No. 18-540

IN THE

Supreme Court of the United States

LESLIE RUTLEDGE, in her official capacity as Attorney General of the State of Arkansas,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

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

BRIEF OF THE ACADEMY OF MANAGED CARE PHARMACY AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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April 1, 2020

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Academy of Managed Care Pharmacy (AMCP) is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments, also known as managed care pharmacy. AMCP is a diverse professional association of pharmacists, physicians, nurses, and professionals in managed care pharmacy organizations, including health plans, pharmacy benefit managers (PBMs), and integrated delivery networks, as well as researchers and those employed by life sciences and biopharmaceutical companies. AMCP's more than 8,000 members nationally improve health outcomes of nearly 300 million Americans served by private and public health plans, PBMs, and emerging care models.

AMCP's mission—and the goal of managed care pharmacy—is to improve patient health by ensuring access to high-quality, cost-effective medications and other therapies. To achieve this goal, AMCP and its member professionals leverage their specialized expertise in clinical evidence and economics to optimize the design of pharmacy benefit plans in order to ensure that patients access safe and appropriate medications that will lead to the best possible health outcomes at the lowest cost. AMCP advocates at both the national and state level for the development and application of evidence-based medication use

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* AMCP states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae* and its counsel, made any monetary contribution toward the preparation and submission of this brief. Pursuant to Rule 37.3, AMCP states that all parties have consented to the filing of this brief.

strategies that improve access to medication, ensure effective medication use, enhance patient and population health outcomes, and safeguard the wise use of health care dollars. As explained in Part I, *infra*, research demonstrates that these managed care pharmacy tools lead to both improved health outcomes for patients and reduced medication costs.

Because AMCP works to develop and promote the implementation of evidence-based medication use strategies at the population level, AMCP and its members have a direct interest in ensuring that such measures can be widely implemented. To that end, AMCP has an interest in advocating that ERISA's broad preemptive force be preserved, so that ERISA-governed pharmacy benefit plans are not foreclosed by state regulations from incorporating medication use management strategies in their plan designs. What is more, if managed care pharmacy organizations are required to comply with a multitude of disparate state regulations, compliance costs will ineluctably rise, thus offsetting the cost-saving benefits of managed care pharmacy tools or causing organizations to forgo the development and implementation of such tools altogether.

This case addresses whether an Arkansas statute, Ark. Code Ann. § 17-92-507 ("Act 900"), whereby Arkansas seeks to regulate ERISA-governed health plans specifically in the area of prescription-drug benefits, "relates to" ERISA plans and is therefore preempted by ERISA. 29 U.S.C. § 1144(a). Should the Court reverse the Eighth Circuit's holding that Act 900 is preempted, and permit Arkansas's restriction of employee health benefit plans to go into effect, the goals of managed care pharmacy to improve health outcomes by ensuring use of appropriate and cost-effective medications will be impeded. Moreover, the

threat of further state regulation of pharmacy plan benefits—and further balkanization of such regulations—risks yet greater disruption in the development and implementation of managed care pharmacy strategies. AMCP submits this brief to ensure the Court has a complete picture of the health and cost-saving benefits of evidence-based measures through managed care pharmacy—and the risks that may follow if state regulations are permitted to create obstacles to these measures.

SUMMARY OF ARGUMENT

Pharmaceuticals play an increasingly important role in the prevention, cure, and management of disease. An essential component of ERISA-governed health benefit plans, therefore, is the ability of plan beneficiaries to acquire clinically appropriate medication to treat their medical needs. At the same time, however, expenditures for drugs have been increasing at rates higher than or comparable to expenditures for other health-related products and services. Prescription drug spending is projected to increase by 3.7% in 2020, accelerating to an increase of 5.4% to 5.9% per year from 2021 through 2028. Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Projections 2019-2028*, at 4, https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf.

With the costs of prescription drugs rising, and as medications continue to be more specialized, pharmacy benefit plans must balance patient access to prescription medications with the critical need for affordability. More specifically, pharmacy benefit plan sponsors must align the necessity of ensuring that plan beneficiaries have access to the effective and safe medications they need, on the one hand, with the

importance of controlling rapidly increasing costs for prescription medications, on the other. Managed care pharmacy professionals aim to achieve this critical balance by structuring pharmacy benefit plans so that all patients receive the highest-quality, safest, and most cost-effective medications that will best enhance the patients' health outcomes.

