No. 18-540

In the Supreme Court of the United States

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF ARKANSAS,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

BRIEF FOR CALIFORNIA, 44 OTHER STATES, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether Arkansas's statute regulating drug-reimbursement rates set by pharmacy benefit managers, which is similar to laws enacted by a substantial majority of the States, is preempted by the Employee Retirement Income Security Act of 1974.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

OTHER AUTHORITIES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

INTERESTS OF AMICI STATES

The States of California, Alabama, Alaska, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin, and the District of Columbia, submit this brief as amici curiae in support of petitioner. Amici States have a compelling interest in protecting the health and welfare of their residents. In furtherance of that interest, many States have enacted laws regulating pharmacy benefit managers (PBMs), companies that act as intermediaries between pharmacies, health insurance plans, and patients. The unduly expansive approach to ERISA preemption applied by the court of appeals below and advocated by respondent here would interfere with States' traditional authority to regulate the conduct of business entities—including PBMs—for the purpose of protecting the health of their residents.

INTRODUCTION

In response to troubling business practices that have harmed patients, independent pharmacies, and state governments, the vast majority of the States have adopted statutes regulating pharmacy benefit managers. These statutes serve important interests and are consistent with the traditional role of the States in protecting the health and welfare of their residents. ERISA does not preempt the Arkansas

statute challenged here or similar statutes in dozens of other States.

To facilitate the Court's consideration of this important case, this brief first addresses the serious concerns—involving drug costs, access to care, competition, and consumer protection—that have prompted States to regulate PBMs. In recent years, for example, PBMs have used their market power to pay pharmacies unsustainably low reimbursement rates; to diminish access to less-profitable drugs; to restrict pharmacies from informing patients about lower-cost generic options; and to steer patients away from independent pharmacies and toward pharmacies owned by PBMs. These practices have contributed to increased drug prices and a wave of pharmacy closures—especially in rural, inner-city, and other underserved areas—and have harmed patients by increasing the cost of healthcare and curtailing access to certain drugs. Nearly every State has adopted legislation responding to these concerns. Like Arkansas, many States regulate the reimbursement rates that PBMs pay to pharmacies, and effectuate that rate regulation by, for example, requiring PBMs to update their rates on a timely basis and to offer an appeal mechanism allowing pharmacies to dispute questionable rates.

Next, we address why ERISA does not preempt the Arkansas statute challenged here or similar laws enacted by other States. This Court has adopted workable standards governing ERISA preemption, with a view towards avoiding the limitless application of ERISA's preemption clause. State laws are preempted only if they make "reference to" ERISA plans or have an impermissible "connection with" ERISA plans. Arkansas's statute does not qualify for preemption under those standards. It regulates the

practices of PBMs, not ERISA plans; and while it refers to health plans generally, it does not single out ERISA plans for special treatment or impose any significant administrative burdens on ERISA plans. Moreover, the Arkansas statute addresses matters that are outside of the objectives of the ERISA statute, which is principally concerned with regulating the administrative practices of ERISA plans. It is implausible that Congress intended ERISA to preclude States from enacting the type of commonsense measures challenged by respondent.

ARGUMENT

I. STATES REGULATE PBMS TO PROTECT CONSUMERS AND PROMOTE ACCESS TO AFFORDABLE HEALTHCARE

Prescription drugs are a critical component of modern healthcare and account for an increasingly large fraction of overall healthcare spending. Pharmacy benefit managers play a central role in the financing and delivery of prescription drugs. In recent years, certain PBM business practices have contributed to substantially increased prescription drug prices while diminishing consumers' access to vital drugs. As this Court has emphasized, healthcare is a traditional subject of state regulation. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). And as part of their obligation to protect the health and well-being of their residents, the States have adopted sensible legislative measures to address problems created by PBMs.

A. PBMs Play a Major Role in the Modern Healthcare System

Some background helps explain why PBMs are commonly regulated by the States. Before reaching the patient, prescription drugs make their way

through a web of intermediaries with various and sometimes competing incentives. Normally, a prescription drug is made by a manufacturer, delivered by a wholesale distributor to a pharmacy, and then dispensed at the pharmacy to a patient, according to terms set by the patient's health insurer. At the first stage, the manufacturer sells a drug to a distributor at a list price set by the manufacturer, which reflects any discounts that have been negotiated. The distributor then sells the drug to a pharmacy at a price stemming from the list price. A patient buys the drug at the pharmacy after paying any cost-sharing required by his or her health insurer.[1]

Although PBMs have existed since the 1970s, they initially played a modest role in the healthcare system, doing little more than processing claims for health insurers.[2] That generally entailed verifying that a patient had coverage, determining whether a drug was on the plan formulary, and calculating the appropriate copayment. But the role of PBMs expanded during the 1980s, when healthcare and prescription drugs costs were rising and employers looked to contain costs by carving out pharmacy benefits for

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[1] *See, e.g.*, U.S. Government Accountability Office, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, But Some Had Extraordinary Price Increases (Aug. 2016), at 6, https://tinyurl.com/yd9aeky8; MedPAC, Overview: The Drug Development and Supply Chain (June 2016), at 12, https://tinyurl.com/rcj3tjy.

[2] *See*, *e.g.*, Minority Staff of the U.S. Senate Committee on Finance, A Tangled Web: An Examination of the Drug Supply and Payment Chains (June 2018), at 26, https://tinyurl.com/yx4y33ke; HealthAffairs Health Policy Brief, Prescription Drug Pricing: Pharmacy Benefit Managers (Sept. 2017), https://tinyurl.com/vlf22ng.

separate management.[3] In the decades since then, PBMs have grown in influence and size.

Today, nearly every health insurer contracts with a PBM, which often manages all aspects of the pharmaceutical-benefit portion of the health plan.[4] Modern PBMs act as middlemen between insurers, drug makers, and pharmacies. They develop drug formularies; contract with pharmacies; negotiate discounts and rebates with drug manufacturers; conduct drug-utilization reviews; assist with disease management; establish pharmacy and wholesaler networks; and run mail-order and affiliated pharmacies that often compete with independent pharmacies.[5]

B. PBM Business Practices Have Caused Widespread Harm

The expanded role of PBMs, and certain business practices of modern PBMs, have had profound consequences for pharmacies, patients, and States.

1. Harm to pharmacies

PBMs have affected pharmacies in two primary ways. First, PBMs often pay excessively low reim-

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[3] Janet Brierton, Conn. Office of Legislative Research, OLR Research Report: Pharmacy Benefit Managers (Dec. 24, 2003), https://tinyurl.com/rw2mvl7; Helene L. Lipton, et al., *Pharmacy Benefit Management Companies: Dimensions of Performance*, 20 Ann. Rev. Public Health 361, 363-364 (1999), https://tinyurl.com/sb8zefg.

