12. Every health care service can be described as a plan benefit. If ERISA preempted State regulation of benefits, States could not regulate health care at all. Yet "nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995).

In *Fort Halifax Packing Co.*, the Supreme Court held that "[t]he argument that ERISA pre-empts state laws relating to certain employee benefits, rather than to employee benefit *plans*, is refuted by the express language of the statute, the purposes of the preemption provision, and the regulatory focus of ERISA as a whole." 482 U.S. at 9 (emphasis in original). The Supreme Court noted that "ERISA's pre-emption provision" "does not refer to state laws relating to 'employee benefits,' but to state laws relating to 'employee benefit *plans*." *Id.* at 7.

If preemption applied "expansively" to invalidate state laws that regulate how benefits are provided, "the word 'plan' [would] in effect be read out of the statute." *Id.* at 8. Such a reading would far exceed Congress's goal of affording "employers the advantages of a uniform set of administrative procedures." *Id.* at 12.

By focusing on the administration of benefits, PCMA fails to distinguish PBMs from hospitals, which similarly create networks of providers to administer health care services to beneficiaries. The Supreme Court established in *Travelers* that generally applicable laws regulating how health care is provided usually will not trigger ERISA preemption. It held that treating a surcharge on certain health care services provided by hospitals as a regulation of ERISA plan administration for purposes of preemption would "bar any state regulation of hospital costs." 514 U.S. at 665. It described such a result as "unsettling" and "startling," particularly because "there is not so much as a hint in ERISA's legislative history or anywhere else that Congress intended to squelch these state efforts." *Id.*

Additionally, any suggestion that PBMs' administration of pharmacy benefits is a matter of plan administration is irreconcilable with PCMA's denial that such activities are plan administration to avoid ERISA's fiduciary obligations. *Compare* PCMA Br. at 23-25 with PCMA Br. at 9. PCMA cannot have it both ways. PBMs' management of pharmacy benefits cannot be a "central matter of

plan administration" for ERISA preemption without triggering ERISA's fiduciary obligations.

Because PCMA focuses on arguing how Section 16.1 and 16.2 regulate *benefits* rather than *plans*, it does not even try to explain how laws that merely regulate how PBMs transact with pharmacies could interfere with the uniform administration of ERISA plans when PBMs, as non-fiduciaries, are disqualified categorically from exercising discretion to administer plans. Even a brief analysis of the challenged provisions in Sections 16.1 and 16.2 confirm that those provisions do not "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." *Rutledge*, 141 S. Ct. at 480.

Sections 16.1(11), 16.2(4), and 16.2(5) prohibit a PBM from requiring pharmacies to forgo dispensing drugs that they are licensed by the state to dispense as a condition for inclusion in a PBM's networks. Sections 16.1(8) and 16.1(9) prohibit a PBM from requiring pharmacies to forgo dispensing drugs by mail and charging shipping and handling fees. These laws limit how PBMs can leverage market power to channel transactions to their affiliated pharmacies without interfering with plan administration.

In these provisions, North Dakota merely defines the privileges conferred by the pharmacy licenses that it issues. The provisions do not impact plan structure or administration any differently than, for example, a state law that only a licensed doctor may perform surgery. They do not dictate plan choices by requiring an ERISA plan to cover any drug or include any pharmacy in a network. As a result, they are distinguishable from the "any willing provider" law at issue in *Kentucky Association of Health Plans v. Miller*, 538 U.S. 329 (2003), which required plans to include providers in their networks. *See* PCMA Br. at 23. The North Dakota licensing provisions merely provide that a PBM cannot forbid a pharmacy in its network from dispensing a drug that the pharmacy is licensed to dispense in a manner that State law allows.

PCMA also challenges two provisions that permit, but do not require, pharmacists to disclose information to patients and ERISA plans. Section 16.1(5) allows pharmacists to disclose how much a PBM paid the pharmacy. Section 16.1(7) allows pharmacists to provide "relevant information to a patient if the patient is acquiring prescription drugs," including "the cost and clinical efficacy of a more affordable alternative." Both provisions override gag clauses that PBMs commonly use to prevent pharmacists from informing patients that they could save money by paying out-of-pocket because the PBM-set co-payment is more expensive than the pharmacy's price for the drug. *See* R. Pear, *Why Your*

Pharmacist Can't Tell You That $20 Prescription Could Cost Only $8, N.Y. Times, Feb. 24, 2018.[30] These provisions do not require an ERISA plan to do anything. Moreover, ensuring that health care providers have freedom to provide accurate information to patients falls squarely within the category of "general health care regulation" that ERISA was never intended to preempt. *See Travelers*, 514 U.S. at 661.