Managed care pharmacy organizations, including PBMs, have developed a wide variety of managed care tools to effectuate this aim. The managed care pharmacy toolkit includes innovative strategies to optimize utilization of appropriate and cost-effective prescription drugs by the population of beneficiaries covered by a pharmacy benefit plan. These strategies use evidence-based guidelines to promote consistent use of those medications that produce the best clinical outcomes and the greatest value for patients. Evidence shows that these strategies—including prior authorization requirements, step therapy programs, and other population health–driven utilization management tools—have meaningfully enhanced patient outcomes while helping to maintain the affordability of prescription drug benefits.

The uniformity and predictability of pharmacy benefit regulation that ERISA provides is critical to the development and implementation of such managed care pharmacy strategies. State regulations that dictate how pharmacy benefit plans are to be administered undercut the ability of managed care pharmacy professionals both to develop and to deploy these clinically beneficial and cost-saving measures. This has already happened in the sphere of fully insured pharmacy benefit plans, which are not governed by ERISA, and which therefore are subject to a wide variety of state regulations. For plans that are not governed by ERISA, some states have restricted

the use of medication utilization strategies. In order to preserve the benefits of managed care pharmacy—benefits of both improved outcomes and reduced costs—it is critical that, where ERISA applies, federal law is read broadly to preempt state regulation of how pharmacy benefit plans are designed and administered.

At issue in this case is a tool that pharmacy benefit plans and PBMs use in determining reimbursements paid to pharmacies for prescription drugs: Maximum Allowable Cost (MAC) pricing and MAC lists. A MAC list is a continuously updated schedule of generic drugs covered by a pharmacy benefit plan, setting forth the maximum allowable cost the plan will cover for that drug. By reimbursing pharmacies based on MAC pricing rather than using a cost-reimbursement model, pharmacy benefit plans and PBMs incentivize pharmacies to dispense cost-saving generic drugs (rather than more expensive brand-name equivalents). Moreover, the use of MAC pricing ensures that pharmacies will seek out the lowest possible price for generic medications, so that employers and consumers—those purchasing health insurance benefits—do not pay more than necessary. In these ways, MAC pricing—like the medication use strategies described in Part I, *infra*—promotes the goal of managed care pharmacy to incentivize the use of cost-effective generic drugs at the lowest possible price, increasing the predictability and efficiency of pharmacy benefit plans. Yet, as respondent demonstrates, Arkansas's Act 900—and the MAC pricing regulations that many other states have imposed—regulate the administration of pharmacy benefit plans to constrain plans' use of this cost-saving tool.

State-specific regulations on the administration of ERISA pharmacy benefit plans like Act 900 should not be permitted to stand. Nor should state regulations be permitted to undermine the other critical tools that managed care pharmacy professionals have developed to enhance patients' health while controlling pharmacy benefit plan costs. As AMCP demonstrates here, these tools are best developed and employed by managed care pharmacy organizations with the expertise necessary to evaluate clinical data and medical guidance in order to identify evidence-based strategies that will ensure patients consistently receive the highest-value, most cost-effective, and safest drugs available. Disparate state regulations have doubly adverse effects: not only do such regulations remove innovative tools from the hands of managed care pharmacy professionals, but in addition the lack of uniformity itself undermines managed care pharmacy and the level of care provided to patients. Rather than developing, assessing, and implementing new strategies to improve patient outcomes, managed care pharmacy professionals would instead spend time and resources ensuring compliance with differing localized requirements.

In sum, if regulation of pharmacy benefit plans can be balkanized through a patchwork of state regulation, AMCP's goal of promoting managed care pharmacy—and the population-wide health benefits that managed care pharmacy professionals work to advance—will be significantly impeded. ERISA exists to prevent that outcome. The decision below should be affirmed.

ARGUMENT

I. WHEN PHARMACY BENEFIT PLANS ARE ABLE TO INCORPORATE EVIDENCE-BASED MANAGED CARE PHARMACY STRATEGIES INTO PLAN BENEFIT DESIGN, THEY IMPROVE HEALTH AND LOWER COSTS.

