#### **IN THE**

# Supreme Court of the United States

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ARKANSAS ATTORNEY GENERAL,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF OF AMICUS CURIAE AMERICA'S HEALTH INSURANCE PLANS, INC. IN SUPPORT OF RESPONDENT AND AFFIRMANCE

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#### INTEREST OF AMICUS CURIAE1

America's Health Insurance Plans, Inc. ("AHIP") is the national trade association representing the health-insurance community. AHIP advocates for public policies that expand access to affordable healthcare coverage to all Americans through a competitive marketplace that fosters choice, quality, and innovation. Along with its predecessors, AHIP has more than 60 years of experience in the industry. AHIP's members provide health and supplemental benefits through employer-sponsored coverage as well as the individual insurance market and public programs such as Medicare and Medicaid. As a result, AHIP's members have broad experience working with virtually all healthcare stakeholders to ensure that patients have access to needed treatments and medical services. That experience gives AHIP extensive first-hand and historical knowledge about the nation's healthcare and health-insurance systems, and a unique understanding of how those systems work.

AHIP's members provide coverage to millions of individuals who are participants in, or beneficiaries of, employee benefit plans under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001 *et seq.* 

As health-insurance and administrative serviceproviders to ERISA plans, AHIP's members have a direct interest in ERISA's proper application,

<sup>&</sup>lt;sup>1</sup> Counsel for all parties have consented in writing to the filing of this brief. Pursuant to Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and no person or entity, other than *amicus* and its counsel, made a monetary contribution to the preparation or submission of the brief.

including its uniform application throughout the nation under its preemption provision, 29 U.S.C. § 1144(a). On its members' behalf, AHIP previously has challenged successfully on ERISA preemption grounds state laws that regulate ERISA plans, e.g., America's Health Ins. Plans, Inc. v. Hudgens, 742 F.3d 1319 (11th Cir. 2014), and it has participated in prior ERISA preemption cases in this Court. E.g., Gobeille v. Liberty Mut. Ins. Co., No. 14-181 (U.S.); United Healthcare of Az. v. Spinedex Physical Therapy, USA, Inc., No. 14-1286 (cert. denied Oct. 13, 2015); The Rawlings Co. v. Wurtz, No. 14-487) (cert. denied Feb. 23, 2015). In similar fashion, AHIP has an interest in the Court's determination as to whether ERISA preempts the Arkansas law at issue in this case.

#### SUMMARY OF ARGUMENT

I. The question before the Court – namely, whether ERISA preempts Ark. Code Ann. § 17-92-507, known as "Act 900" – arises against the backdrop of an ERISA framework aimed at encouraging employers voluntarily to form and maintain ERISA plans. ERISA's preemption provision is part and parcel of that framework: by including an express preemption provision, Congress sought to ensure predictable, uniform rules for ERISA plans and their administration nationwide.

Also central to the current preemption inquiry is the role that third-party administrators ("TPAs") play in the daily administration of ERISA plans, given that Act 900 targets a particular type of TPA, namely, pharmacy benefit managers ("PBMs"). TPAs provide a broad range of services, most commonly including claims administration, data management and reporting, utilization review, and

flexible spending account administration; those tasks often are so complicated that ERISA plans turn to TPAs to act on their behalf, or these tasks might not be performed at all.

PBMs act on behalf of ERISA plans in the complex and expensive area of administering prescription-drug benefits. PBMs assist with plan design, employ structural cost-savings tools such as clinical guidelines on quantities dispensed, negotiate drug reimbursement discounts for plans, create preferred pharmacy networks to achieve even greater cost savings, ensure low-cost access to generic drugs, and efficiently process claims for participants. At bottom, PBMs' activities are closely intertwined with ERISA-plan sponsors', so that, together, they ensure the seamless and cost-effective provision of prescription-drug benefits to ERISA-plan participants.

II. Application of Act 900 and similar laws would cause upheaval in the administration of ERISA-governed prescription-drug claims. First, it would increase plan costs markedly. Most notably, Act 900 nullifies an ERISA plan's benefit terms by imposing a reimbursement scheme that overrides the ERISA plan's own cost-effective benefit design. Second, Act 900 and laws like it prevent nationally uniform, efficient administration of ERISA benefits, including, in the case of Act 900, its requirement authorizing pharmacies to "appeal" reimbursements and to reopen completed benefit claims to obtain amounts greater than the plan's otherwise-applicable allowance. Third, laws like Act 900 negatively affect plan design, because – due to the increased costs of complying with such laws – employers would need to adjust plan terms to accommodate the increased costs and inefficiencies. Fourth, if allowed to survive on the theory asserted by Petitioner and the United States, laws like Act 900 would threaten the broad use of TPAs that is critical for the sound working of ERISA plans.

III. Fortunately, the negative and disruptive effects that easily can be envisioned from the operation of Act 900 and similar laws in the ERISA context should not come to pass, because ERISA preempts Act 900. While Respondent has persuasively established that the Eighth Circuit was correct to find preemption, some additional legal points are worth emphasizing. One is that ERISA preemption operates equally when the target of a state law is an agent of an ERISA plan as when the state law targets the ERISA plan itself.

Another is that there is no presumption in this case against ERISA preemption.

Last, the Court can easily resolve this case — in favor of preemption — by applying the "reference to" strand of its ERISA-preemption jurisprudence as it historically has and to which the Eighth Circuit paid fidelity. The Court's prior cases hold that a law focused on "benefits" and "plans," without excluding ERISA plans, necessarily refers to ERISA plans, and Act 900 fails under that test.