[4] Oversight Hearing of the S. Comm. on Bus., Professions and Econ. Dev., Pharmacy Benefit Managers 101: Background Paper (Cal. Mar. 20, 2017), at 2, https://tinyurl.com/uw36tjn.

[5] *Id.*

bursement rates, which sometimes fall below a pharmacy's cost of acquiring a particular drug.[6] These reimbursement practices have contributed to a wave of pharmacy closures, particularly in rural, inner-city, and otherwise underserved areas.[7]

A "significant source" of PBMs' net revenue is the "retail spread," which is the difference between the reimbursement rate that the PBM pays to the pharmacy and the rate the PBM receives from the health insurer.[8] PBMs create "maximum allowable cost" (MAC) lists that "designate[] the upper limit a plan will pay for generic drugs and brand name drugs that have generic versions available."[9] In establishing those lists, PBMs have an obvious economic incentive

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[6] *See, e.g.*, Altarum Healthcare Value Hub, Research Brief No. 23, Pharmacy Benefit Managers: Can They Return to Their Client-Centered Origins? (Jan. 2018), https://tinyurl.com/s2rm9e8; Steven Ross Johnson, *Poor Communities Hit Hard by Pharmacy Closures*, Modern Healthcare (Oct. 21, 2019), https://tinyurl.com/rublyqq.

[7] *See, e.g.*, Johnson, *supra* note 6; National Rural Health Association Policy Brief, Pharmacy (May 2009), at 1, https://tinyurl.com/sgt9mcq; Abiodun Salako, et al., *Issues Confronting Rural Pharmacies After a Decade of Medicare Part D*, RUPRI Center for Rural Health Policy Analysis, Rural Policy Brief No. 2017-3 (Apr. 2017), at 1, https://tinyurl.com/yx3aejjc.

[8] Advisory Council on Employee Welfare and Pension Benefit Plans, Report to the Honorable Thomas E. Perez, United States Secretary of Labor: PBM Compensation and Fee Disclosure (Nov. 2014), at 10, https://tinyurl.com/tvc7spa.

[9] New York State Senate, Committee on Investigations and Government Operations, Final Investigative Report: Pharmacy Benefit Managers in New York (May 31, 2019), at 10, https://tinyurl.com/v7pxof8.

to expand the retail spread by paying pharmacies low reimbursement rates.

Even when these low reimbursement rates threaten their economic viability, pharmacies often have no choice but to contract with PBMs. Any pharmacy refusing to do so would likely lose substantial business, because many customers would be unable to use their health insurance to obtain prescription drugs at the pharmacy. Pharmacies thus "have little negotiation power"—especially if they are independent operations—and they are often provided with a "take-it-or-leave-it contract."[10]

This imbalance in negotiating power is compounded by the significant market power of the major PBMs. The largest three PBMs combine to serve approximately 80 percent of the market.[11] The growth and consolidation of PBMs "giv[es] them immense power to affect the price of pharmaceuticals being paid by consumers and the State."[12] Due to "a lack of transparency, oversight, and accountability," they "are able to engage in anticompetitive practices at the detriment of consumers and pharmacists."[13]

As a New York State Senate committee report found, "[b]elow-cost reimbursements significantly con-

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[10] Lisa L. Causey, *Nuts and Bolts of Pharmacy Reimbursement: Why It Should Matter to You*, Health Law Perspectives (June 2009), at 6, https://tinyurl.com/sbbmpdx; *see also* National Rural Health Association Policy Brief, *supra* note 7, at 1.

[11] HealthAffairs Health Policy Brief, *supra* note 2, at 2.

[12] Pharmacy Benefit Managers in New York, *supra* note 9, at 2.

[13] *Id.* at 6.

tribute to declines in an independent pharmacy's revenue."[14] For example, PBMs charged Ohio Medicaid managed care organizations $662.7 million for generic drugs between April 2017 and March 2018, but reimbursed pharmacies only $454.3 million—a spread of more than 31 percent.[15] And closures of independent pharmacies in Ohio appear to be correlated with increases in the spread between the rates PBMs charge health plans and their reimbursement rates to pharmacies.[16]

Pharmacy closures are often felt most acutely by underserved patients in rural or isolated areas. Between 2003 and 2018, 630 rural communities went from having one or more retail pharmacy to having none.[17] Unfair PBM reimbursement and list-pricing practices were a major contributing factor.[18] This trend is especially troubling because pharmacies are often the main—or only—healthcare providers available in those areas. Thus, when aggressive reimbursement practices drive rural pharmacies out of business,

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[14] *Id.* at 66.

[15] Ohio Auditor of State, Ohio's Medicaid Managed Care Pharmacy Services, at 12 (Aug. 16, 2018), https://tinyurl.com/sqtn6ge.

[16] *Id.* at 15.

[17] Abiodun Salako, et al., *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis, Rural Policy Brief No. 2018-2 (July 2018), at 1, https://tinyurl.com/rsuj7zd; *see also* Paulina Firozi, *The Health 202: Here's Why Rural Independent Pharmacies Are Closing Their Doors*, Washington Post (Aug. 23, 2018), https://tinyurl.com/wlvh324.

[18] Salako, *supra* note 7, at 1.

there are "grave implications for the population's access to health services."[19]

Second, PBMs harm independent pharmacies by steering patients toward pharmacies that are owned by, or otherwise affiliated with, the PBMs. That trend raises obvious concerns about self-dealing. The Ohio State Auditor noted complaints that PBMs have a "conflict of interest since they can require their customers to obtain prescriptions only from mail-order and specialty pharmacies they own."[20] And PBMs often reimburse their own pharmacies at significantly higher rates than they offer to independent pharmacies. For example, while the PBM operated by CVS reimburses a CVS pharmacy $400.65 for a fentanyl patch and $5.86 for Ibuprofen, it reimburses non-CVS pharmacies only $75.74 for the patch and $1.39 for the Ibuprofen.[21] That puts independent pharmacies at a substantial competitive disadvantage.

2. Harm to patients

PBM business practices have also harmed patients by contributing to rising drug prices and curtailing access to certain drugs. Prescription drug costs have increased sharply in the United States in recent years. Adjusting for inflation, Americans spent around $90 per year on average on prescription drugs in 1960; by 1997, that figure was approximately $400; by 2015, it

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[19] Salako, *supra* note 17, at 1.

[20] Ohio's Medicaid Managed Care Pharmacy Services, *supra* note 15, at 1.

