No. 18-540

In the Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as Arkansas Attorney General,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

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

BRIEF FOR PETITIONER

OFFICE OF THE ARKANSAS ATTORNEY GENERAL
323 Center St., Ste. 200
Little Rock, AR 72201
(501) 682-6302
nicholas.bronni@arkansasag.gov

LESLIE RUTLEDGE
Arkansas Attorney General
NICHOLAS J. BRONNI
Solicitor General
Counsel of Record
VINCENT M. WAGNER
Deputy Solicitor General
ASHER STEINBERG
DYLAN L. JACOBS
Assistant Solicitors General
SHAWN J. JOHNSON
Senior Assistant Attorney General

Counsel for Petitioner

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QUESTION PRESENTED

The question presented is:

Whether the Eighth Circuit erred in holding that Arkansas's statute regulating pharmacy benefit managers' drug-reimbursement rates, which is similar to laws enacted by a substantial majority of States, is preempted by the Employee Retirement Income Security Act of 1974 (ERISA), in contravention of this Court's precedent that ERISA does not preempt rate regulation.

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OPINIONS BELOW

The court of appeals' opinion (Pet.App.1a-11a) is reported at 891 F.3d 1109. The district court's order (Pet.App.12a-36a) is reported at 240 F. Supp. 3d 951.

JURISDICTION

The court of appeals entered judgment on June 8, 2018. After Justice Gorsuch twice extended the time to file a petition for certiorari, the petition was timely filed on October 22, 2018. This Court granted the petition on January 10, 2020, and has jurisdiction under 28 U.S.C. 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution provides:

> 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, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

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

The "other laws" provision of the Employee Retirement Income Security Act, 29 U.S.C. 1144, is set forth in the appendix to this brief at 1a-7a.

Arkansas's Maximum Allowable Cost Lists statute, Ark. Code Ann. 17-92-507 (Repl. 2018), is set forth in the appendix to this brief at 8a-13a as it was in effect at the time of the court of appeals' decision. Although

Arkansas has subsequently amended Section 17-92-507, *see* 2019 Ark. Laws Act 994, the amendments do not materially affect its operation and are not relevant here, *see* Br. of United States at 4 n.2.

STATEMENT

This case is about an obscure but singularly powerful industry: pharmacy benefit managers (PBMs). Few know what a PBM is, but over 266 million Americans—roughly 80% of the population—get their prescription drugs through one. *Examining the Drug Supply Chain: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 115th Cong. 77 (statement of Mark Merritt, President, Pharmaceutical Care Management Association). PBMs' singular power is compounded by their industry's unusual concentration. The three largest PBMs control 85 percent of the market. Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad* 10 (2018).[1] Those three largest PBMs—some of which own their own retail pharmacies and mail-order pharmacy services that compete with rural and independent pharmacies—are CVS/Caremark, OptumRX, and Express Scripts. JA301-03.

PBMs are not prescription-drug plans, but third parties that provide a variety of services. Most relevant here, those services include organizing pharmacy networks, giving prescription-drug plans access to those networks, processing claims for prescription-drug coverage, and reimbursing pharmacies for the drugs plans cover. Advisory Council on Employee Welfare and Pension Benefit Plans, U.S. Dep't of Labor, *PBM*

[1] https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

Compensation and Fee Disclosure 6 (2014).[2] This case concerns the last of those services: PBMs' reimbursements of pharmacies for generic drugs *after* approving and processing a beneficiary's claim.

A. Background

1. Prescription-Drug Transactions

When a person with prescription-drug insurance goes to her pharmacy to buy a drug, that person makes a claim on her prescription-drug plan to cover all or some of the drug's cost. In other health-insurance contexts, that would trigger a claims-processing procedure that could take weeks or months. In the prescription-drug context, however, a beneficiary's claim is processed before she ever leaves the pharmacy, and critically, before her plan reimburses the pharmacy or finalizes how much it will reimburse.

This is how the process works. A typical prescription-drug purchase involves a patient, a pharmacy, a prescription-drug plan, and a PBM. "When a patient has a prescription for [a] medication, the pharmacy files a claim on behalf of the patient to the patient's prescription insurance." 84 Fed. Reg. 2340, 2341 (Feb. 6, 2019) (proposed rule on PBMs' receipt of manufacturer rebates). That claim makes one simple request: for the plan to cover the drug's cost less the amount for which the patient is responsible. *PBM Compensation and Fee Disclosure* 9.

The PBM then processes the claim on the plan's behalf. *Id.* This requires the PBM to determine whether the patient is a plan beneficiary, whether the

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

patient's plan covers the prescribed drug, and, if so, how much of its cost the plan requires the patient to pay. *PBM Compensation and Fee Disclosure* 6, 9.

After making these determinations, the PBM conveys that information to the pharmacy, which then completes the sale of the drug to the patient. *Id.* Once the PBM approves (or denies) the patient's claim and determines how much the patient owes the pharmacy under the plan, the processing of the patient's claim is at an end.

For generic prescription drugs—the subject of this case—most plans make beneficiaries responsible for a co-pay. *See* Kaiser Family Foundation, *2019 Employer Health Benefits Survey: Prescription Drug Benefits* (2019)[3] (co-pays account for 81% of cost-sharing in employer plans for generic drugs). Co-pays are flat, plan-fixed amounts that beneficiaries pay for broad "tiers" of generic drugs.

Under less common plans, beneficiaries pay a co-insurance percentage of a generic's cost or pay a generic's full cost until they reach a deductible. *Id.* But even there, while reimbursement rates may affect how much a beneficiary pays, reimbursement decisions never affect what percentage of costs a beneficiary shares. That percentage is fixed in the plan and settled before any reimbursement dispute.

Regardless of whether a beneficiary is responsible for a co-pay, co-insurance, or a deductible, the claims-processing work is complete when the beneficiary pays the pharmacy.

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[3] https://www.kff.org/report-section/ehbs-2019-section-9-prescription-drug-benefits/

2. PBM Reimbursement Process

After the beneficiary purchases a medication, the PBM reimburses the pharmacy, using PBM assets. Unlike healthcare providers in other contexts, pharmacies do not negotiate reimbursement rates with plans. Instead, pharmacies agree in their network agreements with PBMs to be reimbursed at whatever rate the PBM—not the plan—sets.

The PBM's reimbursement rate for generic drugs is known as a maximum allowable cost rate (MAC). The MAC purports to reflect the average cost incurred by "well-run pharmacies" to purchase a particular generic drug at wholesale. BIO 7. But as Respondent admitted below, in a rapidly moving wholesale market, that is often not the case. Instead, a PBM's MAC may reflect a price that is no longer available because that rate is associated with a manufacturer who no longer sells that particular drug or whose version of that drug is temporarily unavailable. JA324. And contractually, nothing prevents PBMs from setting a MAC far below any pharmacy's attainable acquisition cost. JA327.

After the PBM informs the pharmacy what it will be reimbursed, the PBM gives the pharmacy an opportunity to appeal. Today, 36 States (including Arkansas) statutorily require PBMs to afford pharmacies MAC appeals. *See infra* n.9 and accompanying text. Even before those laws were enacted PBMs generally provided pharmacies MAC appeals by contract and had employees dedicated to reviewing those appeals. JA137, 177-78, 192, 208-09, 349. But absent state regulation, PBMs vested themselves with unlimited discretion to adjudge the reasonableness of their MACs and made no commitment to adjust rates that fell short of pharmacies' costs. JA108-09, 203-04.

After reimbursing the pharmacy, the PBM bills the prescription-drug plan under the terms of its agreement with the plan. Agreements between PBMs and plans provide for two types of drug pricing: "lock-in" or "spread" pricing, and transparent or "pass-through" pricing. JA316.

Under spread pricing, plans agree to pay a set of fixed, theoretically advantageous rates that exceed PBMs' MACs—thus the name "spread." JA316-17. Spread-pricing rates are typically calculated in terms of a percentage discount from nominal list prices. *PBM Compensation and Fee Disclosure* 10. What PBMs actually reimburse pharmacies under this model is undisclosed to the plans. JA317. Nationally, most contracts between PBMs and plans use this methodology.[4] *Id.*

Under less common pass-through agreements, PBMs nominally pass through their actual reimbursement expenditures to plans and earn their profits from administrative fees rather than spread mark-ups. JA318. But even in pass-through agreements, financial-performance guarantees ensure that MAC fluctuations ultimately do not affect a plan's total spending. JA318-19. Thus, as Respondent admitted below, those guarantees "ensure that PBMs and health plans in pass-through contracts arrive at the same result as a lock-in/spread contract." *Id.*

3. Effects of PBM Reimbursement Practices

These methods of calculating drug reimbursements are rife with potential for abuse, both downstream and

[4] After the decision below, Arkansas banned spread pricing by amending a different statute than the one challenged by PCMA. *See* Ark. Code Ann. 23-92-505(c).

upstream. Downstream, nothing protects pharmacies from systematic under-reimbursement besides PBMs' good intentions. Whether at initial reimbursement or on appeal, PBMs set MACs unilaterally. And a discontented pharmacy is left with a Hobson's choice: accept a significant number of unprofitable reimbursements or exit a vast PBM network that provides a large proportion of their revenue. JA226. And because virtually all prescription-drug claims are processed by PBMs, pharmacies have no real choice but to participate in PBM networks. JA217-18, 262. The result of these arrangements is systematic under-reimbursement. Indeed, Respondent has acknowledged that across all payers approximately 10% of prescriptions are reimbursed below wholesale cost. JA314. And a study of one Iowa community pharmacy found that PBMs reimbursing for the local market's two largest private insurers reimbursed below cost 12.3% and 25.9% of the time, for an average loss of over seven dollars a prescription. Logan Murry et al., *Third-party reimbursement for generic prescription drugs: The prevalence of below-cost reimbursement in an environment of maximum allowable cost-based reimbursement*, 58 J. Am. Pharmacists Ass'n 421, 423 (2018). By contrast, at the same pharmacy, the study found that Iowa's Medicaid program reimbursed below cost just 4.1% of the time. *Id.*

PBMs' below-cost reimbursements also have adverse upstream effects on plans. These reimbursements have not reduced plans' prescription-drug spending, contrary to Respondent's claim. BIO 4. Instead, the savings are largely captured by PBMs. Under the predominant type of agreement between PBMs and plans, plans agree to pay PBMs a fixed discount off of a drug's list price, while PBMs' actual reimbursements to pharmacies remain hidden. The predictable result

of that pricing mechanism is massive markups that fail to pass along PBMs' punishing savings to plans, who are the ultimate payers.