Section 16.2(2) is similarly permissive as it applies to plans. It provides that "[i]f requested by a plan sponsor," a PBM that has an ownership interest in a pharmacy must disclose "any difference between the amount paid to [the] pharmacy and the amount charged to the plan sponsor." Indeed, the only provision PCMA challenges that requires a disclosure is Section 16.1(10), which requires PBMs to disclose information about their networks to pharmacies so that pharmacies can make an informed decision before contracting to join a PBM's network. As noted above, PBMs assert that the organization of pharmacy networks is the PBM's business, and not plan administration, to avoid ERISA's fiduciary duties.

These provisions do not "govern central matters of plan administration" because they impose no obligations whatsoever on ERISA plans. PCMA's attempt to analogize the law struck down in *Gobielle v. Liberty Mutual Insurance Co.*, 577

[30] https://www.nytimes.com/2018/02/24/us/politics/pharmacy-benefit-managers-gag-clauses.html.

U.S. 312 (2016), to these provisions—most of which merely *permit* disclosures *to plans and beneficiaries*—underscores the fallacy of equating PBMs with the ERISA plans they serve at arms length. In *Gobielle*, an ERISA plan sued to prevent disclosure of its information to state regulators under a Vermont law that "compel[ed] plans to report detailed information about claims and plan members." 577 U.S. at 323. The Supreme Court struck down the law because "[d]iffering, or even parallel, regulations from multiple jurisdictions" requiring ERISA plans to record and report information about claims and beneficiaries could interfere with the uniform nation-wide administration of ERISA plans. *Id*.

In this case, the PBMs' trade association is suing to avoid disclosures about PBMs to ERISA plans and beneficiaries. Sections 16.1(5), (7), (10) and 16.2(2) do not require an ERISA plan or its TPA to report any information to anyone. Sections 16.1(5), (7), and 16.2(2) are purely permissive. Congress' intent for ERISA preemption was to facilitate "the nationally uniform administration of employee benefit plans." *Travelers*, 514 U.S. at 657. It was not to empower PBMs to keep ERISA plans and beneficiaries in the dark about how PBMs profit at their expense.

North Dakota's anti-self dealing provision likewise does not "govern a central matter of plan administration." Section 16.2(3) prohibits a PBM from having an ownership interest in certain pharmacies and programs unless the PBM

agrees to avoid transactions that would benefit the PBM at the expense of a plan or an insurer. PCMA does not even try to explain how a provision that merely limits when a PBM can transact with itself could burden plan administration. At most, the provision might "affect a plan's shopping decisions" by limiting when a PBM can include its affiliated pharmacy in a network that it proposes to an ERISA plan. *See Travelers*, 514 U.S. at 645.

Finally, Sections 16.1(2), (3), and (4) limit fees that PBMs charge pharmacies and prevent PBMs from clawing back copayments after the point of sale. These provisions are "merely a form of cost regulation" indistinguishable from the Arkansas law that the Supreme Court upheld in *Rutledge*. 141 S. Ct. at 481. *Rutledge* made clear that states may regulate the financial terms of transactions between PBMs and pharmacies both at the point of sale of a drug and afterwards by upholding the "reverse and rebill" procedure in the Arkansas law at issue. *See id.* at 479. North Dakota's provisions regulating post-transaction fees that PBMs charge pharmacies are no different, and PCMA does not even try to distinguish *Rutledge* on this point.

IV. Medicare Does Not Preempt All State Regulation of PBMs.

PCMA overstates the scope of preemption under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) when it argues that "express Medicare preemption is coextensive with field preemption." PCMA Br. at

36. The relevant provision, 42 U.S.C. § 1395w-26(b)(3), explicitly requires that a state regulation overlap with a federal "standard" to trigger preemption. As this Court held in *PCMA v. Rutledge*, the MMA preempts state law only "when (1) Congress or [CMS] has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." 891 F.3d 1109, 1113 (8th Cir. 2018), *rev'd on other grounds*, 141 S. Ct. 474 (2020).[31]

CMS likewise has stated that preemption applies "only when CMS actually creates standards in the areas regulated." *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. at 4,320. It also said in its Part D rulemaking that "[n]othing in this rule directly regulates PBMs, positively or negatively, or directly encourages or discourages their use over alternative methods of managing drug benefits." *Id.* at 4,510.

