No. 18-540

IN THE

Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as Attorney General 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 RESPONDENT

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QUESTION PRESENTED

Whether the Employee Retirement Income Security Act of 1974 (ERISA) preempts a state law regulating the administration of prescription-drug benefits on behalf of an ERISA-governed employee benefit plan.

CORPORATE DISCLOSURE STATEMENT

Respondent Pharmaceutical Care Management Association has no parent corporation, and no publicly held company owns more than ten percent of its stock.

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BRIEF FOR RESPONDENT

INTRODUCTION

To encourage formation of employee benefit plans, the Employee Retirement Income Security Act of 1974 (ERISA) aims to establish a "uniform regulatory regime over employee benefit plans." *Aetna Health* v. *Davila*, 542 U.S. 200, 208 (2004). Central to that objective is ERISA's "comprehensive" preemption provision. *Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016). Congress sought to ensure that "employee benefit plan regulation would be 'exclusively a federal concern,'" *Davila*, 542 U.S. at 208, because "[r]equiring ERISA administrators to master the relevant laws of 50 States … would undermine the congressional goal of

minimiz[ing] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries," *Gobeille*, 136 S. Ct. at 944 (quotation marks omitted).

Arkansas's Act 900 exemplifies that concern. It directly regulates the administration of prescription-drug benefits on behalf of ERISA-governed plans. It establishes state-specific rules controlling the amount plans must pay for benefits, the methodology for determining the amount to be paid, the timing and procedures for updating payment schedules, and dispute-resolution processes and remedies—matters that are central to plan administration. *See Egelhoff* v. *Egelhoff*, 532 U.S. 141, 147-148 (2001); *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 9 (1987). By granting pharmacies a right to decline to dispense, Act 900 even controls whether plan participants will receive benefits promised under their plans. Dozens of other States have imposed their own differing obligations on the management of prescription-drug benefits.

By directly affecting the administration of plan benefits, Act 900 plainly "relates to" ERISA plans and is preempted, regardless of whether the plan manages the benefit itself or engages a third-party administrator to do so. 29 U.S.C. §1144(a). Arkansas disputes that conclusion on the theory that Act 900 is a necessary "incident to" permissible rate regulation. But Act 900 does not regulate rates for goods and services in the marketplace—it is silent as to pharmacy pricing. And Arkansas's unsupported "incident to" theory would eviscerate ERISA's preemption provision. Nor is there any merit to Arkansas's attempt to sever pharmacy reimbursement from the core functions of benefit administration. Determining reimbursements and paying

for benefits are central to processing claims and to the very design of plan benefits.

The United States offers a different theory, contending that ERISA preemption applies only when a plan manages benefits directly and not when it engages a third party to do so on the plan's behalf. But there is no support for that distinction. And accepting it would penalize employers and their beneficiaries for obtaining help in the massive task of administering employee health benefits. The Court should reject these theories and affirm the judgment.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant provisions of the U.S. Constitution, ERISA, and Arkansas Code §17-92-507 are reproduced in the appendix.

STATEMENT

A. Factual Background

1. ERISA plans and prescription-drug benefits

Employers are the principal source of health benefits in the United States, covering about 153 million Americans. Kaiser Family Found., *Employer Health Benefits: 2019 Annual Survey*, at 65 (2019) ("Kaiser Survey"). To provide those benefits, employers may sponsor employee benefit plans governed by ERISA. Employers that do so decide what benefits to offer and on what terms. *See Black & Decker Disability Plan* v. *Nord*, 538 U.S. 822, 833 (2003).

The vast majority of employee health plans include coverage for prescription drugs—a significant expense for many Americans. Kaiser Survey 156. In 2018, Americans spent an estimated $335 billion on prescription drugs, accounting for nearly 10% of total annual healthcare costs. CMS, *National Health Expenditures Data*, tinyurl.com/yx3t7d2v. Sponsors of prescription-drug benefit plans seek to reduce those costs, and the costs of plan administration, to maximize the proportion of their spending that goes toward benefits for plan participants.

Achieving that goal is difficult for employers because providing prescription-drug coverage is a massive undertaking. To provide the benefit, an employer must (among other things) identify which drugs should be covered; determine how costs should be shared between the plan and participants; contract with thousands of pharmacies and negotiate how they will be reimbursed; and communicate to plan participants what benefits are covered and how participants will share in the costs. The employer must also develop a system for processing thousands of claims in real time—instantaneously determining while the patient is at the pharmacy counter whether the patient and the prescribed drug are covered, what if any payment is due from the patient, and how much the plan will reimburse the pharmacy for the prescription. Those tasks add substantially to a plan's administrative costs, reducing the benefits employees receive and exposing plans to risks of uncertainty and cost overruns.

Managing prescription-drug benefits is all the more challenging because prescription-drug costs are difficult to determine. *See* Congressional Research Service, *Frequently Asked Questions About Prescription Drug Pricing and Policy*, at 9 (April 2018). Manufacturers

publicly report a price for each drug called the "wholesale acquisition cost" (WAC). Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, at 3 (Jan. 2007) ("*Prescription Drug Pricing*"). The WAC, however, is not the price actually paid by wholesalers. *Id.* Manufacturers and wholesalers typically negotiate prices and do not disclose what the wholesaler pays. *See* Sood *et al.*, *The Flow of Money Through the Pharmaceutical Distribution System*, at 1 (June 2017) ("*Flow of Money*").

Wholesalers in turn sell drugs to pharmacies. The theoretical price is known as the "average wholesale price" (AWP). Office of Inspector General, Dep't of Health and Human Servs., *Review of Drug Costs To Medicaid Pharmacies And Their Relation To Benchmark Prices*, at 1 (Oct. 2011) ("OIG Report"). But like the WAC, the AWP is not the actual price paid by any pharmacy. Instead, it represents a benchmark against which wholesalers and pharmacies negotiate pharmacies' actual prices. Large pharmacy chains conduct these negotiations directly, while most independent pharmacies join a "pharmacy services administrative organization" (PSAO) to negotiate on their behalf, leveraging their purchasing power to procure concessions from suppliers. JA110, 189. In Arkansas, approximately 87% of independent pharmacies belong to such a group. JA107-110.[1]

As a result of these negotiations, pharmacies typically receive discounts and other financial incentives from suppliers. *See* OIG Report 4 & n.7, 5. But these

[1] Of the approximately 700 pharmacies in Arkansas, roughly 400 are independent. JA109-110, 310; *cf.* JA223. Of those 400 independent pharmacies, about 350 are affiliated with a PSAO that negotiates on their behalf. JA107.

are not reflected in pharmacies' invoice prices. *Id.*; *see* JA135, 163-164, 198. Invoice prices thus do not reveal the actual costs to pharmacies of prescription medications.

Against this pricing uncertainty, plan sponsors must decide how to design the benefit so as to minimize costs, maximize predictability, and determine how costs should be shared between the plan and its participants. For example, an employer might choose a copay model, under which the beneficiary pays a fixed amount; alternatively, under a coinsurance model, the beneficiary pays a percentage of a drug's cost. Kaiser Survey 107, 158. If the employer includes a deductible, the patient pays the total cost of prescriptions until the deductible is exhausted, and then pays either nothing or a copay or coinsurance for the rest of the year. *Id.* at 107, 166. The employer's choice among these models defines the benefit promised to participants, and that choice depends on the employer's expectations about the costs of providing the benefit.

2. The role of pharmacy benefit managers

Given the complexity of the tasks involved in providing health benefits, ERISA plans typically hire "third-party administrators" (TPAs) to manage benefits on the plan's behalf. An employer might contract with a health insurer to manage medical benefits, or a vision or dental TPA to manage vision or dental benefits. Similarly, most plan sponsors engage TPAs called pharmacy benefit managers (PBMs) to manage prescription-drug benefits on behalf (and at the direction) of the plan. About 65% of large employers contract with PBMs directly, while another 30% do so indirectly through health insurers. Danzon, Testimony before U.S. Dep't of Labor, 2014 ERISA Advisory Council,

PBM Compensation and Fee Disclosure, at 3 (June 19, 2014). Approximately 60 PBMs operate in the United States, *see* 84 Fed. Reg. 2340, 2354 (proposed Feb. 6, 2019), of which "'at least ten'" are considered by the Federal Trade Commission to be "'significant competitors'" in the market, Letter from Gavil, FTC, to Good, ERISA Advisory Council, at 3 (Aug. 19, 2014); *see* FTC, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, at 8-9 (Aug. 2005) ("FTC Report"); JA184-187.

Like other TPAs, PBMs act at the direction of the plan's fiduciaries to provide services to the plan and manage benefits in accordance with the contract between the PBM and the plan sponsor. For example, based on input from pharmacists and physicians, PBMs develop drug formularies—*i.e.*, lists of covered drugs, to be used in administering the benefits. *See* FTC Report 10-12; Sealed JA365-366. Plan sponsors decide whether to use a PBM's standard formulary or to customize a formulary tailored to a particular plan. FTC Report 12; Sealed JA365-366.

Formularies help plans contain prescription-drug costs because beneficiaries tend to purchase drugs on the formulary instead of therapeutically equivalent drugs not on the formulary. FTC Report 6-7. Plan sponsors can enhance these cost-containment effects by differentiating the plan's payment terms—*i.e.*, the copay, coinsurance, or deductible features—across different tiers of drugs, so that the price for beneficiaries is more favorable for drugs in preferred tiers. *Id.* at 11; Kaiser Survey 158. Pharmaceutical manufacturers in turn can compete for favorable formulary placement when there are multiple drugs available to treat the same condition by offering discounts or rebates. FTC Report 6-7; *Prescription Drug Pricing* at 7.

PBMs also develop networks of pharmacies where plan participants can fill their prescriptions. Pharmacies benefit from inclusion in a network because it attracts business from plan participants and allows pharmacies to obtain reimbursements without undertaking collection efforts. *See* FTC Report 4-5. Pharmacies accordingly negotiate to join networks, either on their own or through PSAOs, JA182-183, 189, 282-283, and about 95% of retail pharmacies nationwide are included in one or more PBM networks, Hyman, *The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs ("MACs") for Pharmacy Reimbursement*, at 5 (Apr. 2015) ("*Unintended Consequences*"). Employers can decide what size networks they want for their plans, balancing the convenience of a larger network against the cost advantages of a smaller network that pharmacies can compete to join. JA192-193.