Little data on the spreads PBMs charge private plans, or the administrative fees they charge private plans under pass-through contracts, is publicly available. But a series of recent studies of drug spending by Medicaid managed care organizations (MCOs)—which if anything have more bargaining power than individual employer plans—illustrates the severity of the problem. For example, a study by the Ohio Department of Medicaid found that in 2017-18, PBMs reimbursed pharmacies $454.3 million for Ohio MCO beneficiaries' generic drugs and charged Ohio MCOs $662.7 million—a 45.9% markup. Ohio Auditor of State, *Ohio's Medicaid Managed Care Pharmacy Services* 12 (2018).[5]

Similarly, a recent study of MCO reimbursements in the fourth quarter of 2017 in New York found that while pharmacies made an average of just $0.53 per generic prescription and lost money on nearly half, PBMs charged New York MCOs an average markup of $5.62 per prescription. That is almost 40% of the program's total generic spending. 3Axis Advisors, *Analysis of PBM Spread Pricing in New York Medicaid Managed Care* 12, 33 (2019).[6] The study concluded that "PBMs are cutting pharmacy reimbursements . . . much faster than they pass through such savings to MCOs and the state." *Id.* at 19.

And other studies, involving different States, have reached similar conclusions. Kaiser Family Founda-

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[5] https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.

[6] https://files.constantcontact.com/599cc597301/971bd1aa-2a80-464b-a85c-e3afaa8a577a.pdf.

tion, *Pricing and Payment for Medicaid Prescription Drugs* 9 & nn. 52-54 (2020).[7]

4. State Efforts to Regulate PBMs' MAC Reimbursements

PBMs' below-cost reimbursements have left marks on the pharmacy industry, particularly on independent rural pharmacies. In the last 15 years, 16.1% of independently owned rural pharmacies have closed, and 630 rural communities went from having one or more pharmacies to having none. RUPRI Center for Rural Health Policy Analysis, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018* 1 (July 2018).[8] And 12.6% of the independent pharmacies in Arkansas closed between 2006 and 2014 alone. JA310.

In response to the damaging effects of PBMs' MAC reimbursement practices, 40 States and counting have enacted legislation regulating those practices. *See* Pet. 11 n.6 (citing relevant state laws at time Arkansas sought review). All but four of these statutes require PBMs to—as they already did by contract—give pharmacies an opportunity to appeal below-cost MAC reimbursements.[9] The vast majority of state appeal laws add a rule of decision. That rule typically permits a PBM to deny an appeal so long as it can identify a manufacturer's version of the generic in

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[7] http://files.kff.org/attachment/Issue-Brief-Pricing-and-Payment-for-Medicaid-Prescription-Drugs.

[8] https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf.

[9] The exceptions are Florida, Indiana, Mississippi, and North Carolina.

question[10] that at least one national or regional wholesaler sells at a price below the PBM's MAC. *See, e.g.*, Cal. Bus. & Prof. Code 4440(f)(3); Ohio Rev. Code Ann. 3959.111(A)(3)(d); Tex. Ins. Code Ann. 1369.357(d)(2).

In 2013, Arkansas enacted a MAC-reimbursement-appeal law that adopted that relatively relaxed standard. 2013 Ark. Laws Act 1194. It proved inadequate to address the sheer scale of the under-reimbursement problem. Indeed, PBMs regularly denied appeals without identifying alternate versions of the generics at issue or by pointing pharmacies to alternate versions that were not available at wholesale below the MAC. JA260-62, 266-67. So in 2015, Arkansas amended its law to more stringently tether MAC reimbursements to pharmacies' actual acquisition costs. 2015 Ark. Laws Act 900.

Act 900 did this in three ways. First, it required PBMs to promptly update their MACs when a drug's prevailing wholesale cost increases by 10% or more. Ark. Code Ann. 17-92-507(c)(2). Second, Act 900 required PBMs to grant appeals and increase reimbursements if a pharmacy was reimbursed below its acquisition cost, and the pharmacy shows it could not have purchased the drug for less from its primary wholesaler.[11] *Id.* 17-92-507(c)(4)(C)(iii). Third, Act

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[10] These statutes typically require PBMs, if they deny an appeal, to identify a relevant "national drug code," which is a manufacturer- and dosage-specific product code.

[11] As before, to deny an appeal a PBM is initially required to identify a manufacturer's version of the generic that at least one wholesaler sells below the MAC. Ark. Code Ann. 17-92-507(c)(4)(C)(ii). But if a pharmacy's primary wholesaler does not sell the PBM's suggested version for less than the pharmacy paid, the pharmacy prevails and is entitled to an adjustment. *Id.* 17-92-507(c)(4)(C)(iii).

900 allowed pharmacies to decline to dispense a drug if a PBM's MAC is less than what the pharmacy paid to purchase it. *Id.* 17-92-507(e).

B. Proceedings Below

Weeks after Act 900 went into effect, Pharmaceutical Care Management Association ("PCMA"), a trade association of the nation's 11 largest PBMs, filed suit in the Eastern District of Arkansas. It argued that Act 900 was preempted by ERISA and Medicare Part D, violated the dormant Commerce Clause, ran afoul of the Contract Clause, and was void for vagueness. Pet.App.16a. PCMA subsequently moved for summary judgment. In that motion, PCMA clarified that it only sought to enjoin the three 2015 amendments described above and the 2013 law's original requirement that PBMs provide pharmacies a procedure to appeal below cost reimbursements. Dist. Ct. Dkt. No. 75-1 at 2-3, 35.

While that motion was pending, the Eighth Circuit decided *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017). That case involved an ERISA challenge to Iowa's MAC-reimbursement law. Like Arkansas, Iowa required PBMs to provide pharmacies with a MAC appeal. But unlike Arkansas, it did not provide a rule of decision for those appeals. *Id.* at 731.

Gerhart first held Iowa's law expressly and impermissibly referred to ERISA plans by excepting PBMs that represented self-funded ERISA plans. *Id.* at 729. Second, it held the law "also ma[de] implicit reference to ERISA." *Id.* Iowa's law defined PBMs as providers of services to a variety of "covered entities" that "*include* . . . entities [that] are necessarily subject to ERISA regulation" and entities that are not, such as individual insurers. *Id.* (emphasis added); *see* Iowa Code 510B.1(2). Because *some* "covered entities" were

ERISA plans, the Eighth Circuit concluded that Iowa's law made impermissible reference to those plans.

Third, the Eighth Circuit held that Iowa's law had an "impermissible 'connection with' ERISA plans." *Id.* at 730. In that court's view, the requirement of a reimbursement appeal procedure "restrict[ed] an administrator's control in the calculation of drug benefits" and "remove[d] their ability to conclusively determine final drug benefit payments and monitor [plan] funds." *Id.* at 731.

Finding it was bound by *Gerhart*, the district court granted PCMA's motion for summary judgment. In so doing, the district court noted that it had initially reached the conclusion that ERISA did not preempt Arkansas's law. Pet.App.17a-18a. It nevertheless held that because Act 900 "regulate[d] PBMs in ways fundamentally similar to the Iowa statute in *Gerhart*," it was preempted by ERISA, solely as applied to PBMs' service of ERISA plans. Pet.App.19a. It therefore granted "PCMA's motion for summary judgment . . . on PCMA's ERISA claim." Pet.App.36a. It rejected PCMA's Medicare Part D preemption and constitutional claims. *Id.*

PCMA appealed the district court's ruling on Medicare Part D preemption, abandoning its constitutional claims, and Arkansas cross-appealed the district court's ruling on ERISA preemption. Pet.App.5a. The Eighth Circuit affirmed the district court's ERISA ruling and reversed on Medicare Part D. Pet.App.11a.

On appeal, Arkansas argued that given *Gerhart*'s express-reference holding, its implicit-reference and connection-with holdings were unnecessary dicta that conflicted with this Court's precedent. Pet.App.6a. The Eighth Circuit disagreed and held that it was

"completely bound by [*Gerhart*'s] reasoning on the exact question before us." Pet.App.7a.

That court stressed that under *Gerhart*, Arkansas's law implicitly referred to ERISA plans because it regulated PBMs whose customers "*include* . . . entities" that are ERISA plans. Pet.App.6a (emphasis added) (quoting *Gerhart*, 852 F.3d at 729). It likewise found *Gerhart*'s connection-with holding binding on whether Arkansas could regulate PBM reimbursements. Pet.App.7a. The court separately held that Act 900 was preempted by Medicare Part D, as applied to PBMs' service of Medicare Part D plans. Pet.App. 7a-11a.

SUMMARY OF THE ARGUMENT

In holding ERISA preempted Arkansas's efforts to ensure PBMs reimburse pharmacies at reasonable rates, the Eighth Circuit expanded ERISA's preemptive reach. This case is an opportunity to return to the limits this Court has established and reiterate that ERISA does not preempt ordinary state rate regulation and necessary incidents to that regulation.

ERISA undoubtedly preempts many things. It preempts state laws regulating who constitutes a beneficiary, what benefits a plan provides, how a plan goes about answering those questions, and, of course, the matters that ERISA itself regulates. In short, ERISA preempts regulation of the things that make an ERISA plan an ERISA plan so that employers need only administer one plan, not 50.

But when plans enter the market to purchase the goods and services they provide beneficiaries—or anything else they require to function—they are not immune from ordinary market regulation. To the contrary, this Court has long held that ERISA does not

shield plans or their administrators from state laws regulating the rates charged for goods and services. Indeed, more than two decades ago, this Court explained that "ERISA was not meant to pre-empt basic rate regulation" because rate uniformity would be impossible even without state regulation and rate variations do not hamper uniform plan administration. *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 667 n.6 (1995).

Under that rule, Act 900 is plainly not preempted. It regulates drug reimbursement rates and provides mechanisms for enforcing that rate regulation. Those mechanisms include requiring PBMs to provide pharmacies with internal appeals to challenge noncompliant rates (as they already did by contract) and the option to decline to sell drugs to PBMs that refuse to abide by Arkansas's rate regulation. Both are necessary incidents of Arkansas's system of rate regulation, and as such, neither is preempted. Indeed, absent those provisions, Arkansas's rate regulation would be more rate aspiration than rate regulation.