[21] Linette Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the U.S. Will Make Your Blood Boil*, Business Insider (Mar. 30, 2018), https://tinyurl.com/vqph452.

exceeded $1,000.[22] Total prescription drug spending in the United States reached $335 billion in 2018, approximately one-tenth of overall healthcare spending.[23] And consumer spending on prescription drugs is expected to increase by 6.3 percent each year through 2026, the fastest rate of growth of any major part of the healthcare sector.[24]

Evidence indicates that the rebates PBMs negotiate with drug manufacturers have contributed to rising drug prices. For example, manufacturer rebates to PBMs more than doubled in just four years between 2012 and 2016, increasing from $39.7 billion to $89.5 billion.[25] Those rebates have been linked to increased manufacturer list prices, and they often are not passed along to customers.[26]

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[22] Rabah Kamal et al., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, Peterson-KFF Health System Tracker (Feb. 20, 2019), https://tinyurl.com/y22zrsdv.

[23] Centers for Medicare & Medicaid Services (CMS), NHE Fact Sheet (2018), https://tinyurl.com/yx3t7d2v.

[24] CMS Office of the Actuary, Press Release, 2017-2026 Projections of National Health Expenditures (Feb. 14, 2018), https://tinyurl.com/y7ucksl5.

[25] Commonwealth Fund, *Pharmacy Benefit Managers and Their Role in Drug Spending* (Apr. 22, 2019), https://tinyurl.com/y4ytmsls.

[26] *See, e.g.*, *id.*; Geoffrey Joyce, *An Economist's Change of Heart: It's Time to Regulate the Prescription Drug Middlemen*, MarketWatch (Aug. 20, 2018), https://tinyurl.com/vc2b2aa (noting that "PBM profit margins are much higher than other players in the supply chain," such as "manufacturers, wholesalers, pharmacies, and insurers").

While patients are obviously harmed by increasingly expensive prescription drugs, PBMs frequently benefit from the trend. As the Secretary of Health and Human Services recently noted, a "PBM actually wins when list price goes up."[27] He explained:

> Imagine you take a $1,000 drug. The PBM working for your insurance plan negotiates a 30 percent rebate, $300, which gets sent back to your employer, minus a percentage cut for the PBM. Now imagine the list price goes up to $1,500—now the rebate would be $450, allowing the PBM to keep the added $150, while the patient pays significantly more in cost-sharing.[28]

As that example indicates, the rebate structures PBMs negotiate can skew incentives in a way that is likely to increase drug costs. Because "[m]anufacturer rebates to PBMs occur when a drug manufacturer's product is included in a formulary and utilized by plan participants," PBMs may "have incentives to encourage utilization of certain drugs based on the availability of rebates rather than ultimate cost to the plan."[29]

Other PBM practices have also contributed to increased drug costs. Some PBMs, for instance, include "gag clauses" in their contracts with pharmacies, which prohibit the pharmacies from informing customers about less expensive alternatives. Gag clauses

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[27] Alex M. Azar II, U.S. Secretary of Health & Human Services, Fixing Healthcare: Driving Value Through Smart Purchasing and Policy (May 16, 2018), https://tinyurl.com/t4798nu.

[28] *Id.*

[29] PBM Compensation and Fee Disclosure, *supra* note 8, at 3, 11.

sometimes even prohibit pharmacies from informing customers when their copayments exceed the cost of a drug, with PBMs often pocketing the overpayment. According to a recent study in the Journal of the American Medical Association, more than 20 percent of generic drug prescriptions in 2013 resulted in overpayment, costing consumers an aggregate $135 million.[30]

Apart from contributing to increased drug costs, PBMs also play a role in restricting patients' access to certain drugs. In designing their formularies, PBMs commonly create a three-tiered system, under which a "preferential" drug has a lower copayment compared to other (non-preferred) drugs.[31] PBMs negotiate with manufacturers for larger rebates in return for assigning preferential placement to the manufacturers' drugs. Those business-driven decisions often create a barrier between patients and the medications their doctors have prescribed.[32] And that problem is only exacerbated by the highly concentrated nature of the PBM market: If a PBM fails to offer sufficiently wide selection of drugs, patients and health plans often have no alternative.

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[30] Karen Van Nuys, et al., *Frequency and Magnitude of Co-Payments Exceeding Prescription Drug Costs*, J. Am. Med. Ass'n (Mar. 13, 2018), https://tinyurl.com/rrzqqnr.

[31] U.S. Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), at 15, https://tinyurl.com/y2nbvehn; Pharmacy Benefit Managers 101, *supra* note 4, at 3.

[32] Wayne Winegarden, *It's Generics Not PBMs that Keep Pharmaceuticals Affordable*, Forbes (July 12, 2018), https://tinyurl.com/tr2ylm8.

3. Harm to States

These same PBM business practices have had significant consequences for States. Because of the role they play in financing health insurance, States are directly affected by increases in prescription drug costs. As of October 2018, nearly 73 million Americans were enrolled in Medicaid or the Children's Health Insurance Program—programs that are funded partly by States and that account for a significant share of many state budgets.[33] States have observed that "[p]harmacy costs are the fastest growing budget items."[34] For example, in Massachusetts, prescription drug spending has grown twice as fast as the rest of state healthcare spending in recent years, increasing from $1.1 billion in 2012 to $1.9 billion in 2017.[35]

More broadly, States are harmed when PBM practices impair their residents' ability to access affordable, quality healthcare. States have a "vital interest[]" in the "health," "safety," and "economic needs" of their residents. *Veix v. Sixth Ward Bldg. & Loan Ass'n*, 310 U.S. 32, 38-39 (1940). Pharmacy closures resulting from low reimbursement rates (and other PBM practices) threaten that interest. They exacerbate "the

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[33] Kentucky Cabinet for Health and Family Service et al., Medicaid Pharmacy Pricing: Opening the Black Box (Feb. 19, 2019), at 2, https://tinyurl.com/vynbv67.

[34] *Id.*; *see also* Rachel Dolan & Marina Tian, Kaiser Family Foundation, Pricing and Payment in Medicaid Prescription Drugs (Jan. 2020), at 4-5, https://tinyurl.com/s8yrr5e (explaining role of PBMs in the administration of Medicaid pharmacy benefits and the ways drug prices affect Medicaid spending).

[35] Massachusetts Health Policy Commission, HPC DataPoints, Issue 12: Cracking Open the Black Box of Pharmacy Benefit Managers (June 5, 2019), https://tinyurl.com/uw686gc.

wide health gap that exists between poorer and more affluent communities."[36] As one study found, for example, pharmacy closures were associated with "significant declines" in rates of older patients taking their prescribed heart medications.[37]

C. States Are Actively Addressing Harmful PBM Business Practices

States across the Nation have responded to these concerns by enacting an array of measures designed to protect access to affordable prescription drugs. Almost every State regulates PBMs in some way.[38] Within the past five years, at least 44 States have enacted new or amended statutes addressing PBMs.[39] These laws generally fall into four main categories.