PBMs also process and pay benefit claims on behalf of plans, *e.g.*, Sealed JA362—an extraordinarily complex task. When a patient seeks to fill a prescription, the pharmacy communicates electronically with the PBM to ensure the prescription is filled according to the patient's coverage. FTC Report 1; JA97-99. The PBM verifies whether the patient is a covered beneficiary and whether the drug is covered by the plan. The PBM also determines and informs the pharmacy of both the amount of any payment owed by the patient and the amount of reimbursement the PBM will make to the pharmacy. FTC Report 1-2. The pharmacy then dispenses the drug and collects any payment due from the patient, and the PBM reimburses the pharmacy according to the terms of the PBM's contract with the pharmacy. *See id.*

By engaging a PBM to handle these tasks, plans can achieve substantial cost savings for beneficiaries. Indeed, internal administration of prescription-drug benefits is a "practical impossibility" for most plans because doing so would mean "forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer." *PCMA* v. *District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010).

To compensate the PBM, the plan chooses a fee arrangement that best serves the plan's objective of maximizing benefits to beneficiaries. For example, as in many contracting situations, plans can choose between paying PBMs on a cost-plus basis or a flat-fee basis. Under the former, called "pass-through" pricing, the PBM passes its actual costs for pharmacy reimbursements to the plan, which pays the PBM for those costs plus an agreed fee. JA145-146, 187. The PBM bears no risk for cost overruns because it passes the costs directly to the plan. JA146. Alternatively, the plan sponsor can price the contract on a "lock-in" basis, under which the plan agrees to pay the PBM a fixed price per drug. JA146, 187. As with any fixed-fee arrangement, the PBM assumes the risk of cost overruns, thereby reducing risk and enhancing certainty for the plan; but the PBM may also earn a "spread"—the difference between the reimbursement the PBM pays to pharmacies and the fees it collects from the plan—if it succeeds in keeping costs low. FTC Report 9-10.

On average, PBMs operate at a net profit margin of approximately 2.3%. *Flow of Money* 5. Out of a hypothetical $100 prescription drug expenditure, PBMs keep approximately $2 in net profits. *Id.* By comparison, out of that $100, pharmacies keep roughly $3 in net profits (operating at an average net profit margin of 4%), and manufacturers keep $15 in net profits—

operating at an average net profit margin of more than 26% and collecting more than 65% of net profits generated in the supply chain. *Id.*

3. MAC lists

Central to every plan is the process for determining how much the plan must pay the pharmacy—and for keeping those costs in check. Like other aspects of benefit management, a plan could theoretically handle that task on its own, but given the complexity and administrative costs of dealing with thousands of pharmacies and prescriptions, most plans assign that task to a PBM. The plan's contract with the PBM typically requires that beneficiaries be able to fill prescriptions at network pharmacies and addresses how the PBM should reimburse those pharmacies. *See* FTC Report 8-9; JA124-125, 137, 188-190; Sealed JA362-363, 375-376. PBMs' contracts with network pharmacies in turn reflect those reimbursement terms. JA184, 188-190; Sealed JA384-385.

Setting reimbursement terms and procedures by contract is essential to plans' efforts to contain prescription-drug costs and maximize benefits for participants. JA150-152. When buying drugs from wholesalers, a pharmacy can choose between brand drugs and generic drugs, and between more expensive generics and less expensive generics, even when the drugs are therapeutically equivalent. *See* JA150, 272-274. A pharmacy that received unlimited reimbursement for acquisition costs would have little incentive to negotiate the best deals with suppliers. That problem is aggravated by the fact that pharmacies' actual costs for acquiring drugs are usually invisible to plans and PBMs. *Supra* pp. 5-6. Setting reimbursement limits by contract incentivizes pharmacies to purchase the least

expensive medications in each therapeutic class and negotiate for the best prices. JA150-152. This in turn induces manufacturers and wholesalers to compete by offering lower prices. JA151.

The "maximum allowable cost," or "MAC," is the principal tool for establishing reasonable reimbursement limits. The schedule of generic drugs covered by a plan and their respective MACs is known as the MAC list, which may contain more than a thousand unique products. JA125-126, 134-135, 191. MACs were pioneered by the federal and state governments in the late 1980s. To avoid overpaying for medications, the federal government established a maximum reimbursement rate for Medicaid known as the Federal Upper Limit (FUL). JA147-148. The FUL was originally based on published acquisition costs. JA148. But because those published costs do not reflect pharmacies' discounts from suppliers, the FUL "often greatly exceeded prices available in the marketplace." Office of Inspector General, Dep't of Health and Human Servs., *Medicaid Drug Pricing in State Maximum Allowable Cost Programs*, at 4 (Aug. 2013) ("OIG Medicaid Study"). States therefore developed MACs for Medicaid that depended less on published prices. JA148-149. Today, MACs are prevalent in the prescription-drug market. *Id.* Forty-six States, including Arkansas, use some version of MACs in their Medicaid programs. *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State*, Medicaid.gov (Sept. 2019).

In developing and managing MACs, PBMs seek to balance cost containment with the fact that using MACs for a network of pharmacies is "only as valuable as the number of retail pharmacies" in the network. JA96-97; *see* JA153, 183-184. If MACs are too low, pharmacies might not stock an adequate supply of

drugs or even leave the network, rendering the network less valuable for the plan. JA153-154. PBMs accordingly consider many factors in setting MACs, including drugs' average published prices, publicly available Medicaid MAC lists, and PBMs' own market analyses. JA126, 190-193. Plan sponsors in turn "may dictate how many and what type of drugs" should constitute the MAC list for their plans' design. JA191.

4. Claims processing

As discussed, *supra* p. 4, when a plan participant presents a prescription at a network pharmacy, the PBM processes the claim instantaneously—confirming that the participant and drug are covered and determining the reimbursement and participant's cost-share. JA98-99; FTC Report 1-2. Sometimes disputes arise about reimbursements. In those cases, the PBM-pharmacy contract typically requires pharmacies to fill the prescription immediately and resolve the dispute through a separate appeal. JA108, 137; *see* Sealed JA382-385. Doing so avoids putting patients in the middle of disputes, JA137, and ensures compliance with plans' directives that participants have access to medications they need at network pharmacies, JA108; *see* Sealed JA382.

In the vast majority of cases, the MAC-based reimbursement strikes the right balance. JA135. Ninety percent of MACs are equal to or above pharmacies' acquisition costs. JA314. In Arkansas, only 11% of reimbursements fall below the pharmacy's net invoice cost. *See* Satter, *Lawsuit Disputes State Rx Drug Law*, Arkansas Democrat-Gazette (Aug. 15, 2015). And PBM-pharmacy contracts often contain financial-performance guarantees, such as a "generic effective rate" (GER) or "effective rate guarantee," to "enforce stability around

the reimbursements pharmacies will see during the year and prevent them from being over- or under-reimbursed." Amplicare, *What GER Means for Pharmacies* (Apr. 25, 2019); *see* JA325.

Unsurprisingly, then, MACs have not threatened pharmacies' ability to remain in business, including rural independent pharmacies. *See* JA303-304 n.4. According to the National Council for Prescription Drug Programs, the number of independent pharmacies in the United States increased by nearly 13% between 2010 and 2019. *See* PCMA, *Independent Pharmacies in the U.S. are More on the Rise than on the Decline*, at 1-2 (Mar. 2020) ("*Independent Pharmacies*"). In Arkansas, the overall number of pharmacies has remained steady; there were 712 pharmacies in Arkansas in 2007 and 705 in 2017. *Compare* National Community Pharmacists Ass'n, *NCPA 2008 Digest*, at 11 (2008), *with* National Community Pharmacists Ass'n, *NCPA 2018 Digest*, at 11 (2018); *see Independent Pharmacies* 4 tbl. 2 (number of independent pharmacies in Arkansas decreased by only five between 2010 and 2019).

At the same time, MACs yield substantial savings, contributing to the $962 per person per year that PBMs save sponsors and employees. *See* Visante, *The Return on Investment (ROI) on PBM Services*, at 1 (Feb. 2020). The federal government, recognizing the "significant value MAC programs have in containing" costs, has amended the FUL to align more closely with MAC reimbursements. OIG Medicaid Study 21. Three out of four private employer-sponsored health plans also use MACs. *See* Visante, *Proposed MAC Legislation May Increase Costs of Affected Generic Drugs by More than 50 Percent*, at 3 (Jan. 2015).

For those plan sponsors that adopt a MAC-based reimbursement model, the MAC methodology—and the cost-control it facilitates—are fundamental to the plan's benefit design. Decisions about cost-sharing (*i.e.*, whether to use a deductible, copay, or coinsurance), the scope and terms of coverage, and the creation and maintenance of a pharmacy network are all driven by the plan's estimation of how much it will cost to provide the benefit. That estimation necessarily turns on the reimbursement methodology the plan expects the PBM to apply in processing claims. FTC Report 8; JA153, 183.

B. Act 900

PBMs' administration of prescription-drug benefits on behalf of employee benefit plans is subject to comprehensive regulation under ERISA. The Secretary of Labor has authority to regulate PBMs that administer benefits under ERISA-governed plans, 29 U.S.C. §1135, and has exercised that authority as recently as November 2019, when the Department of Labor proposed a rule regarding transparency in PBM reimbursements. 84 Fed. Reg. 65,464, 65,472-65,473 (proposed Nov. 27, 2019); *see* Advisory Council on Employee Welfare and Pension Benefit Plans, *PBM Compensation and Fee Disclosure*, at ii (Nov. 2014) (discussing proposed regulation of PBM compensation).[2]

Increasingly, though, States have moved aggressively to regulate the core services PBMs provide to

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[2] PBMs that administer Medicare or Medicaid programs are subject to regulation under those statutes. PBMs that administer fully insured health plans may also be regulated by state departments of insurance. *See* 29 U.S.C. §1144(b)(2)(A) (exempting state laws regulating insurance from ERISA preemption).