#### **ARGUMENT**

- I. THIRD-PARTY ADMINISTRATORS, SUCH AS PHARMACY BENEFIT MANAGERS, PROVIDE CRITICAL SERVICES TO ERISA PLANS
  - A. ERISA Encourages Employers Voluntarily to Establish Health Benefit Plans Subject to a Uniform Set of Requirements

Congress enacted ERISA to encourage employers voluntarily to establish employee benefit plans. To entice them to create such plans, Congress gave employers great flexibility in plan design and assured "a predictable set of liabilities, under uniform standards of primary conduct and a uniform regime of ultimate remedial orders and awards when a violation has occurred." *Conkright v. Frommert*, 559 U.S. 506, 516 (2010) (quoting *Rush Prudential HMO*, *Inc. v. Moran*, 536 U.S. 355, 379 (2002)).

To fulfill its assurance of national uniformity, Congress adopted ERISA's express preemption section, which states that "the provisions of [ERISA] . . . shall supersede any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan" governed by ERISA. 29 U.S.C. § 1144(a) (emphasis added). ERISA's preemption provision "indicates Congress's intent to establish the regulation of employee welfare benefit plans as exclusively a federal concern." *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 944 (2016) (internal quotation marks and citation omitted).

Congress's invitation for employers to create ERISA plans under the prospect of nationally uniform plan administration has worked: ERISA plans have become the bedrock of the American healthcare system. Employers now provide health benefits for nearly 153 million Americans under the age of 65, which accounts for 47% of the total U.S. population and 55.5% of people under the age of 65. See Kaiser Family Found., Employer Health Benefits: 2019 Annual Survey 65 (2019), <a href="http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019">http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2019</a>.

Given ERISA's state-law preemption provision, Congress has recognized the need for national legislation and has carefully regulated employee benefit plans. As particularly relevant to this case, the Affordable Care Act ("ACA") contains mandates regarding the provision of prescription-drug benefits by ERISA (and other) plans. See 42 U.S.C. § 18022(b)(1)(F); 45 C.F.R. § 156.122(a)(1); see generally U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., Frequently Asked HealthQuestions onEssentialBenefits, https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf (addressing prescription-drug and other benefit mandates for self-funded employer-sponsored health plans). Above and beyond any minimum standards set by the ACA, employers may, at their option, provide any prescription-drug benefits they choose. See Curtiss-Wright Corp. v. Schoonejongen, 514 U.S. 73, 78 (1995).

### B. Third-Party Administrators Are Commonly Relied Upon to Administer ERISA Plans

When an employer decides to provide health benefits to its employees, it typically structures its program in one of two different ways. One way is for the employer to purchase an insurance policy from a health-insurance provider, paying a premium to the health-insurance provider for employees who are covered. This is referred to as a "fully insured" health benefit plan. See Congressional Research Service, Health Insurance: A Primer 4 (Jan. 8, 2015), <a href="https://tinyurl.com/rh5h8lv">https://tinyurl.com/rh5h8lv</a>. Alternatively, an employer can choose to establish a "self-funded" (or "self-insured") plan. With this type of plan, the employer pays for employees' medical claims out of its own assets and consequently bears the risk associated with employees' medical claims. Id. In each instance, the employer defines the health benefits that the plan will provide (along with following federal mandates).

Employer sponsors offering self-funded plans historically have contracted with what are known as third-party administrators, or "TPAs," to help administer health-plan benefits, rather than control the day-to-day operations of their health plans themselves. They do so because TPAs – whether health-insurance providers offering additional services or independent entities – deliver a wide range of services and administrative functions that employers are ill-suited to perform themselves. After all, employers are organized for a business purpose, not for the purpose of providing healthcare services or healthcare reimbursements for their employees. This holds true regardless of whether the employer is a start-up software company or a large hardware chain. Even health-insurance providers supplying coverage under an employer's fully insured ERISA plan will often subcontract with a TPA with particularized expertise to assist in the administration of the plan.

TPAs provide a broad range of services, most commonly including claims administration, data management and reporting, utilization review, and flexible-spending-account administration. John C. Garner, Health Ins. Answer Book Q 10:53 (12th ed. 2014 & 2020-1 Supp. 2019). Other TPA functions could include the administration of dental and vision benefits, network development, provider contracting including telehealth services, direct contracting arrangements (e.g., utilizing accountable care organizations ("ACOs") and Centers of Excellence), healthcare navigation services, and nurse help lines. In the self-funded situation, the employer sponsor determines which aspects of plan administration to delegate to a TPA (or multiple TPAs), and it then negotiates with the TPAs for those services. See Fed. Trade Comm'n, Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies 8 (Aug. 2005), https://tinyurl.com/ujrautt ("FTC, Mail-Order Report"). Ultimately, whether or not a TPA is used is entirely up to an employer when it designs its respective plan.

# C. Pharmacy Benefit Managers Administer Some of the Most Expensive ERISA Health Benefits for Employers: Prescription-Drug Benefits

Both fully insured and self-funded ERISA plans traditionally provide prescription-drug benefits to plan participants. However, such benefits include more than just access to prescription drugs. The benefits include a host of other services and functions designed to reduce costs and improve health outcomes. As a result of a variety of factors, including the ever-increasing prices of prescription drugs and other drug-manufacturer practices,

prescription-drug benefits are one of the fastest growing segments of healthcare costs in the United States.