1. Regulation of pharmacy reimbursement rates

Several States have adopted statutes like the one at issue in this case, which seek to curb unsustainably low reimbursement rates. These laws generally require PBMs to reimburse pharmacies at a rate at least equal to the pharmacies' costs of acquiring prescription drugs. Arkansas, for instance, requires PBMs to reimburse pharmacies at a rate equal to or above "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's

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[36] Johnson, *supra* note 6.

[37] *Id.*

[38] *See, e.g.*, National Conference of State Legislatures, PBM State Legislation (May 16, 2019), https://tinyurl.com/ra48u8n.

[39] National Conference of State Legislatures, 2018 Enacted States Laws Affecting Pharmacy Benefit Managers (Jan. 2019), at 2, https://tinyurl.com/uh7lftn.

billing invoice." Ark. Code Ann. § 17-92-507(a)(6), (c)(4)(A)(i)(b). California directs that the maximum allowable cost for a drug cannot be "below the cost at which the drug is available for purchase by similarly situated pharmacies in the state from a national or regional wholesaler." Cal. Bus. & Prof. Code § 4440(f)(1)(A). Many other States have similar laws that directly or indirectly regulate PBM reimbursement rates to pharmacies.[40]

States also frequently require PBMs to establish an appeal mechanism for pharmacies that believe a particular reimbursement is too low. For example, Arkansas specifies that PBMs must provide a "reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable cost list and reimbursements made under a maximum allowable cost list for a specific drug or drugs." Ark. Code Ann. § 17-92-507(c)(4)(A)(i). At least 35 other States require similar procedures.[41] Many of these laws provide that if the pharmacy is successful in its appeal,

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[40] *See* Alaska Stat. Ann. § 21.27.950(c); Colo. Rev. Stat. Ann. § 25-37-103.5(3)(d); Ga. Code Ann. § 33-64-9(e); Haw. Rev. Stat. Ann. § 328-106(f)(1)(A); Ky. Rev. Stat. Ann. § 304.17A-162(1)(b)(4); La. Stat. Ann. § 22:1865(A); Me. Rev. Stat. tit. 24-A, § 4350(6)(B); Md. Code Ann., Ins. § 15-1628.1(f)(4)(ii); Minn. Stat. Ann. § 62W.08(c)(3); Mo. Ann. Stat. § 376.388(6); N.H. Rev. Stat. Ann. § 402-N:3(I)(b)(3)(B); N.M. Stat. Ann. § 59A-61-4(D)(8); N.D. Cent. Code Ann. § 19-02.1-14.2(2)(d), (f); Ohio Rev. Code Ann. § 3959.111(A)(3)(d); Okla. Stat. Ann. tit. 59 § 360(A)(5); Or. Rev. Stat. Ann. § 735.534(4); Utah Code Ann. § 31A-46-303(4); Wis. Stat. Ann. § 632.865(2)(b)(4); Wyo. Stat. Ann. § 26-52-104(f).

[41] *See* Alaska Stat. Ann. § 21.27.950(a); Ariz. Rev. Stat. Ann. § 20-3331(A)(3); Cal. Bus. & Prof. Code § 4440(f); Colo. Rev. Stat. Ann. § 25-37-103.5(3); Del. Code Ann. tit. 18, § 3324A; Ga. Code Ann. § 33-64-9(d); Haw. Rev. Stat. Ann. § 328-106(f); 215 Ill. Comp. Stat. Ann. 5/513b1(b)(4); Iowa Code Ann. § 510B.8(3); Kan. Stat.

the PBM must "adjust the Maximum Allowable Cost List and permit the pharmacy to reverse and rebill each claim affected by" the pricing error. *Id.* § 17-92-507(c)(4)(C)(iii).[42]

Arkansas and a handful of other States also authorize pharmacies to decline to dispense a drug if the pharmacy would be reimbursed at a rate below its acquisition cost.[43] These laws make clear that a pharmacy has no obligation to provide service if a PBM

Ann. § 40-3830(f); Ky. Rev. Stat. Ann. § 304.17A-162(1)(b); La. Stat. Ann. § 22:1865(A); Me. Rev. Stat., tit. 24-A, § 4350(5); Md. Code Ann., Ins. § 15-1628.1(f); Minn. Stat. Ann. § 62W.08(c); Mo. Ann. Stat. § 376.388(5); Mont. Code Ann. § 33-22-173(1)(a); N.H. Rev. Stat. Ann. § 420-J:8(a)(2); N.J. Stat. Ann. § 17B:27F-4; N.M. Stat. Ann. § 59A-61-4(5); N.Y. Pub. Health Law § 280-a(2); N.D. Cent. Code Ann. § 19-02.1-14.2(2)(e); Ohio Rev. Code Ann. § 3959.111(A)(1)(b)(3); Okla. Stat. Ann. tit. 59, § 360(4); Or. Rev. Stat. Ann. § 735.534(4); 40 Pa. Stat. Ann. § 4533(a); R.I. Gen. Laws § 27-41-38.2(d); S.C. Code Ann. § 38-71-2140(A); 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 Ann. § 19.340.100(3); Wis. Stat. Ann. § 632.865(2)(b); Wyo. Stat. Ann. § 26-52-104(e).

[42] *See also* Alaska Stat. Ann. § 21.27.950(c); Cal. Bus. & Prof. Code § 4440(f)(4); Del. Code Ann. tit. 18, § 3324A(d); Ga. Code Ann. § 33-64-9(f)(1); Haw. Rev. Stat. Ann. § 328-106(f)(5); Kan. Stat. Ann. § 40-3830(f)(3)(C); Ky. Rev. Stat. Ann. §§ 304.17A-162(1)(b)(5), (2)(b); Me. Rev. Stat. tit. 24-A, § 4350(6)(A); Md. Code Ann., Ins. § 15-1628.1 (f)(5)(i)(1); Mo. Ann. Stat. § 376.388(7)(1); Mont. Code Ann. § 33-22-173(3)(c); N.H. Rev. Stat. Ann. § 420-J:8(XV)(a)(2)(D)(ii); N.J. Stat. Ann. § 17B:27F-4(d)(2); N.Y. Pub. Health Law § 280-a(2)(c); Okla. Stat. Ann. tit. 59, § 360(A)(4); Ohio Rev. Code Ann. § 3959.111(A)(1)(e); 40 Pa. Stat. Ann. § 4533(c); Tenn. Code Ann. § 56-7-3108(e)(1); Tex. Ins. Code Ann. § 1369.357(c)(1); Wyo. Stat. Ann. § 26-52-104(g).

[43] *See* Ark. Code Ann. § 17-92-507(e); La. Stat. Ann. § 22:1860.3(B)(1); Miss. Code Ann. § 73-21-155(5)(a); Mont. Code

proposes to pay a reimbursement rate below the minimum set by state law. This type of provision responds to concerns that PBMs frequently reject appeals and that the appeal process is onerous and time-consuming.[44] A 2017 Washington state report confirmed those concerns, concluding that PBMs denied between 77 percent and 94 percent of appeals.[45] Providing a decline-to-dispense option helps to protect pharmacists from the kind of money-losing transactions that have been driving so many of them out of business.