ERISA-governed employee benefit plans, including MACs and pharmacy reimbursement practices. *E.g.*, California Br. 14-21. As explained below, the variation among state laws is substantial. *Infra* pp. 26-32. Dozens of States have enacted laws regulating plans' use of MAC reimbursements and the processing of claims—on varying terms unique to each State.

The law at issue here is one example. Act 900 requires that any "[p]harmacy benefits manager," defined as any "entity that administers or manages a pharmacy benefits plan or program," must comply with certain rules and procedures in its use of MACs to reimburse pharmacies for dispensed drugs. Ark. Code Ann. §17-92-507(a)(7).[3] Specifically, an administrator of a covered pharmacy benefits plan must reimburse pharmacies at a level equal to or above the "pharmacy acquisition cost," which is defined as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice." *Id.* §17-92-507(a)(6). In other words, regardless of the reimbursement methodology an employer chooses in designing its plan, Arkansas law requires administrators of prescription-drug benefits to reimburse pharmacies according to their invoice prices—even though those invoices likely overstate pharmacies' actual costs.

To implement that requirement, Act 900 requires that benefit administrators follow certain procedures

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[3] "Pharmacy benefits plan[s] or program[s]" include any "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." Ark. Code Ann. §17-92-507(a)(9). Arkansas amended its PBM law again in 2019, but the changes were not material. This brief cites the statutory text in effect at the time of the court of appeals' decision.

when processing and reimbursing claims. Administrators must update their MAC lists within seven days after any increase of 10% or more in the invoice prices of at least 60% of wholesalers doing business in Arkansas. Ark. Code Ann. §17-92-507(c)(2). Administrators must disclose their MAC lists to pharmacies and promptly disclose those updates. *Id.* §17-92-507(c)(1), (3).

Benefit administrators must also "[p]rovide a reasonable administrative appeal procedure" allowing pharmacies to challenge MAC-based reimbursements that are below the invoice price. Ark. Code Ann. §17-92-507(c)(4)(A)(i)(b). The administrator must respond within seven days. *Id.* §17-92-507(c)(4)(B). If the MAC is indeed below the invoice price, the administrator may deny the appeal only if it can identify a wholesaler that sells the drug at a price below the plan's MAC. *Id.* §17-92-507(c)(4)(C)(ii). But even then, if the pharmacy shows it cannot purchase the drug for less than the invoice price from the particular wholesaler from which the pharmacy purchases most of its drugs, *id.* §17-92-507(c)(4)(C)(iii), the administrator must adjust the MAC upward and allow the pharmacy to reverse and rebill the claim, *id.* §17-92-507(c)(4)(C)(i), (iii).

Alternatively, a pharmacy may forgo the appeal and simply "decline to provide" the prescribed drug to a patient on the plan's terms if the MAC-based reimbursement is less than the pharmacy's invoice price. Ark. Code Ann. §17-92-507(e). The pharmacy may still dispense the drug if the patient can afford the pharmacy's higher usual and customary price—*i.e.*, the price that pharmacy charges cash-paying customers, JA98-99. Otherwise the patient must either forgo the medication or seek another pharmacy willing to honor its network contract. JA196-198.

As a result of Act 900, a PBM administering benefits on behalf of an employee benefit plan may be prohibited from reimbursing pharmacies according to the MAC list even though the plan's design and its economics for ensuring value to beneficiaries depend on that methodology. The pharmacy's statutory right to reverse and rebill means the PBM must reprocess claims, recalculate coinsurance and deductible amounts, and coordinate with the plan sponsor to revise documents explaining the benefits to plan participants. And the pharmacy's right to decline to dispense can block participants' access to benefits altogether, despite plan terms promising that those benefits will be provided.

Those consequences reach beyond Arkansas plans. Most benefit plans cross multiple States and set pricing and reimbursement terms intended to operate nationally. JA103, 181-182. And beneficiaries frequently fill prescriptions while traveling. JA130, 187. In a six-month period in 2016, 16% of claims submitted to one PBM by Arkansas pharmacies were for out-of-State beneficiaries covered by out-of-State plans. Dist. Ct. Dkt. 75-3, at 380. Yet Act 900 compels PBMs administering benefits on behalf of multistate plans to conform to Arkansas's state-specific rules for processing claims.

C. Proceedings Below

The Pharmaceutical Care Management Association (PCMA), the national trade association of PBMs, brought this litigation to enjoin Act 900 as preempted by ERISA. On cross-motions for summary judgment, the district court held Act 900 preempted as applied to PBMs' administration of benefits on behalf of ERISA-governed employee benefit plans. Pet. App. 17a-19a.

The Eighth Circuit agreed. Pet. App. 5a-7a. Relying on its decision in *PCMA* v. *Gerhart*, 852 F.3d 722 (8th Cir. 2017), the court held that "where, as here, the state law both relates to and has a connection with employee benefit plans"—including through regulation of PBMs that administer benefits on behalf of ERISA-governed plans—the state law "is preempted." Pet. App. 6a-7a.[4]

SUMMARY OF ARGUMENT

Act 900 "relates to" ERISA plans, and is preempted, because it regulates central matters of plan administration, interferes with nationally uniform plan administration, and impermissibly refers to ERISA plans. In doing so, it contravenes ERISA's fundamental purpose of minimizing administrative costs to encourage the formation of benefit plans.

Arkansas imposes its own rules for administering prescription-drug benefits under an ERISA plan—rules that directly restrict the use of MAC-based reimbursements, the processing of benefit claims, and the design of drug-benefit plans. Under the decline-to-dispense provision, Act 900 can even prevent beneficiaries of an ERISA plan from obtaining benefits promised under the plan if the plan's design and implementation do not conform to state law. Those matters are essential to the administration of benefits on behalf of the plan, and ERISA precludes States from regulating them.

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[4] The court of appeals held that the Medicare Part D statute preempts Act 900 as applied to administrators of Medicare Part D plans because it acts "with respect to" federal Medicare standards. Pet. App. 7a-11a. Arkansas did not seek review of that holding.

Act 900 also interferes with nationally uniform plan administration by threatening employers with a checkerboard of inconsistent state laws. In *Gobeille* v. *Liberty Mutual Insurance Co.*, 136 S. Ct. 936, 945 (2016), the Court found the mere possibility of such disuniformity sufficient to trigger preemption. Here, disuniformity is the reality. In recent years, 40 States have imposed varying restrictions and mandates on the claims-processing practices of plans and their benefit administrators. As a result, PBMs and the plans they serve—most of which cover beneficiaries in multiple States—must constantly monitor shifting state-law requirements and adjust their pricing and claims-processing procedures accordingly.

Act 900 cannot be defended as incident to permissible rate regulation. Act 900 does not regulate rates in the marketplace at all—it says nothing about pharmacy prices. It operates directly on the administration of benefits on behalf of ERISA plans, controlling the standards and procedures for determining and paying for benefits and processing claims. Indeed, it goes so far as to dictate whether a beneficiary may even obtain a promised benefit.

Moreover, no authority supports a blanket exception to ERISA preemption for state laws "incident to" valid regulation. Such an exemption would permit 50 States to dictate virtually every aspect of ERISA plan administration, because doing so can almost always be characterized as regulating the cost of benefits. Arkansas's related argument, that Act 900 regulates only a reimbursement process unconnected to the processing of claims, blinks reality. Reimbursement terms and procedures are part and parcel of processing the benefit claim—indeed, they are fundamental to the very design of the plan.

Nor is there any relevant distinction for ERISA preemption purposes between "PBM administration" and "plan administration," as the United States suggests. PBMs administer benefits on behalf of ERISA plans. Were that not so, employers would have to manage the benefits themselves, and they would be subject to the same requirements under Act 900. The same was true in *Gobeille*, where this Court found a state law preempted that regulated the benefit administrator in that case and not the plan itself. 136 S. Ct. at 941-942. Given the prevalence of TPAs and their indispensable role in facilitating the provision of employee health benefits, the Court should not interpret ERISA to allow intrusive and inconsistent state regulation of the administration of ERISA plans simply because the plan sponsor seeks a TPA's help in administering benefits.

ARGUMENT

ERISA seeks to "'encourag[e] the formation of employee benefit plans.'" *Aetna Health* v. *Davila*, 542 U.S. 200, 208 (2004). To that end, Congress established a "comprehensive statute for the regulation of employee benefit plans," *id.*, that would not be "'so complex that administrative costs … unduly discourage employers'" from offering benefits, *Conkright* v. *Frommert*, 559 U.S. 506, 517 (2010). ERISA seeks to "'assur[e] 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.'" *Id.*

ERISA's preemption provision is central to those objectives. Congress recognized that "[r]equiring ERISA administrators to master the relevant laws of 50 States" would undermine Congress's purpose of "'minimiz[ing] the administrative and financial burden[s]'

on plan administrators—burdens ultimately borne by the beneficiaries." *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 149-150 (2001); *see Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943-944 (2016); *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 9-11 (1987). A "principal goal[]" of the statute is "to enable employers 'to establish a uniform administrative scheme,'" with "'standard procedures to guide processing of claims and disbursement of benefits.'" *Egelhoff*, 532 U.S. at 148. But that uniformity is "impossible" if plans may be "subject to different legal obligations in different States." *Id.*; *see Gobeille*, 136 S. Ct. at 944.

ERISA therefore preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by ERISA. 29 U.S.C. §1144(a). This provision secures the value of employee benefits "'by eliminating the threat of conflicting and inconsistent State and local regulation.'" *Shaw* v. *Delta Air Lines*, 463 U.S. 85, 99 (1983). This Court has characterized ERISA's preemption provision as "broad" and "comprehensive," *Gobeille*, 136 S. Ct. at 943, and held that a state law "relates to an ERISA plan" and is preempted under that provision if the law "'has a connection with or reference to such a plan.'" *Egelhoff*, 532 U.S. at 147.