Despite significant reforms and efforts by employer sponsors and health-insurance providers to cost-containment, overall national improve healthcare expenditures are expected to increase 5.5% per year between 2018 and 2027, outpacing average annual growth in the economy. U.S. Dep't of Health & Human Servs.. Centers for Medicare & Medicare Servs., Nat'l Health Expenditure Projections 2018-2027: Forecast Summary 1 (2019), https://tinyurl.com/ya24kgbk. The cost of prescription drugs in particular is expected to increase considerably. In 2010, U.S. consumers spent \$253.1 billion on prescription drugs; by 2020, that cost is projected to increase by almost 50%, to \$378.9 billion, representing more than 10.5% of total projected healthcare costs. U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicare Servs., Nat'l Health Expenditure Projections 2018-2027, csv file Nat'l Health Expenditure (NHE) Amounts by Type of Expenditure and Source of Funds: Calendar Years 1960-2027, rows 670 and 680 (Dec. 2018), https://tinyurl.com/ruyn634. And by 2027, government actuaries estimate that prescription-drug spending will reach \$576.7 billion. *Id.* at row 687.

As a consequence, providing prescription-drug benefits to plan participants has become increasingly expensive, and managing those costs is a top priority for employers, employees, and health-insurance providers. To do so, employers (or their health-insurance providers) have increasingly contracted with pharmacy benefit managers, or "PBMs." A PBM is a specialized TPA that manages an ERISA

plan's prescription-drug benefits. PBMs now administer drug benefits for more than 266 million Americans, including those participating in ERISA health benefit plans. See Health Affairs, Health Policy Brief Series: Prescription Drug Pricing No. 12, Pharmacy Benefit Managers 45 (Sept. 2017), <a href="https://tinyurl.com/rcz5jdx">https://tinyurl.com/rcz5jdx</a> ("Health Affairs, PBMs").

Moreover, the relationship between the employer sponsor (or health-insurance provider) and PBM is a unique contractual relationship reflecting negotiations between parties, designed to tailor benefits in a manner that reflect the employer sponsor's priorities and underlying benefit goals. See PBMI, Trends at 27; FTC, Mail-Order Report at 8-10. These are not one-sided agreements, but the result of arm's length negotiations between sophisticated actors on both sides – for instance, large multi-state employers and health-insurance providers on one side, and the PBMs on the other. The former are able to, and do, negotiate advantageous terms for the benefit of ERISA-plan participants.

As explained in detail by Respondent, PBMs provide the leverage and expertise needed to navigate the complex manufacturing and distribution chain for prescription drugs. Resp. Br. 6-10; see The Commonwealth Fund, Explainer: Pharmacy Benefit Managers and Their Role in Drug Spending 1 (Apr. 2019), <a href="https://tinyurl.com/sd7v22b">https://tinyurl.com/sd7v22b</a> ("The Commonwealth Fund, Explainer"); Health Affairs, PBMs at 45. There are, too, other vital services and functions performed by PBMs on behalf (and at the direction) of employer sponsors and health-insurance providers. Those services can be grouped into six general areas and reflect how Arkansas's Act 900 is, in

effect, regulating the administration of the ERISA plan itself.

- 1. Plan Benefit Design. PBMs are oftentimes involved at the very beginning of the design and development of an employer sponsor's ERISA plan. PBMs act as consultants and provide input on how to design a plan in a way that maximizes benefits for employees in the most cost-effective manner for the employer sponsor. PBMs help define and establish "tiered" copayments, in which lower copays are assigned to lower-cost but therapeutically equivalent drugs to encourage their use over more expensive medications. See The Commonwealth Fund, Explainer at 1; Health Affairs, PBMs at 45; Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Health Care: A Dose of Competition ch. 7, at 12-13 (July https://tinyurl.com/keh4ps3 ("FTC/DOJ 2004), Healthcare Report"). These structures determine the out-of-pocket costs paid by participants and are intended to encourage individuals to utilize the lowest-cost option when faced with a choice between multiple therapeutically equivalent drugs, to the advantage of both the participants and their employer. See The Commonwealth Fund, Explainer at 1.
- 2. Other Structural Cost-Saving Tools. PBMs also implement important drug-management strategies that focus on ensuring, among other things, that clinically appropriate guidelines and drug-quantity and refill limits are followed. See Pharmacy Benefit Mgmt. Inst., Trends in Drug Benefit Design 27 (2018) ("PBMI, Trends"). Other structural cost-saving tools offered by PBMs include clinical and educational programs that target health and safety, with savings derived primarily from preventing potential negative health outcomes. Id. at

- 29-30. And the development and refinement of such tools do not remain static. PBMs are constantly improving upon all of these plan-design elements to meet both evolving market conditions and employer sponsors' shifting needs. *Id.* at 1.
- 3. Negotiating Drug Prices. PBMs represent employer sponsors of self-funded plans and health-insurance providers in the prescription-drug distribution chain and help contain drug costs. They build and manage continuously evolving formularies (i.e., lists of prescription drugs approved for coverage under a client's benefit plan), negotiate significant discounts and rebates from manufacturers (who compete to have their drugs listed), and then at the plan's direction place lower-cost drugs in preferred copay tiers to incentivize participants to use them. FTC, Mail-Order Report at 6; FTC/DOJ, Healthcare Report, ch. 7 at 11-12.
- 4. Pharmacy Networks. Because retail pharmacies are on the "front line" in terms of providing prescription drugs to consumers, PBMs also establish networks of pharmacies to fill prescriptions for plan participants. FTC, Mail-Order Report at 3-4. This is again done at the employer sponsor's direction as a cost-control tool. Overall, PBMs contract with 90% to 95% of the retail drug stores in the regions they serve, and, in return, the in-network pharmacies offer large-scale discounts on ingredient costs and dispensing fees. Id. at 4.
- 5. Lowest-Cost Access to Generic Drugs. A PBM will set the price at which it will reimburse a retail pharmacy for generic drugs on behalf of an ERISA plan, based on a maximum allowable cost ("MAC") pricing list. See Resp. Br. 11. Employer sponsors, and in some cases health-insurance