Desperate to avoid that commonsense conclusion (and eager to swipe away similar regulations in 35 states), PCMA argues that Act 900's enforcement mechanisms impermissibly regulate benefits and claims processing. PCMA's argument fails for two independent reasons.

First, as noted, the challenged enforcement mechanisms are necessary incidents to Arkansas's rate regulation, and, as such, even if those mechanisms bear on benefits or claims processing, they are not preempted. The appeals process is necessary and incidental because Arkansas's rate regulation looks to individual pharmacies' wholesale costs. Absent an

appeal, PBMs have no way of knowing what those costs are and whether a reimbursement is below those costs. In other words, unlike other kinds of rate regulation, Arkansas's indisputably valid rate regulation cannot be enforced ex ante at the point of sale but only ex post through an appeal.

Likewise, Act 900's decline-to-dispense provision is necessary and incidental to Arkansas's rate regulation since, by definition, pharmacies cannot be required to sell drugs to PBMs that do not comply with those regulations. Indeed, all rate regulation necessarily voids contrary rates and contractual promises to sell goods or services at those contrary rates.

Thus, Act 900 is not preempted because any impact on plan administration is necessary and incidental to rate regulation.

Second, Act 900 does not actually regulate claims processing or benefits. It does not regulate claims processing because resolving a pharmacy's reimbursement dispute is not a step in processing a beneficiary's claim. Prescription-drug claims processing is the procedure by which a plan—or its administrator—determines whether a drug claim is covered in whole or in part. It is not the process by which a plan determines the amount it will ultimately pay a pharmacy for that drug.

Rather, that determination is independent of the claims-processing function, whether reimbursement rates are set beforehand by contract, resolved in a reimbursement appeal, or decided in a state-court contract action. And recognizing as much, lower courts have consistently held that ERISA does not preempt providers' state-court contract suits over reimbursement rates.

Act 900 also does not regulate prescription-drug benefits. PCMA suggests that Act 900's decline-to-dispense provision regulates benefits by giving network pharmacies the option not to sell drugs. That is little more than an argument that rate regulation itself is preempted since rate regulation will always mean that sellers do not have to sell at unlawful rates.

Moreover, PCMA's argument vastly overstates ERISA's preemptive reach. Its approach would preempt countless state-law contract rules that excuse providers from their promises to provide goods or services. It would similarly exempt ERISA plans from any number of generally applicable health-and-safety regulations. And that cannot be the case.

Finally, the Eighth Circuit held Act 900 "refers to" ERISA plans, a theory of ERISA preemption that prohibits States from singling out ERISA plans for differential treatment, because it regulates a class of service providers that "include" ERISA plans among their customers. That holding cannot stand. The judgment below must be reversed.

ARGUMENT

I. Act 900 does not have a prohibited "connection with" ERISA plans.

In 1974, Congress enacted ERISA to protect the participants and beneficiaries of employee welfare and pension benefit plans. *See* 29 U.S.C. 1001, 1002(3). ERISA "does not guarantee substantive benefits." *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016). Instead, ERISA mandates certain plan-administration procedures designed to secure the benefits an employer promises to provide. *Id.*

"One of the principal goals of ERISA [wa]s to enable employers 'to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits.'" *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001) (quoting *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987)). In pursuit of that aim, ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. 1144(a).

This Court has eschewed "uncritical literalism" in interpreting ERISA's preemption clause, recognizing that, if it were read literally, "pre-emption would never run its course, for 'really, universally, relations stop nowhere.'"[12] *Travelers*, 514 U.S. at 655 (alteration omitted) (quoting Henry James, Roderick Hudson xli (World's Classics 1980)); *cf. Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 833 (1988) (holding that many "lawsuits against ERISA plans for run-of-

[12] Several circuits once held that Section 1144's definition of "State" as a State or State agency or instrumentality that "purports to regulate, directly or indirectly, the terms and conditions of employee benefit plans," 29 U.S.C. 1144(c)(2), limited ERISA's preemptive scope to "State laws" that regulated plans' terms and conditions, *see Rebaldo v. Cuomo*, 749 F.2d 133, 137-38 (2d Cir. 1984); *Lane v. Goren*, 743 F.2d 1337, 1339 (9th Cir. 1984). *Ingersoll-Rand Co. v. McClendon* rejected that argument, reasoning that Section 1144's seemingly limiting definition of "State" merely "expand[ed]" preemption to include actions of "state agencies and instrumentalities." 498 U.S. 133, 141 (1990). Yet the Court only did so after finding the state law at issue "ma[de] specific reference to, and indeed is premised on, the existence of a pension plan" and thus undeniably related to such plans. *Id.* at 140. Consequently, in deciding whether "a generally applicable statute that makes no reference to . . . an ERISA plan" bears an impermissible relation to ERISA plans, *id.* at 139, Section 1144's definition of "State" arguably provides both a workable and controlling test.

the-mill state-law claims . . . although obviously affecting and involving ERISA plans and their trustees, are not preempted by ERISA").

Instead, this Court has held that ERISA preempts two kinds of laws: those that "make 'reference to' ERISA plans," *Travelers*, 514 U.S. at 656, and those that have "an impermissible connection with ERISA plans," *Egelhoff*, 532 U.S. at 147.

This Court's test for reference-to preemption has posed little difficulty. As discussed in greater detail below, *see infra* 48-51, a law is only reference-to preempted if it acts exclusively on ERISA plans or subjects them to differential treatment. Which laws are connection-with preempted has proved somewhat less clear.

A state law "has an impermissible 'connection with' ERISA plans" if it 'governs a central matter of plan administration' or 'interferes with nationally uniform plan administration.'" *Gobeille*, 136 S. Ct. at 943 (alteration omitted) (quoting *Egelhoff*, 532 U.S. at 148). This connection-with standard has often raised difficult line-drawing questions. *See, e.g.*, *id.* at 958 (Ginsburg, J., dissenting) (disputing Court's holding that plan reporting is a central matter of plan administration); *Egelhoff*, 532 U.S. at 157 (Breyer, J., dissenting) (disputing Court's holding that default rule on beneficiary designation materially interfered with uniform plan administration). And these difficulties have led multiple members of this Court to urge abandoning its connection-with jurisprudence in favor of an approach that would only preempt those laws that conflict with ERISA or regulate in the specific fields ERISA occupies. *See id.* at 153 (Scalia, J., joined by Ginsburg, J., concurring); *id.* at 153-54 (Breyer, J., dissenting).

This case presents no such difficult questions. Instead, this case is about whether rate regulation—specifically, a state regulation of reimbursement rates for generic drugs—is preempted. And this Court has long held that "ERISA was not meant to pre-empt basic rate regulation." *Travelers*, 514 U.S. at 667 n.6; *see also Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 328-30 (1997) (holding ERISA did not preempt state wage law applicable to plans because it was "indistinguishable" from *Travelers* law that "regulated hospital rates"). Nor does this case implicate plan-administration uniformity but only "cost uniformity," which "was almost certainly not an object of pre-emption." *Travelers*, 514 U.S. at 662. Thus, Arkansas's law is not preempted.

A. ERISA does not preempt Act 900's regulation of rates.

1. ERISA does not preempt rate regulation.

This Court's ERISA precedents have long drawn a sharp line between preempted state laws that regulate the relationships between plans and their beneficiaries, and state laws that regulate plans' conduct—or that of their outside administrators—towards third parties. *See Mackey*, 486 U.S. at 832-33 (explaining that while suits "to enforce a participant's rights under a plan" may only be brought under ERISA itself, ERISA does not preempt "run-of-the-mill state-law claims" against ERISA plans for "failure to pay [non-beneficiary] creditors, or even torts committed by an ERISA plan"). *Travelers* crystalizes that distinction.

In *Travelers*, this Court reviewed a rate regulation requiring hospitals to bill insurers at differential rates depending on whether they were favored by New York's legislature. Even before ERISA's enactment,

New York regulated hospital billing rates generally, requiring hospitals to bill under 794-odd diagnostic related group (DRG) rates. *See* 514 U.S. at 649-50, 664-65. Those rates were based on the average cost of treating a given medical condition rather than the actual cost of individual patients' treatment, and then adjusted to reflect individual hospitals' operating costs. *Id*.

The statute challenged in *Travelers* added a differential rate scheme on top of those generally applicable rates. It required hospitals to bill Blue Cross/Blue Shield insurers at the DRG rate and to level a substantial surcharge on top of those rates on all non-Blue insurers. *Id.* at 650. New York's goal in imposing different rates was to induce ERISA plans and other health insurance consumers to switch to the Blues, which New York favored because of their open enrollment practice. *Id.* at 658-59.

The Blues' competitors argued, and the Second Circuit agreed, that ERISA preempted the surcharge because the non-Blues "would pass along" the surcharges to plans, and plans that continued to buy their insurance would be "force[d] . . . to increase either plan costs or reduce plan benefits." *Travelers Ins. Co. v. Cuomo*, 14 F.3d 708, 720 (2d Cir. 1993). Indeed, on the non-Blues' view, the surcharge's effect on those plans' costs alone, apart from its incentive to switch insurers, sufficed for preemption.

This Court reversed and unanimously concluded that even rate regulation that indirectly targets things States cannot directly regulate—like a plan's choice of administrator—is not preempted. Moreover, while the Court granted that a rate regulation so onerous that it effectively mandates a substantive choice of insurers or benefits would be preempted, *see Travelers*, 514

U.S. at 664, 668, it categorically rejected "effects on plan costs" alone as a basis for preemption, *id.* at 661.

As this Court explained, "cost uniformity"—whether between States or between insurers—"was almost certainly not an object of pre-emption," *id.* at 662, because "even prior to state regulation," rates had "varied dramatically across regions" and between providers, *id.* at 660 (quotation marks omitted). Not only, the Court explained, would cost uniformity have been unachievable, it was also not something that Congress plausibly could have aimed to achieve. Indeed, it reasoned, differences in cost between States or insurers neither "bind plan administrators to any particular choice" of benefits, nor "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." *Id.* at 659-60. Rather, they are merely "an influence that can affect a plan's shopping decisions." *Id.* at 660. And that made it unlikely "that federal regulation of benefit plans was intended to eliminate state regulation of health care costs." *Id.* at 661.