2. Regulation of maximum allowable cost lists

Many States also impose restrictions on PBMs that use maximum allowable cost lists, in order to help ensure that their reimbursement practices are fair and transparent. Some States restrict which drugs can be listed. In Kansas, for example, PBMs may "not place a drug on a MAC list unless there are at least two therapeutically equivalent multi-source generic drugs, or at least one generic drug available from at least one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers and the drug is not obsolete." Kan. Stat. Ann. § 40-3830(a). Many other States have comparable laws.[46]

Ann. § 33-22-174(1).

[44] Steve Brawner, *Pharmacists: PBM Laws Helped, But Underpayments Continue*, Talk Business & Politics (Sept. 2, 2019), https://tinyurl.com/rlzqwtl.

[45] Office of the Insurance Commissioner of Washington, Study of the Pharmacy Chain of Supply (2007), at 7, 71, https://tinyurl.com/whbr7xg.

[46] *See* Cal. Bus. & Prof. Code § 4440(d); Colo. Rev. Stat. Ann. § 25-37-103.5(2); Del. Code Ann. tit. 18, § 3323A(a); Ga. Code Ann.

A substantial majority of States require PBMs to update their maximum allowable cost lists in a timely fashion. "[T]he generic drug market is in a constant state of flux," and "[p]rices change as some manufacturers enter the market and others leave."[47] Because "pharmacy acquisition costs are changing constantly," up-to-date price information is critical to "ensure that MAC reimbursement is fair."[48] With this in mind, most States require PBMs to update their maximum allowable cost lists at least once every ten days, if not more frequently.[49] A number of States also require

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§ 33-64-9(c); Haw. Rev. Stat. Ann. § 328-106(d); 215 Ill. Comp. Stat. Ann. 5/513b1(c); La. Stat. Ann. § 22:1864(A); Md. Code Ann., Ins. § 15-1628.1(e); Minn. Stat. Ann. § 62W.08(b); Mo. Ann. Stat. § 376.388(4); N.J. Stat. Ann. § 17B:27F-3(a); N.M. Stat. Ann. § 59A-61-4(C); N.C. Gen. Stat. Ann. § 58-56A-5(a); N.D. Cent. Code Ann. § 19-02.1-14.2(3); Okla. Stat. Ann. tit. 59, § 360(B); Or. Rev. Stat. Ann. § 735.534(2); 40 Pa. Stat. Ann. § 4531(a)(2); R.I. Gen. Laws § 27-41-38.2(c); S.C. Code Ann. § 38-71-2120; Tenn. Code Ann. § 56-7-3106(a); Wash. Rev. Code Ann. § 19.340.100(2)(a); Wyo. Stat. Ann. § 26-52-104(a).

[47] Study of the Pharmacy Chain of Supply, *supra* note 45, at 5.

[48] *Id.*

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

PBMs to disclose their lists to pharmacies. One typical provision is Minnesota's requirement that a PBM "must make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the network pharmacy." Minn. Stat. Ann. § 62W.08(a)(5).[50]

3. Prohibitions on gag clauses

To ensure that pharmacists and customers may speak freely about less-costly generic alternatives, at least 35 States have enacted legislation prohibiting PBMs from including "gag clauses" in their contracts with pharmacies.[51] As the Colorado Legislature declared, "[c]onsumers have the right to know about options to reduce the amount of money they pay at a pharmacy for prescription drugs," and "allowing pharmacists to provide information concerning the cost of prescription drugs" "will save consumers money." Colo. Rev. Stat. Ann. § 10-16-122.7(2)(a), (b). Thus,

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S.C. Code Ann. § 38-71-2130(3); Tex. Ins. Code Ann. § 1369.355(b); Vt. Stat. Ann. tit. 18, § 9473(c)(2); Wash. Rev. Code Ann. § 19.340.100(2)(f); Wis. Stat. Ann. § 632.865(2)(1); Wyo. Stat. Ann. § 26-52-104(d)(iv).

[50] *See also* Kan. Stat. Ann. § 40-3830(c); Me. Rev. Stat. tit. 24-A, § 4350(4)(B); Mont. Code Ann. § 33-22-172(2)(c); N.M. Stat. Ann. § 59A-61-4(D)(11); N.D. Cent. Code Ann. § 19-02.1-14.2(2)(c); Ohio Rev. Code Ann. § 3959.111(A)(1)(a); Okla. Stat. Ann. tit. 59, § 360(A)(1); S.C. Code Ann. § 38-71-2130(2); 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).

[51] *See* PBM State Legislation *supra* note 38 (noting that 33 States have such provisions but omitting Nebraska and Oklahoma); Neb. Rev. Stat. § 71-2484(2); Okla. Stat. Ann. tit. 36, § 6962(C)(1)(a); *cf.* Pub. L. No. 115-263, 132 Stat. 3672, *codified at* 42 U.S.C. § 300gg-19b (similar federal law enacted in 2018).

Colorado bars PBMs from "[p]rohibit[ing] a pharmacy or pharmacist from providing a covered person information on the amount of the covered person's cost share" for a prescription drug. *Id.* § 10-16-122.7(3)(a). The California Legislature similarly concluded that "requiring more extensive transparency" will allow consumers to avail themselves of "lower drug costs."[52] In addition to banning gag clauses, *see* Cal. Bus. & Prof. Code § 4441(k), California also requires PBMs to disclose to plan sponsors upon request information about the PBMs' rebate agreements, fees, and contracts with pharmaceutical manufacturers, *see id.* § 4441(e).

4. Regulation of conflicts of interest and self-dealing

Finally, to preserve a level playing field and avoid market distortions, several States seek to prevent PBMs from favoring their own affiliated pharmacies or otherwise engaging in self-dealing. At least seven States prohibit PBMs from requiring patients to fill prescriptions at the PBMs' own affiliated pharmacies, or reimbursing affiliated pharmacies at higher rates than independent pharmacies.[53] Others require PBMs to disclose both direct and indirect conflicts of interest to health insurance companies, plan sponsors, or the state government.[54] And a number of States explicitly require PBMs to exercise good faith and fair

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[52] California Assembly Floor Analysis, AB 315 (Aug. 28, 2018), at 9-10, https://tinyurl.com/wkxbs3g.

[53] *See* Ark. Code Ann. § 17-92-507(d)(1); Ga. Code Ann. § 33-64-11(a)(7); La. Stat. Ann. § 22:1860.3(A); N.M. Stat. Ann. § 59A-61-4(B); Okla. Stat. Ann. tit. 36, § 6962(B)(3); S.C. Code Ann. § 38-71-2230(A)(3); Tenn. Code Ann. § 56-7-3118(d).