providers, delegate to PBMs the job of developing and managing MAC lists as another cost-control measure, because, in most cases, pharmacies can choose between therapeutically equivalent generic medications produced by multiple manufacturers that are set at different prices. PBMs set MACs in the lower range to encourage pharmacies to purchase the least expensive generic for their inventory, in order to provide significant cost-savings to plans. See id. at 12. Retail pharmacies then offer discounts from the MAC depending on the PBM's plan clients and the exclusivity of the retail pharmacy network. FTC/DOJ, Healthcare Report, ch. 7 at 14. As Respondent correctly observes, setting these reimbursement terms and procedures by contract is essential to plans' efforts to predict and contain prescription-drug costs and maximize benefits for ERISA-plan participants; and MAC lists are among the principal means utilized to contain generic-drug costs. See Resp. Br. 10-11.

6. Claims Processing. PBMs also process and pay benefit claims on behalf of ERISA plans. Claims adjudication is an important and exceedingly complex service on behalf of employer sponsors and health-insurance providers. As described by Respondent, and in more detail below, when a patient seeks to fill a prescription, the pharmacy communicates with the PBM electronically to ensure that the prescription is filled according to the participant's coverage. *Id.* at 8. In response, the PBM instantly verifies whether the patient is a plan participant and whether the drug is covered by the ERISA plan, as well as any cost-sharing amount owed by the participant and the amount of reimbursement the PBM will remit to the pharmacy. Id. The pharmacy then collects the payment due from the patient (if any), and the PBM reimburses the pharmacy according to the rate structure agreed to in the network contract. *Id.* 

In sum, PBMs perform important benefit-administration functions for employer sponsors and health insurance providers with respect to ERISA plans that result in greater predictability and substantial savings in the cost of covering prescription drugs for ERISA-plan participants. They create efficiencies in plan administration, claims costs, and the delivery and coordination of care that is in many instances impracticable for an employer to establish and manage on its own. See The Commonwealth Fund, Explainer at 1; Health Affairs, PBMs at 45; FTC/DOJ, Healthcare Report, ch. 7 at 10-18; see also Resp. Br. 9 (noting that "internal administration of prescription drug benefits would be a 'practical impossibility' for many plans because doing so would mean 'forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer") (quoting PCMA v. D.C., 613 F.3d 179, 188 (D.C. Cir. 2010)).

# D. The Roles of Employers and Health-Insurance Providers on the One Hand, and PBMs on the Other, Are Inextricably Intertwined in Administering a Typical Drug Claim

The interconnected and interdependent relationship between ERISA-plan sponsors and health-insurance providers on the one hand, and PBMs on the other, is illustrated by reviewing the "life" of a typical retail prescription-drug claim. That claim process is designed and administered to result seamlessly in prescriptions being filled for ERISA-plan participants and subsidized by their ERISA plan.

From the initial benefit design, to the payment (*i.e.*, reimbursement) of a claim under that design, the PBM plays an indispensable role in the plan-administration process by facilitating the provision of employee health benefits on behalf of and at the direction of the plan. Ultimately, when one examines a typical claim, one can see how an otherwise exceptionally complex process results in the relatively simple and instantaneous transaction millions of ERISA-plan participants experience at their local pharmacy on a daily basis.

At the outset, the employer defines the prescription-drug benefit through the terms of the ERISA plan. This includes not only determining which of the tens of thousands of prescription drugs will be covered or excluded (and for what conditions), but also calculating and balancing the associated cost of coverage in order then to establish plan participants' cost-sharing amount (i.e., copay, coinsurance, and/or deductible), if any. These cost-sharing amounts could be determined either by the ERISAplan sponsor in consultation with a PBM, by the employer sponsor's health-insurance provider with a PBM, or by the employer sponsor on its own. As Respondent explains in detail, cost-sharing typically requires a plan participant to cover a certain portion (or percentage) of the overall charges until the participant reaches the plan-defined limit, after which the ERISA plan then covers additional amounts or the remaining full cost of plan-year benefits, depending on the terms of the ERISA plan. Resp. Br. 6.

Thereafter, the ERISA-plan sponsor (or healthinsurance provider for a fully insured plan) works with its PBM to administer the benefit. The PBM begins by developing a network contract with pharmacies both nationally and in certain geographic areas. Per the contract's terms, the PBM will outline payment for most generic drugs to the pharmacy based on the PBM's MAC pricing list. If multiple manufacturers have set the generic-drug price at different levels – say, the drug-acquisition prices range from \$10 to \$20 per unit – the PBM will pay in the lower range, perhaps \$12, to encourage pharmacies to buy the least expensive generic for their inventory. In that way, a MAC list will drive savings for plan sponsors. A self-funded plan will reimburse the \$12 cost directly and have the predictability of relying on that \$12 price across its plan. See id. at 9 (describing cost "pass through" to selffunded plans and "spread" pricing). A fully insured plan will be able to offer employers lower premiums that reflect cost savings realized by the health-insurance provider's use of a PBM.

The PBM then codes the MAC pricing and the plan design (copay, coinsurance, and deductible amounts), among other data-entry points, into the point-of-sale adjudication system (i.e., the sale at the pharmacy counter). Because of that coding, the pharmacy gets immediate notice of both the ERISA plan's coverage and payment amount as well as what the pharmacy must collect from the participant. The participant then receives the drug at the counter and pays the cost-share or deductible (if any), and the PBM subsequently facilitates reimbursement of the ERISA plan's share from the employer sponsor or the health-insurance provider.