Act 900 "relates to" ERISA plans under any reasonable approach to that phrase. Fundamentally, Act 900 controls how benefits under a prescription-drug benefit plan are to be administered. Act 900 does not regulate the prices pharmacies may charge at the point of sale, but imposes a complex set of substantive and procedural rules that must be followed when benefits are administered on behalf of an ERISA plan—the kinds of rules that can and do differ from State to State, even though most plans have beneficiaries who live and

work across the nation and may need prescriptions in different States as they travel. Act 900 thus subjects the administration of ERISA plans to a patchwork of nonuniform state regulations and imposes the costs and inefficiencies that Congress sought to avoid—costs that are ultimately borne by beneficiaries and could deter sponsors from forming plans in the first place.

I. ACT 900 HAS AN IMPERMISSIBLE CONNECTION WITH ERISA PLANS

A state law has a "connection with" an ERISA plan when it "'governs … a central matter of plan administration' or 'interferes with nationally uniform plan administration.'" *Gobeille*, 136 S. Ct. at 943. This inquiry considers "the effect of the state law on ERISA plans" in light of ERISA's objectives. *Id.* State laws that "bind[] ERISA plan administrators to a particular choice of rules" for administering benefits, for example, *Egelhoff*, 532 U.S. at 147, or that "prohibit employers from structuring their employee benefit plans" a certain way, *Shaw*, 463 U.S. at 97, are preempted under this test. Act 900 does both, and it undermines nationally uniform plan administration.

A. Act 900 Regulates Central Matters Of Plan Administration

Act 900 regulates a central function of ERISA plans: how plans pay for benefits. Indeed, Act 900 goes beyond that, effectively controlling plan sponsors' choices about to how to design plans in the first place.

"[P]ayment of benefits" is a "central matter of plan administration." *Egelhoff*, 532 U.S. at 148; *see Fort Halifax*, 482 U.S. at 9. ERISA plans must "'specify the basis on which payments are made to and from the

plan'" and administer the benefit in strict accordance with those terms. *Egelhoff*, 532 U.S. at 147 (quoting 29 U.S.C. §1102(b)(4)). Many plans, seeking to ensure value for beneficiaries, engage PBMs that use MAC-based reimbursements to contain costs for medications, reduce administrative expenses, and ensure predictability. But Act 900 binds plans and their administrators to a different rule—requiring them to reimburse pharmacies according to the pharmacy's invoice price regardless of the MAC. Act 900 thus imposes a "particular choice of rules" for designing and administering the benefit, requiring administrators to determine and pay for the benefit in accordance with a substantive rule "chosen by state law." *Id.*

Act 900 further binds administrators of pharmacy benefits to state-specific procedures for processing claims and paying for benefits. First, Act 900 requires benefit managers to continually update their MACs for the thousand or more products on the MAC list—*i.e.*, to constantly reset the reimbursement rules governing every single transaction in the administration of the benefit for generic drugs—whenever prevailing pharmacy invoice prices increase by at least 10%. Ark. Code Ann. §17-92-507(c)(2). That is an onerous requirement—not only because generic drug prices fluctuate frequently, but also because plans and benefit managers cannot know an invoice price until a pharmacy relays it. JA129-130, 198-199, 289.

Second, Act 900 requires administrators to adhere to a state-dictated appeal procedure, with state-dictated remedies that inevitably affect the design of and payment for benefits under a plan. In place of the dispute-resolution procedures and standards that plans or their benefit managers negotiate for in contracts with pharmacies—procedures that plans and PBMs

develop with an understanding that their operations may apply nationwide—Act 900 demands that administrators comply with a particular process, subject to state-specific deadlines, and dictates the substantive standard governing the resolution of the appeal. *See* Ark. Code Ann. §17-92-507(c)(4). Whenever a pharmacy shows that the MAC-based reimbursement is lower than the pharmacy's invoice price, the administrator must adjust the MAC upward and allow the pharmacy to reverse and rebill the claim—*i.e.*, to process the claim all over again, with a revised calculation of the beneficiary's and plan's respective cost-shares. *Id.* §17-92-507(c)(4)(C)(i)(a), (b), (c)(4)(C)(iii). Act 900 imposes those requirements even when the pharmacy has made a profit due to a discount that is not reflected in the invoice price and even if the pharmacy could have acquired the drug for less than the invoice price from any wholesaler in the State other than its primary wholesaler. *Id.* §17-92-507(c)(4)(C)(iii).

Third, even where a plan promises that beneficiaries will be able to fill prescriptions for covered medications at network pharmacies, Act 900 allows pharmacies to decline to dispense—effectively denying benefits to plan participants who need the prescribed medications. Ark. Code Ann. §17-92-507(e). In the face of ERISA's overarching purpose to protect plan participants' rights to contractually defined benefits, *e.g.*, *Massachusetts Mut. Life Ins. Co.* v. *Russell*, 473 U.S. 134, 148 (1985), Act 900 allows beneficiaries in Arkansas to be deprived of their benefits by operation of state law.[5]

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[5] Arkansas compares (at 47-48) Act 900's decline-to-dispense provision to laws allowing pharmacists to decline to fill prescriptions where doing so would be medically unsound, where the legit-

These features of Act 900 directly regulate the rules for administering benefits on behalf of a plan. Indeed, Act 900 interferes with the very design and structure of the plan. Nothing in ERISA mandates what pharmacy benefits a plan must provide, and "employers have large leeway to design … welfare plans as they see fit." *Black & Decker Disability Plan* v. *Nord*, 538 U.S. 822, 833 (2003). ERISA thus preempts state laws that "prohibit[] employers from structuring their employee benefit plans in a [particular] manner." *Shaw*, 463 U.S. at 97.

Act 900, however, effectively prohibits the use of MAC methodology in prescription-drug benefit plans. That tool is foundational to the design of many plans. Cost assumptions—and the certainty that comes from using tools that contain those costs—drive plans' decisions about whether (and how high) to set a copay, coinsurance term, or deductible; which drugs to include in a formulary; what terms to negotiate with manufacturers and pharmacies; and whether and how to use the size and structure of the pharmacy network as a cost-containment tool. *Supra* pp. 6-12; *see* JA153, 169; FTC

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imacy of the prescription is questionable, or where the pharmacist harbors moral objections. But Act 900 bears no similarity to those examples, and finding Act 900 preempted would cast no doubt on them. Act 900 allows pharmacists to decline to dispense based solely on the patient's status as a beneficiary of a plan that has certain features to which the pharmacist—and the State—object (namely, MAC-based reimbursement). *Cf.* 29 U.S.C. §1140 ("It shall be unlawful for any person to … discriminate against a participant or beneficiary for exercising any right to which he is entitled under the provisions of an employee benefit plan."). Indeed, pharmacies can fill prescriptions even where they have invoked the decline-to-dispense provision, as long as the patient—who may have no other way to obtain the medication—pays the pharmacy's higher price in cash. *See* Dist. Ct. Dkt. 44, at 172.

Report 8. Those decisions plainly have a "connection with" ERISA plans, for they shape what benefits are due under a plan and how those benefits will be provided. And whereas plan sponsors make those decisions with the expectation that pharmacies will be reimbursed according to a particular methodology and procedure, Act 900 makes uniformity and predictability impossible by substituting state-specific standards and procedures in place of those built into the plan. JA153, 183-184.

B. Act 900 Interferes With Nationally Uniform Plan Administration

Act 900 also has an impermissible connection with ERISA plans because it requires the administration of benefits to be "'tailor[ed]'" to "'the peculiarities of the law of each jurisdiction,'" undermining nationally uniform plan administration. *Egelhoff*, 532 U.S. at 151. Absent preemption, prescription-drug benefit plans would face "a body of disuniform state … laws" governing benefits administration. *Gobeille*, 136 S. Ct. at 945.

Gobeille involved a Vermont law that required healthcare plans or their TPAs to report certain information concerning costs, prices, and quality to a state agency. 136 S. Ct. at 940-941. The Court held that the law intruded on "'a central matter of plan administration' and 'interfere[d] with nationally uniform plan administration.'" *Id.* at 944-945. Vermont argued that there was no evidence its law had "in fact … caused" economic harm to ERISA-governed plans. *Id.* at 945. The Court held, however, that plans "need not wait to bring a pre-emption claim until confronted with numerous inconsistent obligations and encumbered with any ensuing costs." *Id.* It sufficed that "[d]iffering, or even parallel, regulations from multiple jurisdictions could

create wasteful administrative costs and threaten to subject plans to wide-ranging liability." *Id.* Preemption, in other words, was "necessary to prevent the States from imposing novel, inconsistent, and burdensome" requirements on plans. *Id.*

Here, the "possibility" of inconsistent obligations that resulted in preemption in *Gobeille*, 136 S. Ct. at 945, is already the reality. As Arkansas and its amici admit, most States have imposed their own rules and procedures regulating the administration of prescription-drug benefits on behalf of ERISA-governed plans, particularly with respect to pharmacy reimbursement practices. Pet. Br. 41-42; California Br. 14-21. And while Arkansas seeks to downplay the inconsistencies, Pet. Br. 41-42, its amici concede that States have "taken different approaches," California Br. 33. As a result, plans and their benefit managers face a thicket of inconsistent obligations and the burden of complying with dozens of state-specific regulatory regimes.