[54] *See* Cal. Bus. & Prof. Code § 4441(d); D.C. Code Ann. § 48-

dealing in their relationships with plan sponsors, pharmacies, or both.[55] State legislatures have determined that these laws are necessary to ensure that PBMs perform their duties "with care, skill, prudence, diligence, and professionalism."[56]

II. ERISA DOES NOT PREEMPT ARKANSAS'S ACT 900 OR SIMILAR STATE LAWS

Like dozens of other States, Arkansas has exercised its sovereign prerogative to regulate the reimbursement rates PBMs pay to pharmacies. It also imposes certain procedural obligations on PBMs to help effectuate that rate regulation. This Court's longstanding precedent makes clear that ERISA does not preempt those provisions. Arkansas's Act 900 and similar statutes in other States regulate the conduct and business relationships of PBMs in order to protect consumers and facilitate access to prescription drugs—subjects that ERISA does not address. And they impose obligations on PBMs, not on ERISA plans. These statutes reflect States exercising their traditional role in protecting the health and welfare of their residents, and do not implicate the core concern of ERISA's preemption clause: ensuring "nationally uniform [ERISA] plan administration." *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 148 (2001).

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

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

[56] *E.g.*, Pharmacy Benefit Managers in New York, *supra* note 9, at 10.

A. ERISA Does Not Preempt Healthcare Regulations with No "Reference to" or "Connection with" ERISA Plans

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). As this Court has observed, "'if 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes [ERISA] preemption would never run its course.'" *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). Because "[t]hat is a result no sensible person could have intended," the Court has developed "workable standards" that "reject 'uncritical literalism' in applying" ERISA's preemption clause. *Id.* (internal quotation marks omitted). These standards seek to "avoid[] the clause's susceptibility to limitless application." *Id.*

This Court has identified two categories of state laws that ERISA preempts. The first category includes laws that have an impermissible "'reference to' ERISA plans," meaning that the "law acts immediately and exclusively upon ERISA plans," or that "the existence of ERISA plans is essential to the law's operation." *Gobeille*, 136 S. Ct. at 943 (internal quotation marks omitted). The second category includes laws that have "an impermissible 'connection with' ERISA plans," meaning that the law "governs a central matter of plan administration or interferes with nationally uniform plan administration." *Id.* (alteration and internal quotation marks omitted).

In applying this framework, the Court starts with the presumption that the "historic police powers of the States were not to be superseded by [ERISA] unless

that was the clear and manifest purpose of Congress." *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997).[57] "That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety." *Medtronic*, 518 U.S. at 485. It is also consistent with ERISA's text and history, because "nothing in the language of the Act or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers*, 514 U.S. at 661.

B. The Arkansas Statute Challenged Here Is Not Preempted

Like many of its sister States, Arkansas has adopted sensible and focused regulations to respond to the harms that PBMs can cause to patients, pharmacies, and state governments. As discussed above, Arkansas's Act 900 prohibits PBMs from reimbursing a pharmacy at a rate below the pharmacy's cost of acquiring a drug. Ark. Code Ann. § 17-92-507(a)(6), (c)(4)(A)(i)(b). It also establishes procedures that PBMs must follow to ensure compliance with that requirement. PBMs must update their MAC lists to accurately reflect the prices charged by pharmaceutical wholesalers in the State, *id.* § 17-92-507(c)(2); they must provide "a reasonable administrative appeal procedure to allow pharmacies to challenge . . . reimbursements", *id.* § 17-92-507(c)(4)(A)(i); if an appeal is upheld (or if the pharmacy is not able to purchase the drug from its wholesaler at a rate lower than what it

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[57] *See also, e.g.*, *Egelhoff*, 532 U.S. at 151; *De Buono v. NYSA-ILA Med. & Clinical Serv. Fund*, 520 U.S. 806, 814 (1997); *Travelers*, 514 U.S. at 655.

previously paid), the PBM must update its MAC list to reflect the actual wholesale price of the drug, *id.* § 17-92-507(c)(4)(C)(i), (iii); if an appeal is denied, the PBM must identify a pharmaceutical wholesaler where the drug in question is available and "currently in stock at a price below" the MAC list price, *id.* § 17-92-507(c)(4)(C)(ii). In addition, Act 900 allows a pharmacy to decline to dispense a prescription if the pharmacy would be reimbursed by the PBM at a rate below its acquisition cost for the drug. *Id.* § 17-92-507(e). Under this Court's precedent on ERISA preemption, none of these provisions is preempted.

1. Act 900 does not make any "reference to" ERISA plans. *Gobeille*, 136 S. Ct. at 943. It does not "act[] immediately and exclusively upon ERISA plans," nor are ERISA plans "essential to [its] operation." *Id.* Although Act 900 refers to "plan[s]," Ark. Code Ann. § 17-92-507(a)(9), that term is not limited to ERISA plans. The Act does not specifically mention ERISA plans and "functions irrespective of[] the existence of an ERISA plan." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990). In other words, it applies the same regardless of whether a health plan is an ERISA plan or not, rather than "singl[ing] out" ERISA plans "for different treatment." *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 830 (1988).

Because Act 900 regulates a group of entities—only some of which are ERISA plans—in an evenhanded way, it does not have an impermissible "reference to" ERISA plans. In *Dillingham*, for instance, the Court held that a California law did not make "reference to" ERISA plans because the regulated entities "need not necessarily be ERISA plans," although they might be. 519 U.S. at 325. Likewise, in *Travelers*, the Court held that a New York law regulating the prices hospitals

charged to health insurers did not make "reference to" ERISA plans because it applied the same "regardless of" whether the insurer was "ultimately secured by an ERISA plan" or a non-ERISA plan. 514 U.S. at 656. The same is true of Act 900.[58]

2. Nor does Act 900 have an impermissible "connection with" ERISA. Recognizing that "'connection with' is scarcely more restrictive" than the statutory language itself ("relate to"), the Court has "cautioned against an 'uncritical literalism' that would make preemption turn on 'infinite connections.'" *Egelhoff*, 532 U.S. at 147 (quoting *Travelers*, 514 U.S. at 656). Instead, the "connection with" inquiry "'look[s] both to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive, as well as to the nature of the effect of the state law on ERISA plans.'" *Id.* (quoting *Dillingham*, 519 U.S. at 325); *accord Gobeille*, 136 S. Ct. at 943.