If all of this seems easy, it isn't. Neither should the resulting seamless and cost-effective delivery of such benefits be taken for granted. It is facilitated by the uniform administration of benefits that employers are able to provide as a result of ERISA's critically important preemption provision.

# II. ARKANSAS'S LAW AND LAWS LIKE IT IN OTHER STATES SUBSTANTIALLY HAM-PER THE ADMINISTRATION OF ERISA PLANS

Application of state laws like Arkansas's Act 900 significantly undermines the administration of ERISA plans and, specifically, their administration of prescription-drug benefits.

# A. Act 900 Increases ERISA-Plan Costs by Interfering with the Administration of the Employer Sponsor's Defined Benefits

The operation of laws like Act 900 would markedly increase the cost of providing ERISA benefits, an already expensive endeavor that employers need not undertake in the first place. For example, Act 900 sets generic-drug reimbursement rules for a "[p]harmacy benefits plan or program." Ark. Code Ann. § 17-92-507(a)(9); see id. § 17-92-507(a)(6). As the Eighth Circuit noted, "[t]he Act mandates that pharmacies be reimbursed for generic drugs at a price equal to or higher than the pharmacies' cost for the drug based on the invoice from the wholesaler." Pet. App. 4a.

Act 900, in effect, requires administering plan benefits in a manner that will inevitably increase an ERISA plan's reimbursement terms – indeed, override them – for generic drugs. This intrudes on a core function of what plans do: determining how both the plan and its participants must pay for a given benefit.

In the above example where the PBM has established a MAC price of \$12 for a generic drug that the pharmacy can acquire anywhere from \$10 to \$20 per unit, the pharmacy that purchases the higher-acquisition cost generic will be rewarded, under Act 900, for purchasing the higher-cost drug. Rather than abiding by a contractual agreement to accept the ERISA plan's MAC-based reimbursement for the lower-cost version, the pharmacy would instead be allowed to seek reimbursement at the higher invoice cost at which it elected to acquire the drug. And this is despite the fact that pharmacy invoice costs exclude discounts and financial incentives pharmacies receive from drug suppliers and therefore do not reflect the actual cost to the pharmacy. See Resp. Br. 5-6, 15, 24, 29.

For the self-funded ERISA plan, the impact of the increased reimbursement cost is pronounced, insofar as the plan must draw from its own assets to reimburse the pharmacy directly in an amount greater than the \$12 the PBM would have otherwise facilitated. In addition, plan participants' cost-sharing amounts established by the employer sponsor in its ERISA plan will likewise be affected. In a case where a participant's cost obligation is not a fixed copay, but rather coinsurance calculated as a percentage of the reimbursement amount, the individual's cost obligation will increase in direct proportion to the additional amount the plan is required to reimburse the pharmacy as a result of Act 900's requirements. If a participant is subject to an unmet deductible, the participant may face even more outof-pocket costs. All of this works to alter fundamentally what participants (and their employer sponsor) would otherwise owe and pay under their existing ERISA plan's benefits. And it does so in a manner that materially increases costs.

#### B. Act 900 Prevents the Uniform Application of ERISA-Plan Benefits

Next, application of state measures like Act 900 would decrease efficient drug-claim adjudication nationally. An ERISA plan and its PBM would no longer enjoy nationally uniform reimbursement terms for prescription-drug benefits. Instead, for a multistate plan, each state would have its say in the reimbursement amount for a pharmacy, replacing the otherwise uniform administration of a plan's benefits across state lines. An ERISA plan would have to tailor its benefits administration to each state, with the PBM needing to set up different systems dependent on the specific pricing authorized under each state's laws.

In the case of Arkansas, Act 900's provisions allowing for "administrative appeal procedures" for dissatisfied pharmacies highlights how the state's law thwarts efficient, uniform plan administration. Pet. App. 4a (citing Ark. Code Ann. § 17-92-507(c)(4)(A)(i)). These procedures

allow[] the pharmacies to reverse and rebill each claim affected by the pharmacies' inability to procure the drug that is equal to or less than the costs on the [PBM's] relevant MAC list where the drug is not available "below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale."

*Id.* (quoting Ark. Code Ann. § 17-92-507(c)(4)(C)(iii)).

In those situations, the ERISA plan must reopen its benefits claims process to readjust the reimbursement already determined for the pharmacy. This not only extends an ERISA plan's claims process, but also raises a series of benefit-administration questions regarding how a plan would resolve the resulting cost-sharing issues. For example, must participants return to the pharmacy to make good on what they owe? Will the ERISA plan set up a different procedure through the plan (or other means) to ensure participant compliance with the coinsurance and deductible terms? Will the pharmacy offset the amount the participant owes on the next prescription to make up the difference, and, if so, how? These questions clearly implicate matters central to the administration of an ERISA plan's prescriptiondrug benefits. Moreover, extending beyond just Arkansas, depending on the laws in place in any given state, the answers to such questions could very well be different, not only for the employer sponsor and its ERISA plan, but also any participants who may seek their prescription-drug benefits under the same plan but in a different state (e.g., when travelling for work).

#### C. Act 900 Impacts ERISA-Plan Design

Application of Act 900 and other states' analogues negatively affects ERISA-plan design by forcing employers to decrease other benefits in order to account for the increased costs caused by such laws. With regard to Act 900, it is unrealistic to assume that employers will simply accept the costs foisted on them. Already facing increasing health-care costs driven in large part by ever-increasing prescription-drug expenditures, and with no legal obligation to provide ERISA benefits in the first instance,

employers will inevitably seek to truncate their plans in one way or another to account for cost increases imposed by laws like Act 900.