With respect to MAC lists, 39 States besides Arkansas require regular updates.[6] Yet those laws vary in what triggers the update requirement and how quickly the lists must be updated. Act 900's requirement is triggered by changes in invoice prices (if reported by pharmacies), but other States require updates upon the occurrence of other events. *E.g.*, Alaska Stat. §21.27.945(a)(5) ("significant price update or modification" by "national drug database provider"); Iowa Code §510B.7(3) (notification from manufacturer or supplier of price increase). And other States require

[6] *See infra* pp. 27-28 & n.8 (citing statutes).

updates to be made regularly without specifying a triggering condition.[7]

The schedule on which MAC lists must be updated following the triggering event also varies. Two States require updates every three business days. Miss. Code Ann. §73-21-155(2); Tenn. Code Ann. §56-7-3107(b)(1). Two require updates every ten calendar days. Mont. Code Ann. §33-22-172(2)(a); R.I. Gen. Laws Ann. §27-41-38.2(b)(1). Another requires updates every fourteen days. N.H. Rev. Stat. Ann. §402-N:3(II)(c). Georgia requires updates every five or fourteen business days, depending on the type of plan. Ga. Code Ann. §33-64-9(a)(1). Thirty-two States require updates within seven days after a triggering event, but those States vary as to whether they count calendar days or business days or simply fail to specify.[8]

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[7] *E.g.*, Cal. Bus. & Prof. Code §4440(e) (update using "most recent data sources available"); 215 Ill. Comp. Stat. Ann. 5/513b1(b)(1), (2) (update to "remain consistent with changes in pricing data"); N.M. Stat. Ann. §59A-61-4(D)(2), (3) (update to "remain consistent with pricing changes and product availability in the marketplace").

[8] *Calendar days*: Fla. Stat. §641.314(2)(a); 215 Ill. Comp. Stat. 5/513b1(b)(1); Ky. Rev. Stat. Ann. §304.17A-162(6); La. Stat. Ann. §22:1864(B)(2); N.J. Stat. Ann. §17B:27F-2(a)(2); Okla. Stat. tit. 59, §360(A)(1); 40 Pa. Cons. Stat. §4532(a)(2); S.C. Code Ann. §38-71-2240(B)(2) (effective Jan. 1, 2021); Utah Code Ann. §31A-46-303(5)(b); Vt. Stat. Ann. tit. 18, §9473(c)(2).

Business days: Alaska Stat. §21.27.945(a)(4); Ariz. Rev. Stat. Ann. §20-3331(A)(1); Del. Code Ann. tit. 18, §3323A(b)(3) (effective June 1, 2020); Kan. Stat. Ann. §40-3830(d); Me. Stat. tit. 24-A, §4350(4)(C); Minn. Stat. §62W.08(a)(2); N.M. Stat. Ann. §59A-61-4(D)(2); N.C. Gen. Stat. §58-56A-5(b); N.D. Cent. Code §19-02.1-14.2(2)(b); Or. Rev. Stat. §735.534(2)(f); Wash. Rev. Code §19.340.100(2)(f); Wis. Stat. §632.865(2)(a)(1); Wyo. Stat. Ann. §26-52-104(d)(iv).

Appeal procedures and remedies also vary. Besides Arkansas, 36 States require some procedure for pharmacies to challenge MAC reimbursements.[9] But those laws vary in both the substantive rules of decision and the remedies available. For example, Arkansas provides that a pharmacy's appeal should prevail whenever the pharmacy cannot purchase the drug from its preferred wholesaler for less than the invoice price—regardless of the price available from other wholesalers. *Supra* p. 24. Washington permits a pharmacy to appeal if the MAC-based reimbursement is less than the *net* amount the pharmacy paid to a supplier, and a Washington pharmacy must prevail on appeal if it "demonstrate[s] that it is unable to purchase" a therapeutically equivalent product at the MAC—but only if the pharmacy has fewer than fifteen retail outlets in the State. Wash. Rev. Code §19.340.100(3). Alaska allows an appeal if the reimbursement is "less than the amount that the network pharmacy can purchase from two or more of its contracted suppliers." Alaska Stat. §21.27.950(b). And while such an appeal is not required to be upheld, a denial may result in a

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Not specified: Cal. Bus. & Prof. Code §4440(e); Colo. Rev. Stat. §25-37-103.5(1)(a); Haw. Rev. Stat. §328-106(e); Ind. Code §27-1-24.8-4; Md. Code Ann., Ins. §15-1628.1(c)(1); Mo. Rev. Stat. §376.388(3); Ohio Rev. Code Ann. §3959.111(A)(1)(a); Tex. Ins. Code Ann. §1369.355(b); Va. Code Ann. §38.2-3407.15:3(B)(1), (2).

[9] *Infra* n.10; *see also* Ala. Code §34-23-112; Alaska Stat. §21.27.950(a); Ariz. Rev. Stat. Ann. §20-3331(A)(3); Colo. Rev. Stat. §25-37-103.5(3); Haw. Rev. Stat. §328-106(f); Me. Stat. tit. 24-A, §4350(5), (6); N.H. Rev. Stat. Ann. §420-J:8(XV)(a)(2); Or. Rev. Stat. §735.534(4); R.I. Gen. Laws Ann. §27-41-38.2(d); Utah Code Ann. §31A-46-303(5)(c), (6); Vt. Stat. Ann. tit. 18, §9473(c)(3); Va. Code Ann. §38.2-3407.15:3(C); Wash. Rev. Code §19.340.100(3); Wis. Stat. §632.865(2)(b).

hearing before the state Director of Insurance. *Id.* §21.27.950(e).

When a pharmacy prevails in a reimbursement appeal, 22 States besides Arkansas require a revision to the MAC list so that other pharmacies can take advantage of the increased MAC, while other States do not; some States even require notifying other pharmacies of the MAC list update.[10] Twenty-four States besides Arkansas allow a prevailing pharmacy to reverse and rebill the claim; other States do not.[11] Six States,

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[10] Cal. Bus. & Prof. Code §4440(f)(4); Del. Code Ann. tit. 18, §3324A(a), (d)(2) (effective June 1, 2020) (notify similarly situated pharmacies); Ga. Code Ann. §33-64-9(d), (f)(2); 215 Ill. Comp. Stat. 5/513b1(b)(4)(E); Kan. Stat. Ann. §40-3830(f)(3)(B); Ky. Rev. Stat. Ann. §304.17A-162(1)(b), (2) (notify network pharmacies); La. Stat. Ann. §22:1865(A), (B) (notify network pharmacies); Md. Code Ann., Ins. §15-1628.1(f)(5)(ii) (notify similarly situated pharmacies); Minn. Stat. §62W.08(c), (d); Mo. Rev. Stat. §376.388(5), (7); Mont. Code Ann. §33-22-173(1)(a), (3)(b); N.J. Stat. Ann. §17B:27F-4(d)(2); N.M. Stat. Ann. §59A-61-4(D)(5), (7), (9) (notify network pharmacies); N.Y. Pub. Health Law §280-a(2)(a), 2(d); N.D. Cent. Code §19-02.1-14.2(2)(e); Ohio Rev. Code Ann. §3959.111(A)(3)(f); Okla. Stat. tit. 59, §360(A)(4); 40 Pa. Cons. Stat. §4533(a), (c); S.C. Code Ann. §38-71-2240(B)(5), (D)(1)(d) (effective Jan. 1, 2021); Tenn. Code Ann. §56-7-3108(a), (e)(2); Tex. Ins. Code Ann. §1369.357(a), (c)(2); Wyo. Stat. Ann. §26-52-104(e), (g).

[11] *See* Alaska Stat. §21.27.950(c); Cal. Bus & Prof. Code §4440(f)(4); Del. Code Ann. tit. 18, §3324A(d)(1)(b); Ga. Code Ann. §33-64-9(f)(3); Haw. Rev. Stat. §328-106(f)(5); Kan. Stat. Ann. §40-3830(f)(3)(C); Ky. Rev. Stat. Ann. §304.17A-162(2)(d), (e); La. Stat. Ann. §22:1865(B)(2); Md. Code Ann., Ins. §15-1628.1(f)(5)(i); Me. Stat. tit. 24-A, §4340(6)(A); Mo. Rev. Stat. §376.388(7)(3); 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.M. Stat. Ann. §59A-61-4(D)(7); N.Y. Pub. Health Law §280-a(2)(c); Ohio Rev. Code Ann. §3959.111(A)(3)(e), (f); Okla. Stat. tit. 59, §360(A)(4); Or. Rev. Stat. §735.534(7)(a)(B); 40 Pa. Cons. Stat. §4533(c); S.C. Code Ann. §38-71-2240(D)(1)(c) (effective Jan. 1,

however, allow even other pharmacies to reverse and rebill claims involving the same product.[12]

Three other States' laws feature decline-to-dispense provisions, but they differ from Act 900. For example, they generally allow a pharmacy to decline to dispense if the pharmacy's reimbursement would be less than the "acquisition cost" of the covered drug, but they do not define the acquisition cost, like Arkansas's law does. *See* La. Stat. Ann. §22:1860.3(B)(1); Miss. Code Ann. §73-21-155(5)(a); Mont. Code Ann. §33-22-174.

Plans and their benefit managers cannot comply with this crazy-quilt regime while maintaining "'nationally uniform plan administration.'" *Gobeille*, 136 S. Ct. at 945. Most plans operate in multiple States. JA181-182, 187. And even a plan that operates in only one State must comply with another State's laws whenever a plan participant fills a prescription in another State. An employer that operates exclusively in Tennessee and does no business in Arkansas would nonetheless have to "adjust its employee benefit plan for any employees that choose to live across the state line in Arkansas." JA130. And that employer, operating exclusively in Tennessee, could not "access the full negotiated benefits of MAC pricing" if any employees crossed state lines to fill prescriptions. *Id.* Congress intended

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2021); Tenn. Code Ann. §56-7-3108(e)(1); Tex. Ins. Code Ann. §1369.357(c)(3); Wyo. Stat. Ann. §26-52-104(g).

[12] Del. Code Ann. tit. 18, §3324A(d)(2)(b)(2) (effective June 1, 2020); Ky. Rev. Stat. Ann. §304.17A-162(2)(e), (f); La. Rev. Stat. Ann. §22:1865(B)(2), (4); Md. Code Ann., Ins. §15-1628.1(f)(5)(ii)(2)(B); N.M. Stat. Ann. §59A-61-4(D)(10); Ohio Rev. Code Ann. §3959.111(A)(3)(f).

ERISA to preempt such a "patchwork scheme." *Fort Halifax*, 482 U.S. at 11.