The objectives of the ERISA statute are "to make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures." *Gobeille*, 136 S. Ct. at 943. ERISA therefore covers subject matters such as "'reporting, disclosure, fiduciary responsibility, and the like,'" *Travelers*, 514 U.S. at 661 (quoting *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 98 & n.19 (1983)), as well as

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[58] Respondent now appears to argue that Act 900 makes an impermissible "reference to ERISA-covered benefit plans" because it refers to plans that provide services to individuals who "'are *employed*'" in the State. Supp. Br. 6-7 (quoting Ark. Code Ann. § 17-92-507(a)(9)); *cf.* Opp. 28-30. While that definition encompasses some ERISA plans, it encompasses many non-ERISA plans as well. *See* U.S. Invitation Br. 8-9. This Court has never held a statute to be preempted by ERISA under such circumstances.

"determining the eligibility of claimants, calculating benefit levels, making disbursements, [and] monitoring the availability of funds for benefit payments," *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987). In contrast, the purpose of the challenged provisions of Act 900 is to regulate the rates at which PBMs reimburse pharmacies for prescription drugs. That is an "'area[] where ERISA has nothing to say.'" *Egelhoff*, 532 U.S. at 148 (quoting *Dillingham*, 519 U.S. at 330).

The Court's opinion in *Travelers* is directly on point. That case concerned a similar New York law regulating hospital rates for inpatient care. 514 U.S. at 649. The law "require[d] hospitals to collect surcharges from patients covered by a commercial insurer but not from patients insured by a Blue Cross/Blue Shield plan," and it imposed surcharges on certain health maintenance organizations. *Id.* It was undisputed that the law made "the Blues more attractive . . . as insurance alternatives" than health maintenance organizations and other types of health plans. *Id.* at 659. The Court nonetheless held that the law was not preempted by ERISA, emphasizing that "ERISA was not meant to pre-empt basic rate regulation." *Travelers*, 514 U.S. at 667 n.6. Although the New York law had an "indirect economic effect on choices made by insurance buyers, including ERISA plans," such an effect did not give rise to ERISA preemption because it did "not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself." *Id.* at 659. Nor did the law have such "acute, albeit indirect, economic effects . . . as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *Id.* at 668.

What was true of hospital rate regulation in *Travelers* is true of pharmacy rate regulation here. Just as the New York law in *Travelers* may have influenced some ERISA plans to contract with a Blue Cross entity rather than a commercial insurer or health maintenance organization, so too Act 900 might theoretically influence decisions by ERISA plans about whether and on what terms to contract with a PBM. But Arkansas does not "bind plan administrators to any particular choice," and the Act's economic effects are not so "acute" as to effectively dictate an ERISA plan's decisions. *Travelers*, 514 U.S. at 659, 668. Act 900 does not restrict ERISA plans in their choice of PBMs, force ERISA plans to use PBMs in a specific way, or so restrict PBMs in carrying out their functions as to limit the benefits provided by ERISA plans. Arkansas's law thus does not have any impermissible "connection with" ERISA. *See* U.S. Invitation Br. 10-13.

Any other outcome would be untenable. As the Court has repeatedly observed, "'myriad state laws' of general applicability . . . impose some burdens on the administration of ERISA plans but nevertheless do not 'relate to' them within the meaning of the governing statute." *De Buono*, 520 U.S. at 815. "Congress could not possibly have intended to eliminate" such a broad swath of state laws. *Travelers*, 514 U.S. at 668; *see id.* at 661 (noting other types of "common state actions with indirect economic effects on a plan[]"); *Dillingham*, 519 U.S. at 334 (reasoning that it would "do[] grave violence" to the presumption against preemption to find state laws preempted based on their economic effects on the choices of ERISA plans).

For similar reasons, ERISA does not preempt Arkansas's provision allowing pharmacists to decline to dispense prescriptions when a PBM proposes to pay a

reimbursement rate below Arkansas's regulatory floor. *See* Ark. Code Ann. § 17-92-507(e). This law, too, treats beneficiaries of ERISA and non-ERISA plans alike and does not implicate any central matter of plan administration. It merely specifies that a pharmacy need not perform its obligations under a contract with a PBM that violates the State's rate regulation. In that respect, it is similar to other state contract-law doctrines—such as unconscionability, mistake, or frustration—that would allow a pharmacy to void its network agreement with a PBM, or excuse a pharmacy's non-performance under that agreement, in certain circumstances. *See* Pet. Br. 28-29, 46-47. And many other state laws similarly allow (or require) pharmacists to decline to dispense prescription drugs for a variety of reasons. *See id.* at 47-48.

Respondent has argued that Act 900 is preempted because it imposes procedural obligations on PBMs, such as by requiring them to disclose pricing information, update maximum allowable cost lists, and provide an appeal mechanism. Supp. Br. 6; *see id.* at 1-2. But those procedural obligations do not provide any basis for preemption because the statute imposes them on PBMs, not on ERISA plans using PBMs to administer their pharmaceutical benefits. And even assuming that the challenged provisions create certain administrative burdens on ERISA plans, those burdens are incidental to Act 900's core purpose of rate regulation. *See* Pet. Br. 24-30. This Court has emphasized that laws with "incidental effect[s]" on ERISA plan administration should be upheld, so long as the effects are in furtherance of some broader "generally applicable" state purpose. *Egelhoff*, 532 U.S. at 147-

148.[59] The procedural requirements of Act 900 fall into that category. Prescription drug markets often lack pricing transparency; indeed, that is one of the concerns giving rise to state PBM regulation in the first place. The procedural mechanisms required by Arkansas allow pharmacies to determine at what rate they are entitled to be reimbursed and to challenge a PBM's reimbursement rate when it falls below that level.

Finally, the "objectives of the ERISA statute" must be viewed as "a guide to the scope of the state law that Congress understood would survive." *Gobeille*, 136 S. Ct. at 943 (quoting *Egelhoff*, 532 U.S. at 148); *see supra* 25-26. Thus, when ERISA preempts state law, Congress generally provides a mechanism at the federal level for addressing the problem the state law targets. *See, e.g.*, *Gobeille*, 136 S. Ct. at 944-945 (discussing the Secretary of Labor's authority to require recordkeeping and disclosure of the sort Vermont sought); *Aetna Health Inc. v. Davila*, 542 U.S. 200, 210 (2004) (federal cause of action under ERISA available where state law cause of action is preempted). But ERISA does not create any federal regulatory regime governing PBM reimbursements to pharmacies or authorize any federal agency to address the issue by regulation. There is no reason to believe that Congress sought to preclude Arkansas and other States from stepping in to fill that void.

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[59] *See also Gobeille*, 136 S. Ct. at 946 (distinguishing a preempted state reporting requirement from a state law of general application that "necessitates incidental reporting by ERISA plans"); *De Buono*, 520 U.S. at 815 (state laws may impose "some burdens" on ERISA plans without triggering preemption).

C. As a General Matter, ERISA Does Not Preempt Typical State PBM Regulations

Although this case concerns only Arkansas's Act 900, the Court's decision may well set a precedent affecting PBM regulations across the Nation. *See supra* 14-21. While the precise contours of ERISA preemption analysis may vary depending on the law at issue, as a general matter, ERISA does not preempt typical state PBM regulations because those laws have no impermissible "reference to" or "connection with" ERISA plans. *Gobeille*, 136 S. Ct. at 943.