Even more directly, Act 900 – with its reimbursement mandate – overrides the ERISA plan's very terms concerning reimbursement for generic drugs. Among other things, a plan might have an "allowance" for generic drugs based on the MAC list established on its behalf by a PBM. An "allowance" is the specified reimbursement level keyed (perhaps as a percentage) to a particular benchmark stated in the plan, such as a "negotiated" amount with the provider, the Medicare payment level, or the "usual, customary, and reasonable" charge. Yet, Act 900 overtly nullifies that element of the plan's design, by substituting a state-law benchmark for the plan's. And still further, Act 900's "decline-to-dispense" option," which applies to instances where the invoice price exceeds the MAC price, significantly qualifies or curtails the plan's prescription-drug benefit. See Ark. Code Ann. § 17-92-507(e). It makes the benefit unavailable from a network pharmacy that (by being in the network) has agreed to provide services to the participant and to which the plan has steered the participant.

# D. Upholding Act 900 May Threaten the Efficient Use of Other TPAs

Upholding state laws like Act 900 – especially if on the grounds presented by Petitioner and the United States in this case – will threaten ERISA plans' ability to use TPA services more generally. As noted, PBMs are only one type of TPA. Just as states seek to regulate how PBMs provide services to plans, they may, if the Court adopts the rationales posited by Petitioner and the United States, likewise seek to

regulate TPAs more generally in the same way. States might pursue a variety of new measures that they may believe fall within the expansive "ordinary market regulation" standard Petitioner asserts in this case or under the similar theory advanced by the United States. *See* Pet. Br. 13; U.S. Br. 20-21.

Courts have consistently held that ERISA preempts state attempts to regulate ERISA-plan TPAs. E.g., America's Health Ins. Plans v. Hudgens, 742 F.3d 1319, 1325 (11th Cir. 2014) (Georgia TPA law); NGS Am., Inc. v. Barnes, 998 F.2d 296, 300 (5th Cir. 1993) (Texas TPA law); Self-Ins. Inst. of Am. v. Gallagher, No. 86-7308, 1989 U.S. Dist. LEXIS 13942, at \*31 (N.D. Fla. June 2, 1989), aff'd mem., 909 F.2d 1491 (11th Cir. 1990) (Florida TPA law); see generally Nat'l Ass'n of Ins. Comm'rs, Registration and Regulation of Third Party Administrators (Oct. 2011), https://tinyurl.com/wf3ukag (model law).

Other TPA services may also be swept into the bull's-eye of state regulation, including efforts by states to establish minimum reimbursements that TPAs must pay for certain facilities, providers, items, or services, which in turn would have the effect of increasing costs and forcing employer sponsors to make adjustments in other plan benefit designs. For example, ERISA plans' ability to utilize direct contracting arrangements with ACOs and Centers of Excellence might be jeopardized, given such arrangements oftentimes involve contractually provided payment innovations designed to reward wellness education and promote access to quality, cost-effective care based on standards and other criteria agreed to by the employer sponsor. Similarly implicated would be an ERISA plan's ability to design benefits that utilize telehealth (an especially critical tool in the current public-health environment) or near-site clinics — services that may offer no cost-sharing and help participants seek appropriate care for their conditions and avoid unnecessary and expensive emergency room visits.

#### III. ERISA PREEMPTS ACT 900

The negative and disruptive impact of Act 900 and similar state statutes need not come to pass. Respondent has convincingly shown why ERISA preempts Act 900. AHIP writes separately to amplify several points that further demonstrate why ERISA's preemption provision requires the supersession of Act 900: because ERISA preemption encompasses plan agents as much as plans themselves, because there is no presumption against preemption, and because the "reference to" strand of ERISA preemption straightforwardly covers this case.

# A. ERISA Preemption Extends to the Agents of ERISA Plans No Less Than to the Plans Themselves

A theme pervading Petitioner's and its *amicis*' briefs is that Act 900 does not regulate ERISA plans, but only PBMs, so that the state law supposedly does not "relate to" ERISA plans. As Petitioner argues, Act 900 "merely regulate[s] how third-party administrators interact with *fourth parties* that provide the goods that a plan has already chosen to cover." Pet. Br. 25. This argument is contrary to the Court's prior decisions and is otherwise flawed. Act 900 has an immediate impact on ERISA plans as it regulates – indeed, *solely* regulates – "entit[ies] that administer[] or manage[] a pharmacy benefits *plan or program*." Ark. Code Ann. § 17-92-507(a)(7) (definition

of "Pharmacy benefits manager") (emphasis added). Even if the regulation had only an indirect impact on ERISA plans, the Court has long emphasized that ERISA preempts a state law "even if the law is not specifically designed to affect such plans, or the effect is only indirect." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990).

In Gobeille v. Liberty Mutual Insurance Co., 136 S. Ct. 936 (2016), the Court found ERISA to preempt a state law that required data reporting from "any third party administrator' and any 'similar entity with claims data, eligibility data, provider files, and other information relating to health care provided to a Vermont resident." Id. at 941 (quoting Vt. Stat. Ann., Title 18, § 9410(j)(1)(B)); see Liberty Mut. Ins. Co. v. Donegan, 746 F.3d 497, 508 n.10 (2d Cir. 2014) "It is of no moment that the law is being applied to, and the subpoena targeted at, Liberty Mutual's TPA rather than Liberty Mutual itself. . . . '[T]he objective of uniformity in plan administration' is not 'for some reason inapplicable simply because a plan has contracted with a third party to provide administrative services.") (quoting PCMA v. D.C., 613 F.3d 179, 182 (D.C. Cir. 2010)).