As Arkansas's decline-to-dispense provision illustrates, the lack of uniformity directly affects beneficiaries. Under that provision, a network pharmacy in Arkansas may refuse to serve a covered patient from another State if the patient's plan incorporates a MAC that is less than the pharmacy's invoice price—*i.e.*, reimbursement that is permissible in other States. JA130-131. The only way a plan can ensure pharmacy access for all covered beneficiaries, wherever they might go, is to make state-specific adjustments to the plan terms to comply with each State's rules, while updating the plan documents and communications to keep beneficiaries informed of how their coverage might vary from State to State. *See id.*

In addition, plans and their PBMs "must maintain a familiarity with the laws of" every State and "be attentive to changes in the interpretations of those statutes by state courts"—"exactly the burden ERISA seeks to eliminate." *Egelhoff*, 532 U.S. at 151. Those burdens are "hardly trivial." *Id.* As this Court reiterated in *Gobeille*, "[r]equiring ERISA administrators to master the relevant laws of 50 States" would "undermine the congressional goal of minimiz[ing] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries." 136 S. Ct. at 944 (quotation marks omitted).

C. Permitting Act 900 To Stand Would Impose The Exact Burdens And Inefficiencies ERISA Was Meant To Prevent

The "'nature of the effect of [Act 900] on ERISA plans,'" considered in light of ERISA's objectives,

confirms that Act 900 is preempted. *Gobeille*, 136 S. Ct. at 943. ERISA's preemption provision reflects Congress's concern that conflicting state requirements "would introduce considerable inefficiencies in benefit program operation, which might lead those employers with existing plans to reduce benefits, and those without such plans to refrain from adopting them." *Fort Halifax*, 482 U.S. at 11. Act 900 imposes precisely those burdens by making the administration of benefits more costly and less efficient—reducing the value of benefits to plan beneficiaries. Whereas MAC lists allow plans (or PBMs administering benefits on their behalf) to reimburse pharmacies according to easily determined contractual terms, JA152; Dist. Ct. Dkt. 44, at 56, state laws like Act 900 require plans and PBMs to reimburse according to each pharmacy's individual invoice price for each particular transaction where the invoice price exceeds the MAC, eliminating the efficiency of relying on the MAC list.

Plans and their benefit administrators would have to monitor pharmacy invoice prices on a daily basis—if it is even possible to do so—requiring "considerable administrative costs." JA168 n.47. Pharmacies' right to reverse and rebill claims likewise increases costs, requiring reprocessing of claims and recalculation of coinsurance and deductibles. JA132, 139.[13] And the

[13] Arkansas argues (at 41-42) that many PBMs already provided for reimbursement appeals in their pharmacy contracts before Act 900's enactment. But the fact that a plan or its benefit manager might choose to adopt a particular procedure does not mean a State has authority to impose it by law. Moreover, Arkansas mandates a different procedure that is far more burdensome. JA128-132, 137-139. As one PBM explained, state laws regulating MACs have already produced "a massive increase in appeals," and Act 900 "will cause an even larger increase." JA128.

decline-to-dispense provision would have particularly problematic effects because "[t]he only way" a plan can ensure guaranteed pharmacy access for beneficiaries in light of that provision would be to "conform all MAC lists nationwide to the Arkansas requirements"—if doing so would even be possible without violating other States' laws—or else to "provide every member in the country a different MAC list when they fill prescriptions in" Arkansas. JA130-131; *see* Dist. Ct. Dkt. 44, at 65-66.

Those operational inefficiencies would increase costs for plans and ultimately constrain how prescription-drug benefit plans can be designed, all to the detriment of beneficiaries. Act 900 also increases what plans must spend for prescription drugs themselves. MACs create incentives for pharmacies to purchase less expensive medications and to seek better wholesale price terms. JA167; *see* JA150; OIG Medicaid Study 19, 21. But laws like Act 900 "make MACs less effective, [and] will result in higher payments to pharmacies—thereby increasing pharmaceutical spending." JA167; *see* Washington Health Care Authority, Fiscal Note, 5857 SSB, at 1-2 (Mar. 10, 2015) (concluding that similar legislation in Washington would "significantly increase the costs" of the benefits delivery system).

Ultimately, beneficiaries bear these costs. When a plan's costs rise, it must either "increase [its] prices overall" or "make other modifications to [its] benefit plan." Dist. Ct. Dkt. 44, at 66. For example, a plan might have to eliminate certain pharmacies from the network, resulting in reduced access and convenience for beneficiaries. *Id.* Or plans might have to adapt their coverage terms, such as by modifying what benefits are covered or increasing copayments and deductibles. *Id.* at 66-67; JA131, 138-139, 168-169; *see Fort*

Halifax, 482 U.S. at 10-11. And when a pharmacy invokes the decline-to-dispense provision, covered patients are denied their benefits entirely. Although the plan promises access to particular drugs on specific cost-sharing terms at network pharmacies, the beneficiary must either forgo the medication, pay the pharmacy's usual and customary price out of pocket, or travel to another pharmacy willing to honor its network contract. As FTC staff have explained, such state laws threaten to increase the costs of health benefits and ultimately reduce the number of individuals with prescription-drug coverage. *See* Letter from Cooper et al., FTC, to Sen. Seward, U.S. Senate (Mar. 31, 2009); Letter from DeSanti et al., FTC, to Rep. Formby, Mississippi House of Representatives (Mar. 22, 2011).

Act 900 undermines efficient, nationally uniform plan administration in exactly the way ERISA's preemption provision is intended to prevent. The Arkansas law is preempted.

II. ARKANSAS'S COUNTERARGUMENTS ARE UNPERSUASIVE

Arkansas defends Act 900 on two theories, each of which rests on the premise that Act 900 merely regulates rates for prescription drugs in the marketplace. Arkansas contends that Act 900's restrictions and mandates are either necessary incidents to permissible rate regulation or a mechanism for resolving rate disputes unrelated to the processing of claims. Neither theory has merit. The United States accordingly stands behind little of Arkansas's analysis. Instead, it emphasizes an alternative defense—that States may regulate the administration of benefits on behalf of an ERISA plan as long as the state law operates on TPAs rather than plans directly. The Court should reject that theory as well.

A. Act 900 Regulates The Administration Of Benefits On Behalf Of Plans, Not Rates Charged By Pharmacies

Arkansas principally contends that Act 900's restriction of MAC-based reimbursement regulates "rates" and that all other obligations imposed by Act 900 are necessary incidents to that rate regulation. But Act 900 does not embody mere rate regulation, and Arkansas's novel "incident to" standard would read ERISA's preemption provision out of the statute.

1. Act 900 is not rate regulation

Arkansas contends (at 19-30) that Act 900 is not preempted because it regulates pharmacy rates in a manner that only incidentally raises the cost of providing benefits. Arkansas rests that argument on *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Insurance Co.*, 514 U.S. 645 (1995). In *Travelers*, the Court held that a New York law requiring hospitals to add a surcharge to the bill for patients covered by commercial insurers, but not patients covered by Blue Cross Blue Shield insurers, was "basic rate regulation" not preempted under ERISA. *Id.* at 667 n.6, 668. New York enacted the law, the Court explained, because "the Blues pay the hospitals promptly and efficiently and … provide coverage for many subscribers whom the commercial insurers would reject as unacceptable risks." *Id.* at 658.

Although the Court acknowledged that the law made the Blues "more attractive" and "thus ha[d] an indirect economic effect on choices made by insurance buyers, including ERISA plans," it explained that those indirect economic effects did not trigger ERISA preemption because differential charges merely affected

"a plan's shopping decisions": They did not "bind plan administrators to any particular choice [*e.g.*, pick the Blues] and thus function as a regulation of an ERISA plan itself," nor did they prevent the plans from having "uniform administrative practice" or a "uniform interstate benefit package." *Travelers*, 514 U.S. at 659-660. Instead, the surcharges merely required hospital providers to charge varying rates to patients for services rendered—differentials that had existed long before ERISA's enactment. *Id.* at 660, 664-665, 667 n.6. Given that long history, the Court rejected the suggestion that Congress had intended to require cost uniformity. *Id.* at 662, 665.

Act 900 is nothing like the hospital surcharges in *Travelers*. It does not regulate the price of goods or services in the marketplace. For example, it does not regulate the price a pharmacy charges for prescription medication. *Cf.* U.S. Br. 26. Pharmacies in Arkansas remain free to set their own usual and customary prices and to agree (or not) to contractual rates.

What the Arkansas law actually regulates is the administration of benefits on behalf of a plan. When a plan decides, directly or through a PBM, to manage prescription-drug benefits using a MAC-based reimbursement system subject to specific rules and procedures, the plan is selecting and implementing a "'system for processing claims and paying benefits.'" *Egelhoff*, 532 U.S. at 150. Act 900 effectively dictates that a plan may not choose or implement that system, but must process claims and pay benefits according to a pricing methodology and procedural requirements of the State's design.

Arkansas responds (at 23-24) that Act 900 does not affect a plan's choice among PBMs or raise the prospect

that a plan would have to "sever[] ties with their PBM." This misses the point. The problem with Act 900 is not that it influences plans' choice of administrators, but that it dictates how benefits are administered on behalf of a plan—requirements it imposes regardless of which PBM the plan engages, and indeed whether the plan engages a PBM at all. In doing so, it makes "'administration of a nationwide plan more difficult'" and produces "considerable inefficiencies," *Fort Halifax*, 482 U.S. at 10, triggering ERISA preemption.