In a lengthy coda to its opinion, this Court concluded by observing that the non-Blues' position would likewise have "bar[red] any state regulation of hospital costs," including New York's underlying "basic DRG system." *Id.* at 664. That, this Court found, proved the error of their rule. Preemption of provider rate regulation, it explained, would be both "unsettling" and "startling" given that many States regulated hospital and medical billing rates when ERISA was enacted. *Id.* at 665. Indeed, Congress enacted a statute just months after ERISA that "provi[ded] for comprehensive aid to state health care rate regulation." *Id.* at 667. Had ERISA preempted States' rate regulation, it "would have rendered [that law] utterly

nugatory." *Id.* All this, the Court stressed, militated in favor of its "conclusion that ERISA was not meant to pre-empt basic rate regulation." *Id.* at 667 n.6.

While not seriously claiming that state rate regulation is preempted, PCMA characterizes *Travelers*' endorsement of basic rate regulation as a "footnote holding." BIO 31. But that endorsement is a capstone on four pages carefully explaining why ERISA was not intended to preempt rate regulation, and correspondingly, why it "just ma[de] good sense to reject" the non-Blues' contrary interpretation. *Travelers*, 514 U.S. at 667.

Moreover, far from being an afterthought, that conclusion was critical since the challenged surcharges—which were calculated as an additional fraction of New York's underlying statutory rates—could not have been valid if the underlying statutory rates themselves were preempted. Thus, both that holding and the Court's categorical rejection of national cost uniformity as a basis for preempting the surcharges foreclose any argument that ERISA precludes States from regulating rates.

After *Travelers*, this Court twice reaffirmed that ERISA does not preempt laws that merely bear on plan costs. In *Dillingham*, this Court reviewed a law that regulated the wages ERISA-plan apprenticeship programs paid their apprentices. Though the law gave apprenticeship programs a "wage break" from the otherwise applicable minimum if they followed a set of standards that regulated the substance of apprenticeship plan administration, this Court held that break was a permissible "economic incentive," like the surcharges in *Travelers*. *Dillingham*, 519 U.S. at 332-33.

Subsequently, this Court upheld a tax levied directly on ERISA-plan-owned hospitals, reasoning that that "[a]ny state tax . . . that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 (1997).

2. ERISA does not preempt Act 900's regulation of drug reimbursement rates.

Because ERISA does not preempt rate regulation, ERISA does not preempt Act 900. Indeed, this case and *Travelers* are on all fours, except in respects that make this case an easier one for non-preemption.

Just like New York's surcharge law and its underlying DRG law, Arkansas's law regulates the rates at which third-party plan administrators reimburse providers of healthcare benefits. Like New York's laws, Arkansas's law may "affect a plan's shopping decisions." *Travelers*, 514 U.S. at 660. But also like those laws, "no showing has been made here" that the relatively modest rate increases it calls for "are so prohibitive as to force" plans to sever ties with the third-party administrators whose reimbursements it increases or to alter the benefits plans offer. *Id.* at 664. Indeed, 36 States currently have laws like that challenged here and all but *two* have gone unchallenged and remain in effect. Yet there is no evidence that any plan has severed ties with their PBM, stopped covering generics, or even increased beneficiaries' costs because of those laws.

On the other hand, Arkansas's law is distinguishable from the laws at issue in *Travelers* in ways that make it even farther afield from ERISA preemption.

New York's differential surcharges were designed to influence plans' choice of administrators—a central matter of plan administration that New York could not have regulated directly—and this Court recognized that those surcharges at least had "an indirect economic effect on [such] choices." *Id.* at 659. By contrast, Arkansas's law applies equally to all PBMs—which it broadly defines to include any third-party prescription-drug program administrator—and is not designed to influence plans' choice of administrators. Instead, underscoring that Arkansas's law is pure rate regulation, it regulates rates solely for the sake of regulating provider compensation.

Moreover, unlike *Travelers*, where this Court could safely "presume" that the surcharges leveled on non-Blues would be "passed on at least in part" to plans that purchased non-Blue insurance, *id.,* a similar presumption is not warranted here. To the contrary, PBMs currently pocket most of the savings from below-cost reimbursements, bolstering their ample profits. It is unclear whether absent those savings, PBMs would charge plans still more or plans would agree to pay more. As such, any impact on plans is dubious.

B. ERISA does not preempt Act 900's enforcement mechanisms because they are necessary incidents to its regulation of rates.

Ultimately, PCMA appears to concede that Act 900 is not preempted insofar as it constitutes "basic rate regulation," BIO 31, or "merely govern[s] reimbursement rates," Supp. Br. for Resp. 6. Yet it claims that Act 900's various mechanisms for enforcing that rate regulation impermissibly regulate plan administration. Specifically, it claims Act 900's provisions requiring PBMs to regularly update their reimbursement-rate

lists to comply with the law's rate regulation, to provide pharmacies an appeal procedure to challenge reimbursement rates that do not comply, and allowing pharmacies to decline to sell drugs for non-compliant rates, all regulate the "structure and management of [ERISA] prescription drug benefits." *Id.*

None of these enforcement mechanisms regulate the structure or management of plan beneficiaries' *benefits*. They merely regulate how third-party administrators interact with *fourth parties* that provide the goods that a plan has already chosen to cover. Yet even if PCMA were right, Act 900's enforcement mechanisms are still not preempted because they are necessary and incidental to Arkansas's otherwise permissible rate regulation. Indeed, absent appeals, pricing updates, and a provision allowing pharmacies to refuse to dispense in the event of non-compliance, Arkansas's rate regulation would be merely aspirational.

1. ERISA does not preempt necessary incidents to otherwise permissible laws.

In *Gobeille*, this Court held that ERISA preempted a state law requiring ERISA health plans to report claims data to the State. In so holding, this Court concluded that reporting and recordkeeping were central matters of plan administration specifically addressed by ERISA itself. 136 S. Ct. at 945. As such, the Court concluded that a law like that "before the Court" that pursued reporting for its own sake was preempted. *Id.* at 946. But in reaching that conclusion, the Court added an important caveat, noting that its analysis would likely "be different when applied to a state law, such as a tax on hospitals, the enforcement of which necessitates

incidental reporting by ERISA plans." *Id* (citation omitted).

That caveat is unsurprising given that this Court has twice upheld state laws containing reporting and recordkeeping requirements that were borne by plans in the face of ERISA preemption challenges. For instance, as the Court acknowledged, the state tax on ERISA-plan-owned hospitals upheld in *De Buono* contained a reporting requirement. *See Gobeille*, 136 S. Ct. at 946. And—as the United States pointed out in its amicus brief in *Gobeille*—the wage law upheld as applied to ERISA-plan apprenticeships in *Dillingham* similarly contained a recordkeeping requirement. Br. for United States as Amicus Curiae at 26, *Gobeille v. Liberty Mut. Ins. Co.* (No. 14-181), 2015 WL 5244350 (Sept. 4, 2015).

Indeed, the *Gobeille* dissent focused on those cases, arguing that reporting and recordkeeping were only "ancillary" matters of plan administration because "[r]eporting and recordkeeping incident to state laws of general applicability have been upheld as they bear on ERISA plans." *Gobeille*, 136 S. Ct. at 955-56 (Ginsburg, J., dissenting) (citing *De Buono* and *Dillingham*). And while the majority disagreed that freestanding reporting requirements were ancillary, as noted above, it did not dispute that this Court has long upheld laws that contained incidental reporting requirements. *See id*. at 946.

Notably, immediately after *Gobeille*, this Court vacated and remanded a Sixth Circuit decision presenting the question whether reporting requirements incidental to an otherwise permissible regulation were preempted. *Self-Ins. Inst. of Am., Inc. v. Snyder*, 136 S. Ct. 1355 (2016). The law in that case imposed a tax on paid health claims by, inter alia, ERISA plans, and

required plans to report and keep records on their paid claims—the very same information that *Gobeille* held a State could not require plans to report and record for reporting's sake. *Self-Ins. Inst. of Am., Inc. v. Snyder*, 827 F.3d 549, 553 (6th Cir. 2016).

On remand, the Sixth Circuit understood *Gobeille*'s distinction of *De Buono*'s incidental reporting requirement to "confirm[]" what it had previously found implicit in *De Buono*: that unlike laws that regulated reporting "directly," "laws necessitating incidental reporting did not implicate ERISA's express-preemption provision." *Id.* at 557. It therefore held the State could, incident to a claims tax, mandate plan reporting of claims data. *Id.* at 558. The plaintiff in that case then sought certiorari again, claiming the Sixth Circuit's decision conflicted with *Gobeille*, and this Court denied review. *Self-Ins. Inst. of Am., Inc. v. Snyder*, 137 S. Ct. 660 (2017).

2. Act 900's enforcement mechanisms are necessary incidents to its rate regulation.

Because States may incidentally regulate even central matters of plan administration where that regulation is necessary to enforce otherwise permissible laws, all of the challenged provisions easily survive. Indeed, whatever the merits of PCMA's contention that those provisions regulate plan administration, there is no real dispute that they are incidental and necessary to the enforcement of Arkansas's rate regulation.

Take Act 900's appeal procedure. That procedure is simply a necessary outgrowth of enforcing Act 900's rate regulation, and the least burdensome means possible. Act 900 tethers reimbursement rates to pharmacies' individual wholesale costs. Any regulation of PBMs' reimbursement rates pegged to such costs

requires a reimbursement appeal procedure, because PBMs do not know what those costs are ex ante. *See* JA78-79, 126. Nor do they know the rates at which a pharmacy's primary wholesaler sells generic drugs, and it is that rate that is ultimately necessary to resolve an appeal. *See id*.

In theory, Arkansas could have required the real-time transmission of that information, but that would have required an expensive transformation of how pharmacies and PBMs process retail transactions. Or, Arkansas could have referred reimbursement disputes to an outside regulator. Instead, Arkansas chose a much less burdensome and intrusive means of enforcement: the preexisting internal appeal procedure that PBMs already provided pharmacies by contract. All Arkansas added was a concededly permissible, rate-regulatory rule of decision.

Act 900's MAC-list update requirement, too, is merely a necessary incident to Act 900's rate regulation. Indeed, it is difficult to see how a requirement that PBMs update their reimbursement rate schedules when wholesale costs rise 10% is anything *but* the sort of basic rate regulation PCMA concedes Arkansas may enact. But indulging PCMA's claim otherwise, requiring PBMs to update their rates in light of increases in wholesale costs is simply a necessary incident of requiring PBMs to reimburse at wholesale costs. Absent such updates, PBMs would be in continual non-compliance with that rate regulation. And rather than leave all compliance efforts to post-reimbursement appeals, Arkansas's law reasonably requires PBMs to pursue approximate compliance at the time of reimbursement.