Indeed, treating plan agents differently than ERISA plans themselves, for preemption purposes, would elevate form over substance. Here, TPAs are standing in the shoes of the plan for specified functions in which the TPA and not the plan has expertise. As noted, TPAs, including PBMs, conduct core administrative tasks that the ERISA plan would need to do, absent contracting with a TPA. In the prescription-drug-claim setting, a PBM helps process -i.e., adjudicate -a claim, handling everything from making benefits available under preferred

terms from a network, to facilitating the application of the plan's terms on cost-sharing and deductibles, to ensuring seamlessly that the participant obtains the pharmaceutical immediately rather than delayed until after the plan's payment to the pharmacy (*i.e.*, the ERISA-plan benefit) is completed.

Preemption should not hinge on who does the tasks, but on the nature of the tasks themselves. *Cf.* UNUM Life Ins. Co. v. Ward, 526 U.S. 358, 379 (1999) (holding that ERISA preempted state agency law applied to insurer's adjudication of ERISA-plan benefits under insurance policy); Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 48 (1987) (holding that ERISA preempted state common-law causes of action, when posited against insurer of ERISA plan). It would be an odd legal regime if ERISA preemption could occur only when the ERISA plan's administrator (as opposed to a TPA) does the plan's work, especially when, as in the complicated circumstances of prescription-drug benefits, the ERISA plan's staff may lack the expertise to accomplish all that needs to be done to serve the plan's participants.

The statutory phrase "relate to" itself signifies that ERISA preemption should extend beyond ERISA plans to, at least, the first layer of relationships the ERISA plan forms to administer the plan terms. The preemption provision does not say that "ERISA preempts any and all state laws regulating employee benefit plans." Rather, § 1144(a) preempts any state laws that "relate to" employee benefit plans. The relationship in this case is not a distant cousin to the plan; the TPA is in an immediate relationship with the plan to do the plan's work. There is no special rule for ERISA that its plain text should not matter, particularly with respect to the

preemption provision that the Court has long seen as a key ingredient of the statutory whole. *E.g.*, *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 99 (1983).

# B. There Is No Presumption Against Preemption under ERISA's Express Preemption Provision

There is no presumption against preemption, in light of ERISA's express preemption provision, 29 U.S.C. § 1144(a). Over the past decades, the Court has evolved in its views on whether there is a presumption against preemption of state laws when a federal statute includes an express preemption clause, as ERISA does. The Court should make clear that any remnant of a presumption against express preemption was upended by *Gobeille* and *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938 (2016) ("Franklin").

For the first two decades following ERISA's enactment, the Court largely had not applied any presumption against preemption under § 1144(a). Instead, the Court characterized ERISA's preemption provision as the statute's "crowning achievement" and revolutionary for its time. Shaw, 463 U.S. at 99 (quoting 120 Cong. Rec. 29,197 (1974) (statement of Rep. Dent)); see Franchise Tax Bd. v. Constr. Laborers Vacation Tr., 463 U.S. 1, 24 n.26 (1983) (describing § 1144(a) as a "virtually unique pre-emption provision"). However, consistent with a trend developing at the time with respect to express preemption provisions generally, the Court's decision in New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Insurance Co., 514 U.S. 645, 654-55 (1995) ("Travelers"), reversed the historical course under ERISA and instructed for ERISA's preemption section a "starting presumption that Congress does not intend to supplant state law . . . in fields of traditional state regulation."

Gobeille showed that the Court had now shifted its view back, when it refused to recognize at all the existence of a presumption against preemption. See Gobeille, 136 S. Ct. at 946 ("Any presumption against pre-emption, whatever its force in other instances, cannot validate a state law that enters a fundamental area of ERISA regulation and thereby counters the federal purpose in the way this state law does.") (emphasis added).

Finally, in *Franklin*, the Court formally ruled that, where a "statute contains an express pre-emption clause,' we do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." 136 S. Ct. at 1946 (quoting *Chamber of Commerce v*. Whiting, 563 U.S. 582, 594 (2011)). Though Franklin evaluated the preemption provision in a federal Bankruptcy Code section and thus was not an ERISA case, the Court in Franklin cited Gobeille in support of the proposition that there is no presumption against preemption if a statute contains an express preemption provision. See id. As a result, after Franklin, the Circuits have begun to reject a presumption against preemption when applying ERISA's express preemption provision, determining Travelers to have been overruled on the point. E.g., Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan, 938 F.3d 246, 259 (5th Cir. 2019) ("Given that Franklin specifically references Gobeille - an ERISA case - when holding that there is no presumption of preemption when the statute contains an express preemption clause, we conclude that holding is applicable here.").

In light of Gobeille and Franklin, the Court should reject a presumption against preemption when applying ERISA's express preemption clause, including in this case with respect to Act 900. The key to applying § 1144(a)'s "terse but comprehensive" text is – as Gobeille instructs – to continue to fashion "workable" standards for determining when state laws "relate to" ERISA plans, such as under the "reference to" and "connection with" rubrics, not to rely on an extra-statutory presumption against preemption. 136 S. Ct. at 943; see FMC Corp. v. Holliday, 498 U.S. 52, 58 (1990) (referring to § 1144(a)'s language as "plain" and reiterating that "a law relates to an employee welfare plan if it has 'a connection with or reference to such a plan") (quoting Shaw, 463 U.S. at 96-97).