Pharmacy benefit plans and the PBMs that administer them use a variety of tools to ensure that the population of individuals covered by the plan achieves the best possible health outcomes at the lowest cost. See Fed. Trade Comm'n, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* 10–15 (Aug. 2005), https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf. In particular, managed care pharmacy organizations work to develop population-level strategies that will ensure that patients have access to and consistently use the highest-value, most cost-effective medications that will lead to the best outcomes for the population served by the plan.

By studying data and outcomes of a population over time, managed care pharmacy professionals can design benefit plans to provide coverage for the most appropriate medication to be delivered to the patient. Where evidence demonstrates that a less expensive or lower-risk medication would provide the same or better outcomes, it is substituted; higher-cost medications are used only after lower-cost alternatives have failed; and adherence is maximized through utilization management programs. As detailed in the examples set forth below, where PBMs and pharmacy benefit plans have been able to implement such

evidence-based tools, they have succeeded in improving patients' health while lowering costs.

Without ERISA's guarantee of nationwide uniformity in the administration of employee health benefit plans, however, these positive health outcomes would not have been possible. If managed care pharmacy professionals must account for a patchwork of state regulations of health treatment programs, the increase in necessary compliance costs might make these strategies too costly to pursue. And state laws might foreclose the deployment of medication use strategies even where a careful review of medical evidence supports their application. The broad preemptive force of ERISA is necessary to ensure that ERISA-governed pharmacy benefit plans can continue to use these beneficial tools.

Prior authorization. In order to ensure the use of clinically appropriate, safe, and affordable medications, pharmacy benefit plans may—based on an evidence-based process including evaluation of clinical trials, peer-reviewed literature, and consensus guidelines—provide that certain medications will be covered only if the patient receives prior authorization to use that specific drug. In particular, the plan may require that health care providers certify that a patient's unique clinical needs and therapeutic rationale support the use of certain medications that pose unusually high risks or costs, rather than other safer or less expensive alternatives. See Tricia Lee Wilkins, *Prior Authorization and Utilization Management Concepts in Managed Care Pharmacy*, 25 J. Managed Care & Specialty Pharmacy, 641, 641 (2019). Evidence demonstrates that appropriate deployment of this utilization management tool improves outcomes while reducing costs.

For example, opioids pose a grave risk of addiction and adverse long-term outcomes, and for many patients less-risky alternatives are available. Prior authorization requirements for opioids have been shown to encourage health care providers to prescribe such alternatives to patients for whom the risks of opioids are not warranted. See, *e.g.*, Shellie L. Keast et al., *Effects of a Prior Authorization Policy for Extended-Release/Long-Acting Opioids on Utilization and Outcomes in a State Medicaid Program*, 113 Addiction 1651, 1657–58 (2018) (prior authorization policy reduced extended-release/long-acting opioid use); Daniel M. Hartung et al., *Effect of a High Dosage Opioid Prior Authorization Policy on Prescription Opioid Use, Misuse, and Overdose Outcomes*, 39 Substance Abuse 239, 243–45 (2018) (prior authorization policy caused "significant decline" in high dosage opioid prescriptions fills with a corresponding "significant increase" in substitute medications for neuropathic pain).

Another example is dalfampridine, a medication that improves walking in certain patients with multiple sclerosis. There is no evidence that dalfampridine helps multiple sclerosis patients with severely limited mobility, and dalfampridine poses a heightened risk of seizures in patients with renal impairment or a history of seizures. Patrick P. Gleason et al., *Dalfampridine Prior Authorization Program: A Cohort* Study, 19 J. Managed Care Pharmacy 18, 18–19 (2013). Accordingly, some pharmacy benefit plans require prior authorization before dalfampridine is covered, to reduce use of the medication by patients for whom it will not be effective or for whom it will pose an excessive seizure risk. *Id.* at 19. Analysis of plan data has demonstrated that this prior authorization

requirement both improved patients' safety and reduced dalfampridine costs. *Id.* at 22.

A final example is rosiglitazone, a medication that evidence shows is effective for the management of type 2 diabetes, but which can exacerbate congestive heart failure when used concurrently with nitrates or insulin. Catherine I. Starner et al., *Rosiglitazone Prior Authorization Safety Policy: A Cohort Study*, 18 J. Managed Care Pharmacy 225, 226 (2012). Analysis of medication usage by patients has demonstrated that a prior authorization requirement for rosiglitazone tied to a patient's concurrent use of nitrates or insulin leads to a significant decrease in unsafe use of rosiglitazone, without any long-term harm to patients' overall treatment. *Id.* at 229–31.