Likewise, Act 900's provision permitting pharmacies to decline to dispense drugs that a PBM proposes to

reimburse below wholesale cost is a necessary incident of rate regulation. PCMA complains this provision authorizes pharmacies to breach provisions in their network agreements requiring them to dispense drugs at PBMs' MACs. BIO 32. But that complaint ignores the fact that rate regulation necessarily voids contrary rates and contractual promises to sell goods or services at those contrary rates. *See, e.g.*, *Brooklyn Sav. Bank v. O'Neil*, 324 U.S. 697, 707 (1945) (holding employees cannot "waive[] . . . statutory wages by agreement"); *Total Med. Mgmt., Inc. v. United States*, 104 F.3d 1314, 1320-21 (Fed. Cir. 1997) (voiding promise to pay at rates above "health care provider reimbursement base rates" set by regulation).

Indeed, courts have held the very rate regulation upheld in *Travelers* has that effect. *See Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of N.J., Inc.*, 448 F.3d 573, 581 (2d Cir. 2006) (holding New York's law "abrogate[d]" rates below the statutory rate in hospital-insurer agreements); *Garofalo v. Empire Blue Cross & Blue Shield*, 67 F. Supp. 2d 343, 347-48 (S.D.N.Y. 1999) (Rakoff, J.) (holding New York's law gave insurers "no discretion . . . to contract around" its rates and superseded any contract terms contrary to them). If after *Travelers* a non-Blue insurer simply refused to pay hospitals the non-Blues' surcharge, or DRG rates at all, a hospital would necessarily have the right to refuse to accept their insurance, even if New York's law did not say so expressly. So too here; the very act of setting a reimbursement rate necessarily gives pharmacies the right to decline to dispense drugs to PBMs that refuse to follow it.

The decline-to-dispense provision is also a necessary enforcement mechanism. Reimbursement appeals alone are a poor means of ensuring compliance

because they take time and the amounts at issue are often small. Hence, in practice, no more than a tiny fraction of under-reimbursements are challenged. *See* Office of the Insurance Commissioner, Washington State, *Study of the Pharmacy Chain of Supply* 74 (finding that only 0.25% of MAC reimbursements were appealed under Washington's MAC appeal law in 2015);[13] JA314 (approximately 10% of MAC reimbursements are below-cost). Thus, as a practical matter, giving pharmacies some means to fend off sub-statutory reimbursements at the point of sale is reasonably necessary to assure compliance with Arkansas's rate regulation.

At bottom, PCMA's position amounts to a claim that Arkansas can set PBMs' reimbursement rates but cannot provide a mechanism to enforce the rates it has set. But *Travelers* held both that ERISA was not intended to preempt rate regulation and that it was not "intended to squelch" it. 514 U.S. at 665. Defanging Act 900 of its three enforcement provisions would do just that. The challenged provisions are not preempted.

C. Act 900's enforcement mechanisms do not regulate central matters of plan administration.

Act 900 does not regulate central matters of plan administration. It does not regulate the beneficiary-plan relationship. Indeed, it does not change how plans (or their administrators) process benefits claims and determine coverage and cost-sharing. Rather, it merely provides a methodology for providers to challenge how they are paid by PBMs *after* a claim

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[13] https://www.insurance.wa.gov/sites/default/files/2017-06/pharmacy-supply-chain-study_0.pdf.

has been processed. And as lower courts have long recognized, state laws that merely provide mechanisms for providers to challenge reimbursements for services do not regulate claims processing or otherwise run afoul of ERISA. Thus, Act 900's enforcement mechanisms are not preempted.

1. ERISA does not preempt state-law procedures for resolving reimbursement disputes between plans and service providers.

ERISA preemption has always jealously protected federal primacy over the relationships between plans and their beneficiaries, plans and their fiduciaries (including administrators), and plans and any of the parties ERISA expressly discusses. But it has never had much to say, substantively or procedurally, about relations between plans and the countless outsiders that provide plans with goods and services.

In *Mackey*, for example, explaining why "state-law methods for collecting money judgments" against plans must "remain undisturbed by ERISA," 486 U.S. at 834, the Court said that must be so, in part, because ERISA did not preempt "relatively commonplace" actions "against ERISA plans for run-of-the-mill state-law claims such as unpaid rent, failure to pay creditors, or even torts committed by an ERISA plan," *id.* at 833. And though the Court's examples of creditor suits did not involve creditors who provided goods and services to plan beneficiaries, its example of a permissible tort suit was a claim for defamation by a doctor against a plan that falsely advised beneficiaries he overtreated and overcharged his patients and asked them to shun his practice. *Id.* at 833 n.8 (citing *Abofreka v. Alston Tobacco Co.*, 341 S.E.2d 622 (S.C. 1986)).

This Court has never returned to the matter of third-party suits against plans—most likely because their non-preemption is so uncontroversial. But in light of *Mackey*, and decisions like *Travelers* permitting States to regulate the financial substance of plans' dealings with their providers, lower courts have uniformly held that so long as providers do not challenge plans' determinations of what goods and services they cover, ERISA does not preempt providers' state-law suits for reimbursement.

In theory, these courts could have drawn a distinction between providers of things that plans consume and providers of things plans purchase for their beneficiaries, preempting suits enforcing plans' agreements with the latter on the theory that they interfere with claims processing. But as this Court said in the related context of the McCarran-Ferguson Act's so-called "reverse preemption" of federal insurance regulation, "[t]here is no principled basis upon which a line could rationally be drawn that would extend the McCarran-Ferguson Act exemption only to an insurer's agreement with providers of goods and services to be furnished to its policyholders." *Grp. Life & Health Ins. Co. v. Royal Drug Co.*, 440 U.S. 205, 232 n.40 (1979).

Given that, lower courts have consistently held that ERISA preempts neither state laws regulating how much plans' core providers are paid nor state-law mechanisms for providers to challenge their reimbursements.

Five circuits, for instance, have held that ERISA does not preempt state-law breach-of-contract causes of action asserting that the rates at which a plan (or administrator) reimbursed the provider for covered services breach the plan-provider agreement. *See Montefiore Med. Ctr. v. Teamsters Local 272*, 642 F.3d

321, 331 (2d Cir. 2011) (Cabranes, J.); *Conn. State Dental Ass'n v. Anthem Health Plans, Inc.*, 591 F.3d 1337, 1350 (11th Cir. 2009); *Lone Star OB/GYN Assocs. v. Aetna Health Inc.*, 579 F.3d 525, 530-31 (5th Cir. 2009) (Garza, J.); *Pascack Valley Hosp., Inc. v. Local 464A UFCW Welfare Reimbursement Plan*, 388 F.3d 393, 402-03 (3d Cir. 2004); *Blue Cross of Cal. v. Anesthesia Care Assocs. Med. Grp., Inc.*, 187 F.3d 1045, 1052-54 (9th Cir. 1999); *see also K.B. v. Methodist Healthcare Memphis Hosps.*, 929 F.3d 795, 801-02 (6th Cir. 2019) (Thapar, J.) (holding that a beneficiary's suit alleging billed rates breach plan-provider agreements is not preempted).

And seven circuits—rejecting strenuous arguments that such state-law actions regulate claims processing—have held that ERISA does not preempt state-law negligent-misrepresentation or promissory-estoppel claims alleging that a plan misrepresented the rate it would reimburse, or provided inaccurate information about the extent of a patient's coverage. *See McCulloch Orthopaedic Surgical Servs., PLLC v. Aetna Inc.*, 857 F.3d 141, 149-52 (2d Cir. 2017); *Access Mediquip, L.L.C. v. UnitedHealthcare Ins. Co.*, 698 F.3d 229 (5th Cir. 2012) (en banc), *cert. denied*, 568 U.S. 1194 (2013); *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Tr. Fund*, 538 F.3d 594, 597-600 (7th Cir. 2008); *In Home Health, Inc. v. Prudential Ins. Co. of Am.*, 101 F.3d 600, 604-07 (8th Cir. 1996); *The Meadows v. Emp'rs Health Ins.*, 47 F.3d 1006, 1010-11 (9th Cir. 1995); *Lordmann Enters., Inc. v. Equicor, Inc.*, 32 F.3d 1529, 1532-34 (11th Cir. 1994); *Hospice of Metro Denver, Inc. v. Grp. Health Ins. of Okla., Inc.*, 944 F.2d 752, 754-56 (10th Cir. 1991).

Moreover, in concluding those causes of action were not preempted, the courts of appeals made several

points that apply with equal force to reimbursement appeals. In particular, such causes of action do not seek to enforce or interpret plan terms and do not implicate benefit determinations. Moreover, as the courts of appeals have explained, preempting them would leave providers without any state or federal remedy to challenge under-reimbursements and would discourage providers from serving ERISA beneficiaries and frustrate ERISA's purposes.

First, such claims do not seek to enforce or interpret the terms of ERISA plans under ERISA. Rather, they enforce state-law duties under contract and tort law concerning separate contracts, promises, and representations between plans and providers. *See, e.g.*, *McCulloch Orthopaedic*, 857 F.3d at 149-50; *Lone Star*, 579 F.3d at 530; *Anesthesia Care Assocs.*, 187 F.3d at 1051-52.

Second, so long as a claim only "implicates the *rate* of payment . . . rather than the *right* to payment under the terms of the benefit plan," *Lone Star*, 579 F.3d at 530—or, as in some of the misrepresentation cases, only implicates a misrepresented right to payment that in fact does not exist—the plan's "coverage and benefit determinations are not implicated," *id.* at 532; *see Pascack*, 388 F.3d at 402 (noting that "[c]overage and eligibility" in such cases "are not in dispute"). The contract actions do not decide whether the plan will cover a service, or even to what extent it will cover its cost, but only how much that cost will be. The misrepresentation claims may create rights to reimbursement, but they too do not challenge coverage determinations; the whole point of such claims is that coverage does not exist where the plan says it does.