Moreover, Act 900's restrictions on MAC-based reimbursement share none of the history of the charge differentials the Court was reluctant to displace in *Travelers*. Given the history of differential billing by hospitals and the prevalence of state regulation of hospital charges at the time of ERISA's enactment, the Court found it "unsettling" to think Congress could have intended to preempt those practices merely because of their indirect economic effects on plans. 514 U.S. at 664-665. MAC-based reimbursement, in contrast, did not emerge until well after ERISA's enactment. JA147-149. And state-level regulation of MAC practices arose largely over the past decade. Given their novelty, there is no reason to think Congress would have expected laws like Act 900 to be exempt from ERISA preemption.[14]

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[14] The United States cites (at 23-24) legislative history suggesting that Congress did not expect state regulation of "third-party prepaid prescription programs" to be preempted. But those committee proceedings addressed an emerging practice among insurance companies, and the practice was then subject to little state regulation—quite unlike the longstanding and widespread practices considered in *Travelers*. *Third Party Prepaid Prescription Programs: Hearings Before the House Subcomm. on Envt'l*

For the same reason, there is no substance to the United States' concern that a finding of ERISA preemption here would lead to preemption of state laws regulating "rates charged by drug manufacturers, pharmaceutical wholesalers, and [PSAOs]" or the cost of other benefits such as "death benefits, day care services, and prepaid legal services." U.S. Br. 24. Act 900 does not regulate the prices charged by pharmacies at all. Moreover, Act 900 is preempted not simply because it increases the amount a plan must pay to secure benefits for plan participants but because it dictates how benefits are to be administered on behalf of a plan.

Arkansas's remaining authorities lend no support. *California Division of Labor Standards Enforcement* v. *Dillingham Construction, N.A.*, 519 U.S. 316 (1997), addressed a state law requiring all contractors on public-works projects to pay the local prevailing wage, except that contractors could pay a lower wage to apprentices in approved programs. *Id.* at 319. Although the apprenticeship programs could include programs regulated by ERISA, *id.* at 325, the Court found no preemption, *id.* at 325-334. The wage law was "quite remote from the areas with which ERISA is expressly concerned." *Id.* at 330. It did not "bind ERISA plans to anything," and States had regulated wages long before ERISA's enactment. *Id.* at 332-334. This Court declined to hold such laws with "so tenuous a relation" to ERISA preempted. *Id.* at 334. Similarly, in *De Buono* v. *NYSA-ILA Medical & Clinical Services Fund*, 520 U.S. 806 (1997), the Court addressed a state tax on healthcare facilities. The tax "increase[d] the cost of providing benefits" and would accordingly "have some

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Problems Affecting Small Business of the Select Comm. on Small Business, 92d Cong., 1st Sess. 17 (1971).

effect on the administration of ERISA plans," but it did so only as the incidental effect of a generally applicable law. *Id.* at 815-816. Act 900 is not a generally applicable law that burdens plans only incidentally. It establishes methodology and procedures that must be followed when claims are processed and benefits are paid on behalf of a plan.

2. State regulation of plan administration is preempted even where the state law is incident to permissible rate regulation

Arkansas's argument fails for the independent reason that there is no "incidental regulation" exception to ERISA preemption of the sort Arkansas envisions. According to Arkansas, "States may incidentally regulate even central matters of plan administration where that regulation is necessary to enforce otherwise permissible laws." Pet. Br. 27. That novel argument, if accepted, would unravel virtually all of what Congress accomplished in ERISA's preemption clause.

The sole authority Arkansas cites is a single sentence in *Gobeille*, in which, Arkansas asserts, the Court "added an important caveat" that its analysis "would likely 'be different'" in a case involving the enforcement of a state law that "'necessitates incidental reporting by ERISA plans.'" Pet. Br. 25-26 (quoting *Gobeille*, 136 S. Ct at 946). What the Court actually said, responding to Vermont's citation of the State's traditional power to regulate public health, was that the "analysis *may* be different when applied to a state law, such as a tax on hospitals," that necessitates incidental reporting by ERISA plans, but "that [wa]s not the law before the Court." *Gobeille*, 136 S. Ct. at 946 (citing *De Buono*, 520 U.S. 806) (emphasis added).

As the Court's citation to *De Buono* confirms, the quoted sentence simply acknowledged the principle that "generally applicable laws regulating 'areas where ERISA has nothing to say'" may sometimes be upheld "notwithstanding their incidental effect on ERISA plans." *Egelhoff*, 532 U.S. at 147-148; *see De Buono*, 520 U.S. at 815-816. But it is equally clear that a state law that "governs the payment of benefits, a central matter of plan administration," is not such a generally applicable law. *Egelhoff*, 532 U.S. at 148. Nothing in *Gobeille* cast any doubt on that principle. To the contrary, just two sentences before the dictum Arkansas quotes, the Court stated unequivocally that "ERISA pre-empts a state law that regulates a key facet of plan administration even if the state law exercises a traditional state power." *Gobeille*, 136 S. Ct. at 946. Act 900 fails under that test.

Arkansas's proposed rule would open a significant hole in ERISA's preemptive scope. Allowing States to impose inconsistent requirements on central matters of plan administration merely by tying them to a regulation of rates would defeat ERISA's "principal goal[]" of "enabl[ing] employers 'to establish a uniform administrative scheme'" with "'standard procedures to guide processing of claims and disbursement of benefits.'" *Egelhoff*, 532 U.S. at 148.

B. No Artificial Line Between "Reimbursement" And "Claims Processing" Supports Act 900

Arkansas expends (at 30-48) substantial energy arguing that Act 900 governs only the process for resolving rate disputes between a plan (or a PBM acting on a plan's behalf) and a pharmacy, akin to any breach-of-contract action between a plan and a provider that is separate from the plan's processing of claims for benefits.

That distinction is illusory. Determining how much to pay for benefits is at the core of what plans (and their TPAs) do.

ERISA's preemption provision looks to the "administrative realities of employee benefit plans." *Fort Halifax*, 482 U.S. at 9. It broadly shields from state regulation all aspects of plan administration, from "determining the eligibility of claimants" to "calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records." *Id.* That plainly includes a plan's "uniform administrative scheme for paying benefits" and the procedures attendant to that scheme. *Id.* at 17. Indeed, ERISA's primary focus is ensuring that plans can and do pay benefits. *E.g.*, *Massachusetts* v. *Morash*, 490 U.S. 107, 115 (1989). Act 900 controls the manner in which plans determine and pay for employee benefits, and thus relates to a central function of plan administration.

Indeed, claims processing and reimbursement are inextricably intertwined, particularly for health plans that utilize coinsurance or deductibles. Where a plan uses coinsurance, the beneficiary pays a percentage of the costs of prescriptions, with the plan paying the balance. *See* JA168-169. In a deductible plan, beneficiaries pay the entire cost of their medications until they reach a defined annual limit and may have a copay or coinsurance thereafter. *Id.* For either type of plan, Act 900's appeal provisions and reverse-and-rebill provision directly affect patients' and plans' respective financial responsibility for covered medications and thus the relationship between plans and beneficiaries.

For example, under a coinsurance plan that requires a beneficiary to pay 10% of drug costs, the beneficiary

will pay $1 at the point of sale on a $10 drug. But if the pharmacy establishes on appeal that it cannot purchase the drug from its primary wholesaler for an invoice price of less than $20 (disregarding discounts), the beneficiary would owe an additional $1. If that same beneficiary had a deductible plan and the deductible had not yet been exhausted, the beneficiary could owe another $10. Arkansas responds (at 43) that pharmacies and plans would "[m]ost likely" make no attempt to collect the extra amount. But ERISA's preemption analysis cannot hinge on speculation about what plans or pharmacies might do. The salient point is that Act 900 changes what beneficiaries and plans each owe, altering the very design of the plan and the benefit promised to participants.

That is even more true of Act 900's decline-to-dispense provision. Act 900 entitles the pharmacy to refuse to furnish a benefit due to the patient solely because the patient is covered by a plan that uses MAC lists. Act 900 makes the patient's ability to receive a covered drug on terms that satisfy the plan's requirements dependent on the network pharmacy's decision whether to honor its contractual commitment or invoke its state-law right to abrogate that commitment. If a plan or PBM acting on a plan's behalf uses MAC lists, and the MAC is lower than the pharmacy's asserted invoice price, Act 900's decline-to-dispense provision effectively negates the patient's right to receive the benefit. Arkansas again invokes (at 45) *Travelers* for the proposition that pharmacists' statutory right to decline to dispense is merely incident to the State's regulation of rates. That is like saying that New York could have authorized hospitals, as an alternative to assessing a surcharge, to deny care altogether to patients covered by ERISA plans other than the Blues—all as a mere

"incident" to its rate regulation. But a state law that permits healthcare providers to deny care to which a patient is entitled under a plan, if the plan has features the State finds objectionable, is not rate regulation. To the contrary, there is no matter more central to plan administration than the terms on which covered benefits are provided or denied.

Finally, Arkansas cites (at 31-36) lower-court decisions holding that breach-of-contract and related causes of action brought by third-party service providers against ERISA plans are not preempted.[15] That analogy fails. Rather than mandating that plans prospectively alter the means by which they determine and pay for benefits, the claims in those cases sought to enforce promises made by the plan. Act 900, in contrast, seeks to prohibit plans from adhering to the terms of their contracts and requires them to conform instead to the State's preferred terms.

C. The United States' Attempt To Distinguish ERISA Plans From Their Third-Party Administrators Should Be Rejected

The United States takes a different tack. While recognizing (at 7-8) that PBMs "administer … benefits" on behalf of ERISA plans, the United States emphasiz-

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[15] The cases Arkansas cites (at 32-33) bear limited relevance. They address the doctrine of complete preemption, under which a state-law claim may be removed to federal court despite the well-pleaded complaint rule because a federal statute "'wholly displaces the state-law cause of action.'" *Davila*, 542 U.S. at 207. The application of that doctrine turns on a distinct—and narrower—test than preemption under ERISA's preemption clause, which is the only issue here. *Id.* at 207-214; *see, e.g.*, *K.B.* v. *Methodist Healthcare-Memphis Hosps.*, 929 F.3d 795, 800 (6th Cir. 2019).

es (at 27-33) a purported distinction between "PBM administration" and "ERISA plan administration," contending (at 27) that Act 900 "imposes obligations on PBMs, not plans." That distinction makes little sense. Neither ERISA nor Act 900 draws any relevant distinction between a plan administering benefits on its own behalf and a plan that engages a third party to do so. Indeed, this Court rejected that argument in *Gobeille*.