As these examples demonstrate, by designing benefit plans to implement the procedural requirement of prior authorization where medical evidence supports that additional step, pharmacy benefit plans and the PBMs administering them have improved patient outcomes, ensured appropriate use of medications, and reduced costs. Of course, if evidence does not support the use of prior authorization—if a prior authorization requirement is put in place unnecessarily—that requirement could potentially have adverse consequences, such as imposing avoidable burdens on physicians and impeding patients' access to drugs. See Neil J. MacKinnon & Ritu Kumar, *Prior Authorization Programs: A Critical Review of the Literature*, 7 J. Managed Care Pharmacy 297, 297–98 (2001). Thus, managed care pharmacy professionals must evaluate the available medical evidence to identify those medications for which prior authorization is appropriate. Where prior authorization requirements are well designed to "direct prescribers to follow

evidence-based clinical practice," they can not only reduce costs, but also improve patient outcomes and quality of life. *Id.* at 301–02.

Step therapy. Step therapy, a variant of prior authorization, likewise promotes better outcomes at reduced cost when it is carefully designed to reflect medical evidence. Step therapy is the practice of beginning drug therapy for a medical condition with the safest and most cost-effective drug, and "stepping up" to alternative drugs only when the initial therapy fails. The purpose is to avoid situations where a patient is prescribed a "needlessly expensive" or clinically unproven drug when a safer or "less costly" drug "would be an equal or better choice." Michael A. Fischer & Jerry Avorn, *Step Therapy—Clinical Algorithms, Legislation, and Optimal Prescribing*, 317 J. Am. Med. Ass'n 801, 801 (2017) (citing a study showing that one-third of diabetes patients were not prescribed metformin, an inexpensive medication that is the first step recommended by all major guidelines).[2] If a provider indicates that the first-step medication was ineffective or caused adverse side effects for a particular patient, coverage is authorized for the "step up" option.

Evidence shows that step therapy, too, improves outcomes and appropriate medication use while also reducing costs. For example, one study established

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[2] Indeed, the Centers for Medicare & Medicaid Services recently provided Medicare Advantage plans the option to implement step therapy for physician-administered and other Part B drugs as a way to both lower costs and improve overall quality of care. *Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs*, Ctrs. for Medicare & Medicaid Servs. (Aug. 7, 2018), https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

that step-therapy programs for two of the most commonly used classes of medications—proton pump inhibitors and nonsteroidal anti-inflammatory drugs—led to reduced costs without any increase in use of other related medical services. Brenda R. Motheral, *Pharmaceutical Step-Therapy Interventions: A Critical Review of the Literature*, 17 J. Managed Care Pharmacy 143, 150 (2011). Another study found that step-therapy programs for angiotensin receptor blockers, used to treat hypertension, resulted in antihypertensive drug therapy cost savings of 13% per day. Krista Yokoyama et al., *Effects of a Step-Therapy Program for Angiotensin Receptor Blockers on Antihypertensive Medication Utilization Patterns and Cost of Drug Therapy*, 13 J. Managed Care Pharmacy 235, 239–40 (2007). And a third study determined that step-therapy intervention requiring patients to first utilize a generic antidepressant reduced average cost per day by 9% without any adverse effect to patients' overall utilization of antidepressant medications. Jeffrey D. Dunn et al., *Utilization and Drug Cost Outcomes of a Step-Therapy Edit for Generic Antidepressants in an HMO in an Integrated Health System*, 12 J. Managed Care Pharmacy 294, 298 (2006).

As with prior authorization more generally, poorly designed or unsupported step therapy requirements can have unintended adverse consequences. "[I]f based on poor evidence or implemented inflexibly, the approach can cause clinical problems." Fischer & Avorn, *supra*, at 801–02. But "[w]hen conceived and implemented intelligently," using "evidence-based criteria, with clinically appropriate and reasonable provisions for exceptions," step therapy "encourage[s] more rational prescribing and help[s] control

medication costs, while ensuring that patients are receiving the most data-driven regimens." *Id.* at 801.