Third, providers generally do not have an ERISA cause of action.[14] Therefore, if ERISA preempted providers' state-law causes of action for reimbursement, providers "would be left without a remedy to enforce promises of payment." *McCulloch Orthopaedic*, 857 F.3d at 148. As several courts of appeals have observed, this would strain the ERISA preemption "bargain": an exchange of beneficiaries' "state law causes of action" for "federal causes of action under ERISA." *Lordmann Enters.*, 32 F.3d at 1533-34 (citing *Mem'l Hosp. Sys. v. Northbrook Life Ins. Co.*, 904 F.2d 236, 249 (5th Cir. 1990)). "[T]he countless . . . health care providers in this country were not a party to this bargain." *Mem'l Hosp.*, 904 F.2d at 249.

Fourth, preempting suits by providers "would not further the principal purpose of ERISA to protect plan beneficiaries." *McCulloch Orthopaedic*, 857 F.3d at 148. "If providers ha[d] no recourse under either ERISA or state law" for under-reimbursement or non-payment, they "may require up-front payment by beneficiaries," *Mem'l Hosp.*, 904 F.2d at 247, "or raise fees to protect themselves against the risk" of breach or misrepresentation, *Lordmann Enters.*, 32 F.3d at 1533. This would "not serve, but rather directly defeat[], the purpose of Congress in enacting ERISA." *Mem'l Hosp.*, 904 F.2d at 247-48.

Each of these points applies with equal force to Act 900's reimbursement appeals, which, like state-

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[14] Anti-assignment provisions generally prevent a beneficiary's assignment of claims to a provider. *See McCulloch Orthopaedic*, 857 F.3d at 147-48. And even if they did not, such an assignment would not normally give providers rights to challenge mere under-reimbursement because beneficiaries themselves do not have an ERISA right to challenge a provider's under-reimbursement.

law contract suits, are merely a procedural device for enforcing a State's substantive law on rates. Indeed, the only real difference between the two is that Act 900 is less invasive since it allows PBMs—not judges—to continue to resolve reimbursement disputes and utilizes an appeals procedure that PBMs already provided by contract. And PCMA cannot plausibly argue that Arkansas is foreclosed from providing less intrusive procedures.

2. Reimbursement appeals do not regulate claims processing.

The Eighth Circuit erroneously concluded that reimbursement-rate appeals are preempted because they dictate how PBMs process drug claims and calculate benefits. In particular, it reasoned that merely providing a pharmacy the right to appeal a reimbursement rate "restrict[s] an administrator's control in the calculation of drug benefits." *Gerhart*, 852 F.3d at 730. And echoing that error, PCMA argues that Arkansas's law "dictates *how* ERISA plans must calculate and disburse benefits," BIO 31, and "requires ERISA plans . . . 'to process claims in a certain way in some States but not in others,'" Supp. Br. for Resp. at 3 (quoting *Fort Halifax*, 482 U.S. at 9).

But Arkansas's law does no such thing. While ERISA normally preempts state laws that dictate benefits calculations (unless, as explained above, those dictates are incidental to enforcement of an otherwise permissible law), that principle does not apply here because Act 900 does not dictate how plans calculate or process benefits. Far from it, Act 900 merely provides a process for resolving reimbursement disputes between PBMs and pharmacies *after* a claim has been processed and a beneficiary has received a drug pursuant to plan terms. That conclusion,

moreover, is underscored by the fact that ERISA's claim-processing provisions do not address provider reimbursements and that disputes about them do not impair uniformity of plan administration.

a. Reimbursement disputes occur after a claim has been processed.

At best, the argument that Act 900 dictates how plans calculate drug benefits or process claims rests on a fundamental misunderstanding of what the benefit is. A prescription-drug benefit is not, as the Eighth Circuit suggested, the amount a pharmacy receives in reimbursement. Rather, the benefit is the *drug itself or the right to coverage* for a fixed portion of the drug's cost. Therefore, prescription-drug claims processing is the process of determining whether, and to what extent, the plan *covers a beneficiary's prescription*—not determining how much to reimburse a pharmacy. Any reimbursement disputes occur *after* processing a claim for prescription-drug benefits.

In an employee welfare benefit plan—like the prescription-drug plans here—the "[b]enefits to which a beneficiary is entitled are bargained-for goods, such as 'medical, surgical or hospital care,' rather than a right to payment for medical services rendered." *Rojas v. Cigna Health & Life Ins. Co.*, 793 F.3d 253, 257 (2d Cir. 2015) (citation omitted) (quoting 29 U.S.C. 1002(1)(A)). Those benefits could be characterized as rights to the coverage of the costs of medical goods. But they cannot simply be characterized as rights to the payment of any particular reimbursement amount to a pharmacy.[15]

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[15] For example, if a prescription-drug plan decreases a beneficiary's co-pays, deductibles, or rates of co-insurance, it would be

Thus, a prescription-drug claim is a request to cover a drug's cost or a plan-determined fraction of cost, *whatever that cost turns out to be*. And prescription-drug claims processing is the procedure by which a plan determines whether a drug is covered and how much of its cost the plan and the beneficiary are responsible for.

That process is complete when a beneficiary receives a drug or coverage for some fixed portion of a drug's cost pursuant to a plan's terms. What happens *after that* between the pharmacy and PBM in a reimbursement-rate appeal neither dictates how those benefits were calculated nor alters how the claims was processed.

Indeed, the terms that typically govern a plan's coverage of generic prescription drugs underscore that point. In an overwhelming majority of cases involving generic-drug claims, the PBM simply determines whether the drug is covered, and, if so, directs the pharmacy to collect a flat co-pay amount applicable to all generics. *See* Kaiser Family Foundation, *2019 Employer Health Benefits Survey: Prescription Drug Benefits* (2019).[16] Any subsequent dispute over the pharmacy's reimbursement rate does not alter the benefit the beneficiary receives or the disposition of his claim. To the contrary, as this Court wrote in *Royal Drug*, "[t]he benefit promised to [the] policyholders [in that case] is that their premiums will cover the cost of prescription

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fair to say that the beneficiary's benefits level has increased. But if the cost of a beneficiary's drugs merely goes up, and the plan's reimbursement rates with it, it would make no sense to say that her benefits have gone up.

[16] https://www.kff.org/report-section/ehbs-2019-section-9-prescription-drug-benefits/.

drugs except for a $2 charge for each prescription. So long as that promise is kept, policyholders are basically unconcerned with arrangements made between [the insurer] and participating pharmacies." 440 U.S. at 214.

Thus, as a factual matter, Arkansas's codification of PBMs' established practice of providing pharmacies with "a reasonable administrative appeal procedure" to challenge generic-drug reimbursement rates, Ark. Code Ann. 17-92-507(c)(4)(A)(i), does not regulate how prescription-drug benefits are calculated or processed.

b. ERISA's claims-processing provisions do not address provider reimbursements.

ERISA's text further underscores that Act 900 does not regulate claims processing. ERISA "regulat[es] the manner in which plans process benefits claims" in 29 U.S.C. 1133, a section of ERISA entitled "Claims procedure." *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 830 (2003). That section requires plans to "process claims '[i]n accordance with regulations of the Secretary,'" *id.* (quoting 29 U.S.C. 1133), to "provide adequate notice . . . to any participant or beneficiary whose claim for benefits under the plan has been denied," 29 U.S.C. 1133(1), and to "afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review . . . of the decision denying the claim," 29 U.S.C. 1133(2).

That section says nothing about disputes between plans and providers. Nor does anything in the voluminous "Claims procedure" regulations promulgated

under that section speak to that issue. *See* 29 C.F.R. 2560.503-1.[17]

Accordingly, courts have resisted providers' attempts to invoke ERISA's claims-processing procedures because those procedures are "designed for retail-level disputes between a plan's participants and their employer . . . rather than procedures designed for wholesale-level disputes between an insurer and providers under network contracts." *Pa. Chiropractic Ass'n v. Indep. Hosp. Indem. Plan, Inc.*, 802 F.3d 926, 928 (7th Cir. 2015) (Easterbrook, J.); *see Grasso Enters., LLC v. Express Scripts, Inc.*, 809 F.3d 1033, 1041 (8th Cir. 2016) (pharmacy suit against PBM). Indeed, when providers have tried, lower courts have suggested they bring state-law contract lawsuits instead, which "would not be governed by ERISA and the [Secretary's] Claims Regulation." *Grasso Enters.*, 809 F.3d at 1041.

Such a state-law contract lawsuit would involve a reimbursement dispute between a pharmacy and a PBM—not claims processing or benefits determinations. Act 900's reimbursement appeals operate in much the same way, allowing a pharmacy to challenge a PBM's reimbursement rate only after the completion

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[17] This Court's cases preempting claims-processing regulations confirm this understanding. All either involved substantive rules governing beneficiary determinations, *see Egelhoff*, 532 U.S. at 147-50 (revocation upon divorce), *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 524-26 (1981) (law banning "pension calculation technique"), or procedural rules governing the approval or denial of beneficiaries' claims, *see Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365 (2002) (law requiring independent review of denials); *UNUM Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 366-67 (1999) (rule prohibiting denial based on non-prejudicial late filing).

of claims processing. As such, those appeals are not preempted.

Further, as with contract suits, preempting drug-reimbursement appeals only as applied to ERISA plans would defeat ERISA's purposes. If pharmacies had no means of challenging the below-cost reimbursements of ERISA plans' PBMs—but could appeal below-cost reimbursements by other payers—ERISA-covered customers would become a relatively unprofitable source of business. That might prompt pharmacies to leave their plans' networks. And those that stayed might struggle to survive and ultimately close. While this might benefit PBMs—by allowing them to continue capturing savings from below-cost reimbursements—it would undoubtedly harm the very people ERISA was intended to protect: plan beneficiaries.

c. Act 900's appeal procedures do not compromise nationally uniform plan administration.

Act 900's appeal procedures likewise do not impair uniform plan administration or even meaningfully compromise nationally uniform PBM reimbursement procedures.

PCMA avers that absent preemption its members would have to comply with "a crazy-quilt of conflicting rules governing the administration of prescription drug benefits." Supp. Br. of Resp. 3. But MAC reimbursement appeals were a standard feature of those members' contracts with pharmacies long before Act 900 and the 35 State laws like it were enacted. Perhaps more to the point, "regardless of what this Court may [hold] ERISA forbids," PBMs will still have to provide Act 900-compliant appeals for non-ERISA reimbursements. *Rush Prudential*, 536 U.S. at 381

n.11. And because "it is the [PBM] contracting with a plan, and not the plan itself, that will be subject" to Act 900, "there will be no special burden of compliance upon an ERISA plan beyond what the [PBM] has already provided for" elsewhere. *Id.*

As for disuniformity, though the rates set by reimbursement-appeal laws may differ, their procedural requirements—which are all PCMA contends are preempted—essentially differ with respect only to appeal turnaround time. *Compare* Ark. Code Ann. 17-92-507(c)(4)(C) (requiring a response to an appeal within seven business days), *with, e.g.*, Tex. Ins. Code Ann. 1369.357(b) (requiring a response within ten days).