CMS has confirmed that it has not issued standards regarding some subjects of Section 16.1 and 16.2. When asked about North Dakota's statute "prohibiting PBMs from requiring additional accreditation other than the requirement of the applicable state board of pharmacy," CMS identified no overlapping federal

[31] Contrary to PCMA's argument, this Court analyzed preemption in *Rutledge* by identifying specific areas where the Arkansas law overlapped with CMS standards. 891 F.3d at 1113-14. PCMA previously tried to dismiss this Court's analysis as dicta. *See* Prior PCMA Br. at 32-33 (Mar. 27, 2019). PCMA now admits that "[t]his Court's original decision in *Rutledge* … continues to control for purposes of Medicare Part D preemption," but argues that this Court did not mean what it said. PCMA Br. at 37.

standard and stated that "we continue to believe state pharmacy practice acts represent a reasonably consistent minimum standard of practice." *Medicare Policy and Technical Changes; Contract Year 2019*, 83 Fed. Reg. 16,598 (Apr. 16, 2018).

Sections 16.1(8) and 16.1(9) prohibit PBMs from requiring pharmacies to forgo dispensing drugs by mail and charging shipping and handling fees. CMS has said it has no intention of supplanting such laws regulating how pharmacists deliver drugs. "It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now." *Medicare Policy and Technical Changes; Contract Year 2019*, 82 Fed. Reg. 56,336-01, 56411 (Nov. 28, 2017).

CMS even has concluded that it lacks authority to regulate some PBM misconduct. "In general, we [CMS] do not think we have the authority to preempt State pharmacy licensing laws dealing with the practice of therapeutic substitution and we do not intend to establish standards in this area." 70 Fed. Reg. 4320. If PCMA's overbroad misreading of MMA preemption were correct, no regulation could address how PBMs mandate that pharmacists substitute drugs to maximize the rebates PBMs receive from manufacturers.

Finally, Congress's adoption of provisions like Section 16.1(5) and 16.1(7) in federal statutes after the district court ruled illustrates the valuable role that States play in testing regulation for potential adoption nationwide. This Court has

recognized that it should "not … preempt a state's effort to serve as a 'laboratory of democracy' in the realm of health care." *Boyle v. Anderson*, 68 F.3d 1093, 1109 (8th Cir. 1995).

States first implemented laws to stop PBMs from prohibiting pharmacists from disclosing relevant information to patients. *See Pharmacy Gag Clauses*, American Academy of Family Physicians (Oct. 2019) (listing twenty-nine states that "have enacted legislation banning pharmacy gag clauses").[32] After States proved the wisdom and efficacy of these regulations, Congress adopted them nationwide. *See* Know the Lowest Price Act of 2018, Pub. L. No. 115-262 § 2(a), 132 Stat. 3670 (codified at 42 U.S.C. § 1395w-104(m)) (preventing PBMs that serve Part D plans from barring pharmacies from discussing drug prices with patients). The Representative spearheading the legislation noted that it followed after "States around the country have taken action to address gag clauses, with over 20 States having banned them and countless more considering it." 164 Cong. Rec. H8795-01, H8796 (Statement of Rep. Earl L. "Buddy" Carter).

The fact that "Congress was aware of the existence of state laws restricting" abusive PBM practices, and adopted some of their substance without reiterating or expanding preemption, "strongly supports" "an inference that Congress did not intend to preclude such state regulation." *Pennsylvania Med. Soc. v. Marconis*, 942

[32] https://www.aafp.org/dam/AAFP/documents/advocacy/legal/health/BKG-PharmacyGagClauses.pdf.

F.2d 842, 851 (3d Cir. 1991). As the Third Circuit reasoned, "[s]urely if Congress intended to occupy the field it would have expelled the state intruders." *Id.*

In short, there is no legal basis for PCMA's overbroad misreading of Medicare preemption. This Court should allow States like North Dakota to continue to apply laws that constrain PBM abuses to protect Medicare plans, and thereby provide Congress and CMS with more blueprints for effective federal regulation.

CONCLUSION

The Court should affirm the district court's judgment below.

Dated: July 1, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,407 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Word in 14-point Times New Roman.

Dated: July 1, 2021

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VIRUS CHECK CERTIFICATION

The electronic version of the brief and addendum have been scanned for viruses and are virus-free.

/s/ William E. Copley
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CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2021, I caused the foregoing *Amici Curiae* Brief to be filed with the Clerk of Court for the United States Court of Appeals for the Eighth Circuit by using the Court's CM/ECF system, which will cause notice to be delivered to all counsel of record. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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