Population Health–Driven Utilization Management. Finally, managed care pharmacy professionals work to determine how to maximize patients' adherence to critical medications. In this regard, management of hepatitis C medications shows the benefits of managed care pharmacy—and the harms that can follow when state laws constrain the use of managed care pharmacy strategies. Recent medical advances offer new medication-based hepatitis C treatment regimens, with higher cure rates, fewer adverse effects, and a shortened treatment period. See Shellie L. Keast et al., *Assessment of the Effect of an Enhanced Prior Authorization and Management Program in a United States Medicaid Program on Chronic Hepatitis C Treatment Adherence and Cost*, 58 J. Am. Pharmacists Ass'n 485, 485 (2018). Not surprisingly, however, these new medications are costly. *Id.* Accordingly, in order to achieve the significant outcome benefits these new treatments provide—in terms of both cost-effective management and increased cure rates—patient adherence and successful treatment completion is essential. *Id.* at 490. A 2018 study highlights the positive impact utilization management strategies can have towards achieving these goals.

The study compared outcomes in two patient cohorts: one for which no pharmacist management of hepatitis C medications occurred because an Oklahoma law barred such management, and one for which an enhanced prior authorization and management program was put in place. *Id.* at 486–87. The program included a contract under which each individual pharmacy agreed to counsel members and provide consistent follow-up by pharmacists to

improve adherence. *Id.* at 487. The results were clear: the prior authorization and management program significantly improved adherence to the treatment protocol and decreased treatment gaps while also decreasing overall pharmacy-related treatment costs for the payer. *Id.* at 489–90. Although this meant increased medication costs at the outset, the result was better outcomes for patients and lower long-term costs. *Id.*

The prior authorization and management program used in hepatitis C treatment discussed above is just one example of how a managed care pharmacy program can vastly improve population-wide health. Such programs—by, for example, providing a mechanism to monitor for proper adherence—encourage managed care pharmacy professionals to develop, implement, and take advantage of the long-term cost saving potential and enormous outcome benefits that innovative, but expensive, drug regimens permit. Of course, the form of population-wide utilization programs, and the circumstances in which they apply, matter: some will offer greater benefits and cost-savings than others. Managed care pharmacy professionals thus must evaluate population-based medical evidence to determine how to allocate resources, and to whom, when crafting these strategies.

II. RELAXING THE SCOPE OF ERISA PREEMPTION TO AUTHORIZE ACT 900 WOULD PUT EFFECTIVE MANAGED CARE PHARMACY STRATEGIES LIKE THESE AT RISK.

Experience and data confirm that effective managed care pharmacy requires a delicate balance: pharmacy benefit plans must "deal with rising drug costs," on the one hand, while on the other hand "not denying or

limiting access to those drugs that improve therapeutic outcomes and health-related quality of life." MacKinnon & Kumar, *supra*, at 297. Pharmacy benefit plans can and have achieved this balance through careful use of evidence-based plan design to direct patients into the highest-value, safest, and most cost-effective medication programs.

Unfortunately, intrusion by state and local governments into ERISA-covered pharmacy benefit plans threatens to tip the scales. Arkansas's Act 900 is a clear example, as it impermissibly dictates plan sponsors' choices about how to design pharmacy benefit plans, and disrupts the balance that plans and PBMs have negotiated between reducing costs and maintaining broad access to medications. If Act 900 is permitted to stand, further state intrusions into ERISA-governed pharmacy benefit plans may follow—undercutting the success that managed care pharmacy professionals have achieved in designing and deploying effective utilization management tools. Managed care pharmacy professionals will be forced to spend time and resources on ensuring compliance with disparate state regulations, offsetting the cost-benefits of these population-based utilization management programs, or, perhaps, discouraging their development altogether.

A. Act 900 Impermissibly Regulates Plan Administration.

MAC pricing is another tool that pharmacy benefit plans and the PBMs that administer them use to encourage the appropriate, cost-effective use of generic drugs while promoting the affordability of pharmacy benefits. The use of MAC pricing reduces health care costs in multiple ways. When pharmacies are paid a fixed amount rather than based on their cost, pharmacies have a greater incentive to dispense lower-

cost generic drugs rather than higher-cost brand-name drugs that are no more effective. JA150; Office of Inspector General, Dep't of Health & Human Servs., OEI-03-11-00640, *Medicaid Drug Pricing in State Maximum Allowable Cost Programs* 4–5 (Aug. 2013), https://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf. And where pharmacies receive a fixed rather than cost-based reimbursement, they also have a greater incentive to purchase generic drugs at the lowest possible price, which in turn encourages price competition among generic drug manufacturers and drug wholesalers. JA151. And moreover, the use of MAC pricing results in increased efficiency and predictability for pharmacy benefit plans because costs are clear in advance. That is why both public and private payers use MAC lists as a means of achieving the goals of managed care pharmacy. See Resp. Br. 13.