The Vermont law challenged in *Gobeille* required disclosure of certain healthcare information to the State, and it imposed that requirement on all health insurers—defined to include all "self-insured … health care benefit plan[s]," as well as "any third party administrator" or "similar entity" possessing such data. 136 S. Ct. at 941. The plaintiff, Liberty Mutual, maintained an ERISA-governed, self-insured health plan for its employees, and it engaged Blue Cross Blue Shield to administer claims on the plan's behalf. *Id.* at 941-942. Because the plan was below the statutory threshold for mandatory reporting, the reporting requirement applied only to Blue Cross, which had to report information about plan members. *Id.* at 942.

Although the Court recognized that Vermont's reporting requirement fell only on the TPA, 136 S. Ct. at 942, the Court attached no significance to that distinction. The Court held that the law "compel[led] *plans* to report"—thereby "intrud[ing] upon a 'central matter of plan administration' and 'interfer[ing] with nationally uniform plan administration'"—without suggesting that it made any difference that the reporting obligation fell only on Blue Cross as the TPA. *Id.* at 945 (emphasis added). That analysis was consistent with the central aim of ERISA's preemption provision—minimizing "administrative and financial burden[s] on plan admin-

istrators," *Egelhoff*, 532 U.S. at 149-150, so that "administrative costs" will not discourage employers from forming benefit plans, *Conkright*, 559 U.S. at 517. A patchwork of inconsistent state obligations contravenes those purposes whether imposed on TPAs acting on a plan's behalf or on the plan itself.

The same is true here. Whether a plan manages its own prescription-drug benefits, maintains its own MAC lists, and handles its own dealings with pharmacies, or instead engages a TPA to do so, the impact of Act 900 is the same. Either way, Act 900 mandates a state-specific system of benefits administration that imposes significant complexity and costs on the benefit administrator and forecloses a benefit design the plan sponsor might otherwise choose. *See PCMA* v. *District of Columbia*, 613 F.3d 179, 185 (D.C. Cir. 2010) ("requiring a PBM to follow a specific practice in administering pharmaceutical benefits on behalf of an [ERISA plan]" and "specifying the standard of conduct to which a PBM must adhere" regulates the administration of ERISA benefits).

No authority supports the proposition that States may regulate plan administration so long as the plan engages a third party to do the administering. Congress could hardly have intended ERISA preemption to apply where employers undertake the herculean task of managing their own prescription-drug benefits directly, but not where employers engage a PBM to do so more efficiently on the plan's behalf. In this context, there is no meaningful distinction between "PBM administration" and "ERISA plan administration."

Act 900 also makes no such distinction. Act 900 applies to any entity that administers a prescription-drug benefit plan, including a plan itself. The "[p]harmacy

benefits manager[s]" to which Act 900 applies include any "entity that administers or manages a pharmacy benefits plan or program." Ark. Code Ann. §17-92-507(a)(7); *see id.* §17-92-507(a)(9) (defining "[p]harmacy benefits plan or program" as any "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"). That includes both PBMs and ERISA plans that administer their own benefits, and the burdens imposed by Act 900 apply both to PBMs and plans.

The United States acknowledges this point but suggests (at 30) the Court need not consider whether ERISA would preempt Act 900's application to a plan administering its own prescription-drug benefit. But even considering Act 900's application only to PBMs, it regulates a function that PBMs undertake on behalf of plans—one that plans would have to perform themselves if they decided not to engage a PBM. And by regulating PBMs in this way, Act 900 constrains the plan itself "by forcing it to decide between administering its pharmaceutical benefits internally upon its own terms or contracting with a PBM to administer those benefits upon the terms laid down" by Arkansas law. *District of Columbia*, 613 F.3d at 188. Given the impossibility for most employers of administering pharmacy benefits internally, the "'choice'" that Act 900 imposes on plans "is in reality no choice at all." *Id.* By regulating the management of benefits on behalf of a plan, Act 900 intrudes on central matters of plan administration and interferes with nationally uniform plan administration, and is therefore preempted.

III. ACT 900 REFERS TO ERISA PLANS

The court of appeals additionally held Act 900 preempted because it impermissibly "refers to" ERISA plans. Pet. App. 5a-7a. That conclusion follows from this Court's decisions in *District of Columbia* v. *Greater Washington Board of Trade*, 506 U.S. 125 (1992), and *FMC Corp.* v. *Holliday*, 498 U.S. 52 (1990).

Greater Washington involved a law that required "'[a]ny employer who provides health insurance coverage for an employee'" to maintain the same coverage for employees receiving workers' compensation benefits. 506 U.S. at 128. Although that provision did not mention ERISA by name, it measured the employer's obligation "by reference to 'the existing health insurance coverage' provided by the employer." *Id.* at 130. In the case before the Court, the "existing coverage" was an ERISA-governed plan, triggering preemption. *Id.* at 130-131.

In *FMC*, the Court considered a law that precluded subrogation from any tort recovery with respect to benefits paid by "'[a]ny program, group contract or other arrangement for payment of benefits.'" 498 U.S. at 55 n.2. Those terms "includ[ed], *but [were] not limited to*, benefits payable by a hospital plan corporation or a professional health service corporation.'" *Id.* at 59 (emphasis in original). Emphasizing that definition, the Court found the law "ha[d] a 'reference' to benefit plans governed by ERISA." *Id.*

Act 900 operates in the same way. It applies to any entity administering benefits on behalf of a "plan or program that … provides for pharmacist services to individuals who … are employed in this state"—*i.e.*, an employee benefit plan, including plans regulated by ERISA. Ark. Code Ann. §17-92-507(a)(9). Although

Act 900's definition of a "pharmacy benefits plan or program" extends also to non-ERISA plans, the same was true in *Greater Washington* and *FMC*. *See Greater Washington*, 506 U.S. at 131 & n.3; *FMC*, 498 U.S. at 59. Indeed, the Court observed in *Greater Washington* that the "health insurance coverage" referenced by the D.C. law could include non-ERISA plans, and that fact made no difference. 506 U.S. at 130-131 & n.3.

We acknowledge, as Arkansas notes (at 49-50), that this Court's subsequent decision in *Dillingham* articulated the "reference to" prong of ERISA preemption more narrowly. *See* 519 U.S. at 325-328. But *FMC* and *Greater Washington* have never been overruled. *Dillingham* cited those cases with approval. *Id.* at 324-325. And the divergent outcomes can be explained by the distinction this Court has often drawn between laws that depend on the existence of a plan or make specific reference to plans, including ERISA plans, and generally applicable laws that only happen to touch on employee benefit plans. *See De Buono*, 520 U.S. at 814-815; *Greater Washington*, 506 U.S. at 130 n.1. *Dillingham* fell on the latter side of the line, bearing only a "tenuous … relation" to ERISA. 519 U.S. at 334. *FMC* and *Greater Washington*, in contrast, specifically referred to and depended on the existence of a benefit plan or program, including ERISA-governed plans.

Act 900 bears greater resemblance to the laws in *FMC* and *Greater Washington* than *Dillingham*. Whereas *Dillingham*'s prevailing-wage law regulated contractors' wage obligations to all workers, Act 900 operates by direct reference to employee benefit plans, including ERISA plans—indeed, as Arkansas concedes (at 51), Act 900 would have no operation or effect at all absent a benefit plan. The court of appeals' finding of "reference to" preemption was therefore well taken.

Nothing more than Act 900's "connection with" ERISA plans is necessary to sustain the court's judgment; but Act 900's specific "reference to" ERISA plans further confirms that result.

CONCLUSION

The judgment should be affirmed.

Respectfully submitted.

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APPENDIX

APPENDIX

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

Supremacy Clause, U.S. Const., art. VI, cl. 2

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

29 U.S.C. §1144

§1144. Other laws

(a) Supersedure; effective date

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title. This section shall take effect on January 1, 1975.

(b) Construction and application

(1) This section shall not apply with respect to any cause of action which arose, or any act or omission which occurred, before January 1, 1975.

(2)(A) Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.

(B) Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

* * *

Ark. Code Ann. §17-92-507
(effective Mar. 15, 2018 to July 23, 2019)

(a) As used in this section:

(1) "Maximum Allowable Cost List" means a listing of drugs used by a pharmacy benefits manager setting the maximum allowable cost on which reimbursement to a pharmacy or pharmacist may be based;

(2) "Pharmaceutical wholesaler" means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy;

(3) "Pharmacist" means a licensed pharmacist as defined in § 17-92-101;

(4) "Pharmacist services" means products, goods, or services provided as a part of the practice of pharmacy in Arkansas;

(5) "Pharmacy" means the same as in § 17-92-101;

(6) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice;

(7) "Pharmacy benefits manager" means an entity that administers or manages a pharmacy benefits plan or program;

(8) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager; and

(9) "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.

(b) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:

(1) Shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or has an NR or NA rating by Medispan, Gold Standard, or a similar rating by a nationally recognized reference;

(2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in Arkansas; and

(3) Shall not be obsolete.

(c) A pharmacy benefits manager shall:

(1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology;

(3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and

(4)(A)(i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as:

(a) Not meeting the requirements of this section; or

(b) Being below the pharmacy acquisition cost.

(ii) The reasonable administrative appeal procedure shall include the following:

(a) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals;

(b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a pharmacy service administrative organization; and

(c) No less than seven (7) business days to file an administrative appeal.

(B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within seven (7) business days after receipt of the challenge.

(C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within seven (7) business days after receipt of the challenge either:

(i) If the appeal is upheld:

(a) Make the change in the maximum allowable cost;

(b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Provide the National Drug Code that the increase or change is based on to the pharmacy or pharmacist; and

(d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code and the name of the national or regional pharmaceutical wholesalers operating in Arkansas that

have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(iii) If the National Drug Code provided by the pharmacy benefits manager 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, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(d)(1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(e) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(f)(1) This section does not apply to a Maximum Allowable Cost List maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration.

(2) This section shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the division if, at any time, the Arkansas' Medicaid Program or the division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

(g)(1) A violation of this section is a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, § 4-88-101 et seq., and a prohibited practice under the Arkansas Pharmacy Benefits Manager Licensure Act, § 23-92-501 et seq., and the Trade Practices Act, § 23-66-201 et seq.

(2) This section is not subject to § 4-88-113(f)(1)(B).