1. Like Act 900, typical state PBM regulations do not make "reference to" ERISA because they do not "act[] immediately and exclusively upon ERISA plans," nor are ERISA plans "essential" to their operation. *Gobeille*, 136 S. Ct. at 943. States typically define a PBM as a "person, business, or other entity that . . . manages the prescription drug coverage" provided by a health plan. Cal. Bus. & Prof. Code § 4430(j); *accord, e.g.*, Kan. Stat. Ann. § 40-3822(d)-(e); Ohio Rev. Code Ann. § 3959.01(N). Even if certain state-law definitions of PBMs encompass some ERISA plans that may manage their own pharmacy benefits in part, a PBM need not be an ERISA plan, and (as respondent acknowledges) most are not, *see* Supp. Br. 4.[60] And while state laws typically refer to health plans with which PBMs contract, some of which are ERISA plans, the laws generally do not mention ERISA plans specifically, and they apply in the same way regardless of whether a health plan is an ERISA plan. *See Ingersoll-Rand Co.*, 498 U.S. at 139; *Mackey*, 486 U.S. at 830.

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[60] Moreover, even plans that "may perform some PBM functions in-house" still "contract out other functions" to external PBMs. PBM Compensation and Fee Disclosure, *supra* note 8, at 9.

2. Typical state PBM regulations also do not have an impermissible "connection with" ERISA. As noted above, this inquiry looks "both to the objectives of the ERISA statute" and "the nature of the effect of the state law on ERISA plans." *Egelhoff*, 532 U.S. at 147 (internal quotation marks omitted). Both considerations underscore why ERISA does not preempt state laws regulating PBMs' conduct and business relationships in order to protect consumers.

The matters addressed by state PBM regulations are outside "the objectives of the ERISA statute." *Egelhoff*, 532 U.S. at 147. As noted, ERISA seeks to make employer benefits more secure by mandating standard procedures and requirements, including reporting, disclosure, and fiduciary responsibilities. *See supra* 25-26; *Gobeille*, 136 S. Ct. at 943; *Travelers*, 514 U.S. at 661. The conduct and business relationships of PBMs, and their effects on consumers and public health, are far removed from these core ERISA concerns. They are, rather, "'areas where ERISA has nothing to say.'" *Egelhoff*, 532 U.S. at 148 (quoting *Dillingham*, 519 U.S. at 330). For example, ERISA does not remotely seek to address PBM business practices like imposing "gag clauses" that prevent pharmacies from informing customers about lower-priced prescription drugs, or granting preferential treatment to PBM-affiliated pharmacies. *See supra* 19-21.

An analysis of "the nature of the effect of the state law on ERISA plans," *Egelhoff*, 532 U.S. at 147, also illustrates why ERISA does not generally preempt state laws regulating PBMs. The Court has explained that ERISA's goals include creating "nationally uniform plan administration" and preventing ERISA plans from being "subject to different legal obligations in different States." *Id.* at 148; *see Gobeille*, 136 S. Ct.

at 944-945. As the United States has explained, state PBM regulations do not implicate these concerns where they "impose[] obligations on PBMs, not plans" and "regulate[] PBM administration, not ERISA plan administration." U.S. Invitation Br. 14-15. Such laws "do[] not require plans to do anything." *Id.* at 14.

That is true of the vast majority of state PBM laws. For one thing, many (if not most) of these laws regulate the relationship between PBMs and pharmacies, *not* between PBMs and health plans. Some States, for example, require PBMs to exercise good faith and fair dealing in their contracts with pharmacies, or require PBMs to disclose certain pricing data or other information to pharmacies. *Supra* 18-19, 20-21. While these laws might have some "indirect economic influence" on ERISA plans and beneficiaries, ERISA does not preempt them because they "do[] not bind plan administrators to any particular choice" and thus do not "function as a regulation of an ERISA plan itself." *Travelers*, 514 U.S. at 659.

Even where state laws do address the relationship between PBMs and health plans (including ERISA plans), they generally impose obligations on the PBMs, not on the plans. For example, some States require PBMs to exercise good faith and fair dealing in their relationships with plan sponsors. *Supra* 20-21 & n.55. While ERISA might well preempt a law seeking to impose such an obligation on ERISA plans, it does not preempt state laws imposing the obligation on PBMs. Likewise, some States obligate PBMs to keep records and disclose certain information to plan sponsors. *Supra* 20. While ERISA might preempt such laws if they were applied to ERISA plans, *see Gobeille*, 136 S. Ct. at 945, it does not preempt them as applied to PBMs.

As the Court has emphasized, "Congress preempted state laws relating to *plans*," not other types of entities or their obligations. *Fort Halifax*, 482 U.S. at 11. For example, lower courts have repeatedly held that ERISA does not preempt "state-law malpractice or negligence claims" brought by ERISA plans or beneficiaries "against non-fiduciary plan advisors, such as accountants, attorneys, and consultants." *Gerosa v. Savasta & Co.*, 329 F.3d 317, 324 (2d Cir. 2003) (collecting cases); *see also Paulsen v. CNF Inc.*, 559 F.3d 1061, 1082-1083 (9th Cir. 2009); *cf. Pegram v. Herdrich*, 530 U.S. 211, 236-237 (2000) (ERISA does not preempt state medical malpractice claims). Just as ERISA does not preempt state laws that regulate the conduct of such entities in their dealings with health plans (some of which are ERISA plans), it does not preempt state regulations that regulate PBMs in their dealings with health plans.

Respondent has argued that "[a]bsent preemption" of state PBM regulations, "ERISA plans would have to comply with a crazy-quilt of conflicting rules governing the administration of prescription drug benefits." Supp. Br. 3; *see id.* at 2 (asserting that a "panoply of competing state laws" impose "inconsistent obligations"). The claim of conflicting state laws is significantly overstated. While States have taken different approaches to regulating PBMs, most state laws on the subject can be placed into a handful of categories of relatively straightforward requirements, described above. *See supra* 14-21. And respondent has not identified any practice required by one State but forbidden by another State.

In any event, disuniformity of state law is not a basis for ERISA preemption. "[G]eneral health care regulation" of this sort "historically has been a matter

of local concern," and there is "[n]othing in the language of [ERISA] or the context of its passage" indicating that Congress intended to displace state regulation in this area, even if it varies somewhat from State to State, and even if it imposes some degree of burden on regulated entities. *Travelers*, 514 U.S. at 661. In response to widely recognized concerns about PBM business practices, States have adopted regulations designed to protect their residents' access to affordable prescription drugs. ERISA is not a barrier to these common and important state laws.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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