#### C. Act 900 Makes a "Reference to" ERISA Plans

Finally, there is a simple way to resolve this case in favor of preemption: the Court should hold that Act 900 makes a "reference to" ERISA plans. The Court has "virtually taken it for granted that state laws which are 'specifically designed to affect employee benefit plans' are pre-empted under § [1144(a)]." *Mackey v. Lanier Collection Agency Serv.*, 486 U.S. 825, 829 (1988) (quoting *Pilot Life*, 481 U.S. at 47-48). Act 900's text, and its references to "benefit plans" and "programs," evinces such a design. The Eighth Circuit so held, and its holding was correct. *See* Pet. App. 7a.

The "reference to" rubric is a precise test that focuses on the actual text of the state law at issue. If

a state law, in its language, specifically mentions employee benefit plans, the state law cannot escape "relat[ing] to" them. Either the state law references plans, or it does not. There is no need for turning to matters such as context, structure, or ERISA's legislative purposes – things on which reasonable minds can often disagree, leading to disparate, unpredictable outcomes.

The Eighth Circuit rightly recognized that – by its very text - Act 900 regulates those who administer employee benefit plans. Act 900 applies exclusively to "Pharmacy benefit manager[s]," which it defines as: "an entity that administers or manages a pharmacy benefits plan or program." Ark. Code Ann. § 17-92-507(a)(7). In turn, "Pharmacy benefits plan or program' means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state." Id. § 17-92-507(a)(9). Such a plan or program easily satisfies the definition of an ERISA welfare benefit plan. See 29 U.S.C. § 1002(1) (defining "employee welfare benefit plan" or "welfare plan" as "any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer . . . for the purpose of providing for its participants or their beneficiaries ... medical, surgical, or hospital care or benefits, or benefits in the event of sickness").

By the plain language of its definitions, then, Act 900 references plans that ERISA draws within its compass. In fact, an ERISA plan itself (or at least its plan administrator) is a target of Act 900, since it is an entity that administers a program reimbursing and covering pharmacist services, insofar as the ERISA plan provides prescription-drug benefits

(which they all inevitably do). In this respect, as Respondent notes, see Resp. Br. 48-49, Act 900 is like the state statute that the Court found to be preempted in FMC Corp. v. Holliday, 498 U.S. 52 (1990). There, the Court found that a Pennsylvania anti-subrogation law made an impermissible "reference to" ERISA plans because it addressed benefits and contracts for benefits and contained language extending its reach to benefits payable from a private employer's benefit plan. FMC Corp., 498 U.S. at 59 (noting the state statute "refers to 'any program, group contract or other arrangement for payment of benefits," which "include, but [are] not limited to, benefits payable by a hospital plan corporation or a professional health service corporation.") (quoting Pa. Cons. Stat. § 1719) (emphasis in original). The Pennsylvania law did not work exclusively on ERISA plans, but operated on an enumerated field that encompassed ERISA plans and did not seek to exclude them. See id.

Nor is California Division of Labor Standards Enforcement v. Dillingham Construction, N.A., 519 U.S. 316 (1997) ("Dillingham"), to the contrary. In Dillingham, the Court found no reference because the California wage law at issue – when applied to the universe of private employers subject to ERISA – could cover some private-employer apprenticeship programs that were not ERISA plans (such as those that employers established without trusts). Thus, ERISA plans were not "essential" to the California law's operation even with respect to private-employer apprenticeship plans. Id. at 325.

In contrast, no private employer subject to ERISA can escape application of Act 900 if the employer provides prescription-drug benefits, because Act 900 applies solely to pharmacy benefit plans or programs and no ERISA-governed private employer can establish such a plan or program without also satisfying ERISA's "welfare plan" definition. The same was true in *FMC Corp.*, where the state law *inevitably* would operate (absent ERISA preemption) in situations involving the ERISA-governed community. In a nutshell, under the Court's precedents, a state law makes an impermissible reference to ERISA plans if it facially establishes its scope as extending to "benefits" or "plans" *and* if the law inescapably operates for entities governed by ERISA who provide such benefits and plans; Act 900 meets that test.

To be sure, Act 900 may ensure some arrangements by entities not governed by ERISA (such as government plans, church plans, or individual insurance), which the United States thinks is dispositive. U.S. Br. 13. But so did the Pennsylvania anti-subrogation law in FMC Corp. Similarly, in Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 140 (1990). the Court held that a Texas common-law cause of action made "specific reference to, and indeed was premised on, the existence of a pension plan," given that the cause of action operated where an employer had a "pension-defeating motive"; the Court did not insist that the cause of action apply solely to ERISAgoverned pension plans, but only to pension plans generally. In fact, the Texas Supreme Court had suggested that the same cause of action could operate for "public employees" not subject to ERISA. See McClendon v. Ingersoll-Rand Co., 779 S.W.2d 69, 71 (Tex. 1989). Contrary to the United States' position, the distinguishing feature for state laws that make an impermissible reference to ERISA plans is not whether the state law covers only ERISA situations, but whether by its terms the state law inevitably must operate for all ERISA-governed entities within the state law's scope. See generally D.C. v. Greater Wash. Bd. of Trade, 506 U.S. 125, 130-31 (1991) (holding that even state law addressed to non-ERISA plans references ERISA plans if, in all situations in which ERISA-governed employers establish such non-ERISA plans, they would have to set benefit levels based on their ERISA plans' terms).

#### CONCLUSION

The Court should affirm the decision of the Eighth Circuit.

Respectfully submitted,

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