PCMA, therefore, cannot seriously contend that a procedure mandated by nearly three-quarters of the States and that its members historically provided is preempted merely because of minor differences in detail. *See Egelhoff*, 532 U.S. at 152 (doubting that "slayer" statutes were preempted because "nearly every State" enacted one and they were "more or less uniform nationwide"); *but see id.* at 160 (Breyer, J., dissenting) (observing that slayer statutes applied different standards of proof).

d. Co-insurance and high-deductible plans present unusual circumstances, but do not justify preemption.

PCMA may claim that the small fraction of plans that apply co-insurance percentages or deductibles to generic drugs requires preemption. In particular, PCMA may claim that reimbursement appeals will alter the amount a beneficiary pays, and thus amount to re-processing. *See* BIO 13. That argument fails for at least three reasons.

First, reimbursement appeals will not lead PBMs to somehow recalculate or reprocess a prescription-drug claim. Most likely, successful reimbursement appeals will merely alter the amounts that plan beneficiaries pay for *future* prescriptions under altered MACs. There is no evidence that a pharmacy or plan would attempt to collect the relevant difference from beneficiaries in prescriptions already paid for. It strains credulity to suggest that a pharmacy or plan would dedicate resources to collect something like 20% of a $10 increase. Yet only if that is the case could PCMA even colorably claim that there has been some kind of recalculation or reprocessing.

Second, the determination of a reimbursement rate to which co-insurance applies is not part of claims processing. Rather, only the determination of the applicable co-insurance rate is claims processing. This is true, again, because a prescription-drug claim is a request that a plan cover whatever fraction of a drug's cost the plan is responsible for under the plan's terms. The processing of that claim is simply the determination of the applicable fraction: all, nothing, or something in between. That is why, when a beneficiary believes her plan has applied the wrong co-insurance rate to her claim—e.g., 25% co-insurance instead of 10%—she can sue under ERISA for improper claims-processing. *See Del Greco v. CVS Corp.*, 337 F. Supp. 2d 475 (S.D.N.Y. 2004) (entertaining such a claim).

By contrast, determining a drug's reimbursement rate, either under the terms of pharmacy-PBM contracts or a State's rate regulation, has nothing to do with processing a beneficiary's request for coverage. That is why courts uniformly hold that ERISA does not preempt reimbursement-rate contract suits, even though such suits may collaterally affect the co-insurance

a beneficiary owes. *See K.B.*, 929 F.3d at 802 (holding ERISA did not preempt a beneficiary's suit challenging provider's over-reimbursement under provider's contract, though the suit's purpose was to reduce the beneficiary's cost-sharing); *Lone Star*, 579 F.3d at 530 (holding that the "mere consultation" of plan's co-insurance terms to determine a provider's contract damages did not preempt provider's suit); *Anesthesia Care Assocs.*, 187 F.3d at 1052 (holding that "the economic effects" of "increased co-payment liability" from a reimbursement dispute were "not sufficient for ERISA preemption to occur").

Thus, internal drug-reimbursement appeals to enforce statutory reimbursement rates are materially indistinguishable from state-court civil suits to enforce contract-reimbursement rates, which no court has held preempted. Like contract suits, they do not require the interpretation of plan terms, nor, as just explained, do they implicate plans' benefit determinations or claims procedures.

Third, even if a reimbursement appeal's collateral adjustment of co-insurance payments were deemed claims processing, "the bare possibility," unsupported by the record, that reimbursement appeals would have that effect does not suffice for preemption. *Rush Prudential*, 536 U.S. at 372 (holding a law's "minimal application to noninsurers" would not suffice "to remove a state law entirely from the category of insurance regulation saved from preemption"); *Ky. Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 336 n.1 (2003) (same). That is especially true given that the overwhelming majority of plans that charge co-pays for generics are immune from such effects. There is no preemption.

3. Act 900's decline-to-dispense provision is a typical drug-dispensing regulation.

PCMA separately attacks Act 900's provision permitting pharmacies to decline to provide services to PBMs that refuse to abide by Arkansas's system of rate regulation. It contends that provision "limits the availability of a plan member's promised pharmacy benefits at the pharmacy's election." BIO 32.

But that would be true of any rate regulation; if plan administrators refuse to comply with it, fewer providers will agree to serve their beneficiaries. Indeed, a pharmacy's ability to refuse to serve non-compliant PBMs is a feature—explicitly or implicitly—of any form of rate regulation. As explained in greater detail above, that is true because rate regulation, by definition, voids contract rates that are inconsistent with it and any contractual promises to accept them. *See supra* p. 29. Consequently, PCMA's attack on Act 900's decline-to-dispense provision is little more than a poorly disguised attack on rate regulation. And *Travelers* forecloses that argument.

In addition to that fatal flaw, PCMA's argument fails because it wrongly conflates laws that regulate plans' benefits choices with laws that regulate what is available for sale. ERISA preempts laws that "bind[] ERISA plan administrators to a particular choice" about benefits. *Egelhoff*, 532 U.S. at 148. Thus, subject to the insurance saving clause, it preempts laws requiring plans to provide particular benefits, *Metropolitan Life Insurance Co. v. Massachusetts*, 471 U.S. 724, 739 (1985), or laws that require plans to include certain providers in their networks, *Kentucky Ass'n of Health Plans*, 538 U.S. at 333-34.

ERISA does not, however, preempt regulations that limit the goods and services available for purchase on the market. For example, States may be foreclosed from telling plans what drugs to cover or not cover, but that does not foreclose States from regulating what drugs may be sold. Similarly, while States may not be able to dictate which pharmacies are included in a plan's network, States are certainly entitled to impose regulations that prevent certain pharmacies from operating within their borders. And while States cannot regulate where *plans* promise their beneficiaries they can purchase covered drugs, States are not required to treat *pharmacies'* promises to provide those drugs as inviolable. *C.f. Pegram v. Herdrich*, 530 U.S. 211, 235-37 (2000) (holding that even decisions of plan-administrator-employed physicians to not provide covered treatment are not regulated by ERISA, reasoning such matters are domain of state malpractice law, which ERISA ought not preempt).

Indeed, if ERISA preempted any law that "limits the availability of a plan member's promised pharmacy benefits at *the pharmacy's election*," BIO 32 (emphasis added), ERISA would preempt countless traditional areas of state regulation. For instance, on PCMA's theory, ERISA would preempt any state contract-law doctrine that excused a pharmacy's failure to perform under its network agreement—such as impossibility, frustration, anticipatory repudiation, or material breach—because such doctrines could limit the availability of beneficiaries' promised benefits at the pharmacy's election. It would likewise preempt any state contract-law doctrine that would permit a pharmacy to void its network agreement, including mistake, misunderstanding, misrepresentation, or unconscionability—an act which would far more broadly limit a plan

member's promised benefits than refusing to sell a single under-reimbursed drug.

Equally "unsettling," *Travelers*, 514 U.S. at 665, PCMA's approach would preempt any law that, for health, safety, or conscience reasons, prohibits a pharmacy from selling a covered drug or gives a pharmacist discretion to decline to dispense one. For example, like many states, Arkansas authorizes pharmacies to decline to dispense drugs for a variety of health-and-safety reasons. *See, e.g.*, Ark. Admin. Code 070.00.7-07-04-0006(c) (authorizing pharmacies to decline to dispense drugs such as codeine "if the pharmacist is aware of information indicating that the patient is inappropriately self-medicating"); Cal. Bus. & Prof. Code 733(b)(1) (authorizing pharmacists to decline to dispense drugs if, "[b]ased solely on [their] professional training and judgment," they determine a drug would "adversely affect the patient's medical condition"); Tenn. Code Ann. 53-10-112(c) (authorizing pharmacists to "decline to dispense to a patient [certain drugs] which, in that pharmacist's professional judgment, lacks a therapeutic value for the patient or which is not for a legitimate medical purpose").

Like other states, Arkansas also permits pharmacies to decline to dispense controlled substances or their precursors if the pharmacist doubts a prescription has a legitimate medical purpose. *See, e.g.*, Ark. Code Ann. 5-64-1102(c)(1)(B) (prohibiting dispensing pseudoephedrine, a cold medicine that can be used to make methamphetamine, "with reckless disregard as to how [it] will be used"); Cal. Health & Safety Code 11153(a) (requiring pharmacies to determine whether a prescription was "issued for a legitimate medical purpose" before dispensing); Fla. Admin. Code Ann. r. 64B16-27.831 (authorizing pharmacies to decline to

dispense if they know a prescription "was not issued for a legitimate medical purpose").

And for decades, Arkansas law has given pharmacists the right to "refus[e] to furnish any contraceptive," Ark. Code Ann. 20-16-304(4), as does the law of multiple other States, *see, e.g.*, Colo. Rev. Stat. 25-6-102(9); Fla. Stat. 381.0051(5); Ga. Comp. R. & Regs. 480-5-.03(n).

As *Travelers* held, "[t]he bigger the package of regulation . . . that would fall on the respondents' reading of [the preemption clause], the less likely it is" that that reading is correct. 514 U.S. at 661. That is particularly true of a "reading of [the preemption clause] resulting in the pre-emption of traditionally state-regulated substantive law"—like basic contract law, health and safety regulations, religious conscience laws, or provider rates—"in those areas where ERISA has nothing to say." *Dillingham*, 519 U.S. at 330. Because PCMA's startlingly broad reading of ERISA would preempt any state law permitting providers to elect to deny services, it cannot possibly be correct.

II. Act 900 does not refer to ERISA plans.

The Eighth Circuit held that Act 900 refers to ERISA plans because it regulates a class of third parties, PBMs, that administer benefits for customers who "*include* . . . entities that are necessarily subject to ERISA regulation." Pet.App.6a (emphasis added). That holding, which would preempt all PBM regulation, is wrong. A state law only refers to ERISA plans if it "acts immediately and exclusively upon ERISA plans," or if "the existence of ERISA plans is essential to the law's operation." *Gobeille*, 136 S. Ct. at 943 (alterations omitted) (quoting *Dillingham*, 519 U.S. at 325). Arkansas's law does neither.

First, Act 900 does not act exclusively upon ERISA plans because it also covers PBMs' service of non-ERISA plans. It defines a PBM as any "entity that administers or manages a pharmacy benefits plan or program." Ark. Code Ann. 17-92-507(a)(7). As PCMA's claims below show, that definition includes PBMs who work for Medicare Part D; it includes prescription-drug plans on the individual market; and it expressly includes PBMs employed by two government plans. Ark. Code Ann. 17-92-507(f)(2). None of those plans are covered by ERISA.

Second, the existence of ERISA plans is not essential to the law's operation. Absent ERISA plans, or ERISA plans that employed PBMs, PBMs as defined by Act 900 would still exist and the law would still operate on them. Indeed, this case is identical to *Travelers*, where the non-Blue insurers paid surcharges to hospitals "regardless of whether [their coverage] is ultimately secured by an ERISA plan, private purchase, or otherwise, with the consequence that the surcharge statutes cannot be said to make 'reference to' ERISA plans in any manner." 514 U.S. at 656.

PCMA, though conceding Arkansas has not exclusively regulated ERISA plans, retorts that "'essential to' need not mean exclusively," and claims ERISA plans are essential to the law's operation here. BIO 28. PCMA is correct that essentiality does not require *exclusivity*. But it does require essentiality, and the cases on which PCMA relies show why essentiality is lacking here.

PCMA first relies on *District of Columbia v. Greater Washington Board of Trade*, 506 U.S. 125 (1992), in which the District required employers to provide employees the same health benefits in their ERISA-

exempt workers' compensation plans that they provided in their ERISA-covered health plans. *Id.* at 130-31. That law did not exclusively regulate ERISA plans; arguably, it did not regulate them at all. But ERISA plans were absolutely essential to its operation because they provided the benefits by which its regulation of other plans was measured. No ERISA plans; no regulation.

PCMA next relies on *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133 (1990), where this Court addressed a bespoke wrongful-termination cause of action against employers who terminated employees to avoid contributing to their ERISA pension plans. That cause of action did not directly regulate ERISA plans. It regulated employers. But ERISA plans were deeply essential to it, because to prove the cause of action, a plaintiff had to prove "that an ERISA plan exists" and that the employer terminated the plaintiff to avoid contributing to it. *Id.* at 140. No ERISA plans; no cause of action.

PCMA claims Act 900 is of a piece, reasoning that it defines PBMs as entities that manage pharmacy-benefits plans, that "to enforce Act 900, the State would have to prove the existence of [a] plan," and that "*in the case of ERISA plans*," that would require proving the existence of a plan which happens to be an ERISA plan. BIO 29 (emphasis added). The argument goes off the rails at "in the case of." In *Greater Washington* and *Ingersoll-Rand*, there was no other case—only cases in which an ERISA plan's existence was a prerequisite to regulation. Not so here.

Rather, this case is like *Dillingham*, in which a State required apprenticeship programs—many but not all of which were ERISA plans—to pay a certain wage. To enforce the law, the State had to prove an

entity was an apprenticeship program, which would often entail proving the existence of a program that happened to be an ERISA plan. But the Court held the law "function[ed] irrespective of the existence of an ERISA plan" because it was "indifferent" to whether an apprenticeship program was one. *Dillingham*, 519 U.S. at 328. Likewise, Act 900 is entirely indifferent to what kind of pharmacy benefits plan a PBM administers, so long as it administers one.

CONCLUSION

This Court should reverse the court of appeals' judgment.

Respectfully submitted,

LESLIE RUTLEDGE
Arkansas Attorney General
NICHOLAS J. BRONNI
Solicitor General
Counsel of Record
VINCENT M. WAGNER
Deputy Solicitor General
ASHER STEINBERG
DYLAN L. JACOBS
Assistant Solicitors General
SHAWN J. JOHNSON
Senior Assistant Attorney General

OFFICE OF THE ARKANSAS ATTORNEY GENERAL
323 Center St., Ste. 200
Little Rock, AR 72201
(501) 682-6302
nicholas.bronni@arkansasag.gov

Counsel for Petitioner

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APPENDIX

APPENDIX

29 U.S.C. 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.

(3) Nothing in this section shall be construed to prohibit use by the Secretary of services or facilities

of a State agency as permitted under section 1136 of this title.

(4) Subsection (a) shall not apply to any generally applicable criminal law of a State.

(5)(A) Except as provided in subparagraph (B), subsection (a) shall not apply to the Hawaii Prepaid Health Care Act (Haw.Rev.Stat. §§ 393-1 through 393-51).

(B) Nothing in subparagraph (A) shall be construed to exempt from subsection (a)–

(i) any State tax law relating to employee benefit plans, or

(ii) any amendment of the Hawaii Prepaid Health Care Act enacted after September 2, 1974, to the extent it provides for more than the effective administration of such Act as in effect on such date.

(C) Notwithstanding subparagraph (A), parts 1 and 4 of this subtitle, and the preceding sections of this part to the extent they govern matters which are governed by the provisions of such parts 1 and 4, shall supersede the Hawaii Prepaid Health Care Act (as in effect on or after January 14, 1983), but the Secretary may enter into cooperative arrangements under this paragraph and section 1136 of this title with officials of the State of Hawaii to assist them in effectuating the policies of provisions of such Act which are superseded by such parts 1 and 4 and the preceding sections of this part.

(6)(A) Notwithstanding any other provision of this section–

(i) in the case of an employee welfare benefit plan which is a multiple employer welfare arrange-

ment and is fully insured (or which is a multiple employer welfare arrangement subject to an exemption under subparagraph (B)), any law of any State which regulates insurance may apply to such arrangement to the extent that such law provides–

(I) standards, requiring the maintenance of specified levels of reserves and specified levels of contributions, which any such plan, or any trust established under such a plan, must meet in order to be considered under such law able to pay benefits in full when due, and

(II) provisions to enforce such standards, and

(ii) in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement, in addition to this subchapter, any law of any State which regulates insurance may apply to the extent not inconsistent with the preceding sections of this subchapter.

(B) The Secretary may, under regulations which may be prescribed by the Secretary, exempt from subparagraph (A)(ii), individually or by class, multiple employer welfare arrangements which are not fully insured. Any such exemption may be granted with respect to any arrangement or class of arrangements only if such arrangement or each arrangement which is a member of such class meets the requirements of section 1002(1) and section 1003 of this title necessary to be considered an employee welfare benefit plan to which this subchapter applies.

(C) Nothing in subparagraph (A) shall affect the manner or extent to which the provisions of this subchapter apply to an employee welfare benefit

plan which is not a multiple employer welfare arrangement and which is a plan, fund, or program participating in, subscribing to, or otherwise using a multiple employer welfare arrangement to fund or administer benefits to such plan's participants and beneficiaries.

(D) For purposes of this paragraph, a multiple employer welfare arrangement shall be considered fully insured only if the terms of the arrangement provide for benefits the amount of all of which the Secretary determines are guaranteed under a contract, or policy of insurance, issued by an insurance company, insurance service, or insurance organization, qualified to conduct business in a State.

(7) Subsection (a) shall not apply to qualified domestic relations orders (within the meaning of section 1056(d)(3)(B)(i) of this title), qualified medical child support orders (within the meaning of section 1169(a)(2)(A) of this title), and the provisions of law referred to in section 1169(a)(2)(B)(ii) of this title to the extent they apply to qualified medical child support orders.

(8) Subsection (a) of this section shall not be construed to preclude any State cause of action–

(A) with respect to which the State exercises its acquired rights under section 1169(b)(3) of this title with respect to a group health plan (as defmed in section 1167(1) of this title), or

(B) for recoupment of payment with respect to items or services pursuant to a State plan for medical assistance approved under title XIX of the Social Security Act which would not have been payable if such acquired rights had been executed

before payment with respect to such items or services by the group health plan.

(9) For additional provisions relating to group health plans, see section 1191 of this title.

(c) Definitions

For purposes of this section:

(1) The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) The term "State" includes a State, any political subdivisions thereof, or any agency or instrumentality of either, which purports to regulate, directly or indirectly, the terms and conditions of employee benefit plans covered by this subchapter.

(d) Alteration, amendment, modification, invalidation, impairment, or supersedure of any law of the United States prohibited

Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.

(e) Automatic contribution arrangements

(1) Notwithstanding any other provision of this section, this subchapter shall supersede any law of a State which would directly or indirectly prohibit or restrict the inclusion in any plan of an automatic contribution arrangement. The Secretary may prescribe regulations which would establish minimum

standards that such an arrangement would be required to satisfy in order for this subsection to apply in the case of such arrangement.

(2) For purposes of this subsection, the term "automatic contribution arrangement" means an arrangement–

(A) under which a participant may elect to have the plan sponsor make payments as contributions under the plan on behalf of the participant, or to the participant directly in cash,

(B) under which a participant is treated as having elected to have the plan sponsor make such contributions in an amount equal to a uniform percentage of compensation provided under the plan until the participant specifically elects not to have such contributions made (or specifically elects to have such contributions made at a different percentage), and

(C) under which such contributions are invested in accordance with regulations prescribed by the Secretary under section 1104(c)(5) of this title.

(3)(A) The plan administrator of an automatic contribution arrangement shall, within a reasonable period before such plan year, provide to each participant to whom the arrangement applies for such plan year notice of the participant's rights and obligations under the arrangement which–

(i) is sufficiently accurate and comprehensive to apprise the participant of such rights and obligations, and

(ii) is written in a manner calculated to be understood by the average participant to whom the arrangement applies.

(B) A notice shall not be treated as meeting the requirements of subparagraph (A) with respect to a participant unless–

(i) the notice includes an explanation of the participant's right under the arrangement not to have elective contributions made on the participant's behalf (or to elect to have such contributions made at a different percentage),

(ii) the participant has a reasonable period of time, after receipt of the notice described in clause (i) and before the first elective contribution is made, to make such election, and

(iii) the notice explains how contributions made under the arrangement will be invested in the absence of any investment election by the participant.

Ark. Code Ann. 17-92-507 (2018 Repl.)

Maximum Allowable Cost Lists

(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 often 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 defmed 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).