Attempting to avoid the force of ERISA's broad preemption provision, petitioner and its *amici* seek to minimize the impact of Act 900 on the administration of health benefit plans, describing it as mere "rate regulation." *E.g.*, Pet'r Br. 14 (asserting that Act 900 "regulates drug reimbursement rates and provides mechanisms for enforcing that rate regulation," which are said to be "necessary incidents of Arkansas's system of rate regulation"). The *amici* pharmacist associations likewise assert that "[t]he focus of this litigation is on laws regulating the rates at which PBMs reimburse pharmacies," which the pharmacists assert do not "regulate[] plan administration." Br. of Arkansas Pharmacists Association et al., as *Amici Curiae* 21.

But Act 900 is far more intrusive on pharmacy benefit plan administration than would be a mere regulation of prices. See Resp. Br. 22–26. Act 900 works not by imposing specified rates, but by setting

detailed, Arkansas-specific standards for the structure and administration of ERISA-governed plans, specifically related to MAC pricing schemes. It requires disclosure of detailed plan information to pharmacies, Ark. Code Ann. § 17-92-507(c)(1); it sets specific criteria and timelines by which plans (and the PBMs acting as their agents) must update their MAC lists in response to pharmacies' asserted acquisition costs, *id.* § 17-92-507(c)(2); it dictates detailed appeal procedures that plans must establish for pharmacies to challenge MAC list rates and particular claim reimbursements, *id.* § 17-92-507(c)(4)(A); it requires plans to permit the reversal or rebilling of claims when the MAC list rate is less than the pharmacy's acquisition cost, *id.* § 17-92-507(c)(4)(C)(iii); and it permits a pharmacy to refuse to serve a plan participant altogether if the pharmacy concludes that the MAC list rate is below the pharmacy's acquisition cost, *id.* § 17-92-507(e). These requirements do substantially more than regulate rates: they regulate the conduct of PBMs, the plans that PBMs serve, and the administration of plan benefits overall.

What is more, Arkansas's Act 900 is just one of the many state-specific regulations that interfere with the design of pharmacy benefit plans and undercut nationally uniform plan administration. See Resp. Br. 27–31 (collecting disparate state laws addressing the administration of prescription-drug benefits on behalf of ERISA-governed plans); Emma J. Chapman, Am. Health Lawyers Ass'n, *Pharmacy Maximum Allowable Cost (MAC) Laws: A 50 State Survey* (2017), http://garnerhealth.com/wp-content/uploads/2014/02/Final_AHLA_Pharmacy_MAC_50_State_Survey.pdf (detailing the varied state requirements related to MAC pricing); Br. of State of California et al., as *Amici Curiae* 33 (acknowledging that "States have taken

different approaches to regulating PBMs"). Thus, pharmacy benefit plans and PBMs not only must comply with state regulations that intrude on benefit plan design and administration, but also must do so *differently* in the many states that impose their own idiosyncratic forms of regulation.

This, of course, is exactly what ERISA's preemption clause aims to prevent. Because regulation of employee health benefit plans is "exclusively a federal concern," *Aetna Health, Inc.* v. *Davila*, 542 U.S. 200, 208 (2004), ERISA preempts any state law that "has an impermissible 'connection with' ERISA plans, meaning a state law that 'governs … a central matter of plan administration' or 'interferes with national uniform plan administration.'" *Gobeille* v. *Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (quoting *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 148 (2001)). ERISA's preemptive scope serves to promote uniformity and to enable health benefit plans, including the PBMs that administer their pharmacy benefits, to maximize value for plan beneficiaries without having to negotiate disparate local requirements. See *id.* (ERISA "seeks to make the benefits promised to an employer more secure by mandating certain oversight systems and other standard procedures").

Congress recognized that plan administration includes a host of obligations. These include, for example, "determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements." *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 9 (1987). "The most efficient way to meet these responsibilities is to establish a uniform administrative scheme, which provides a set of standard procedures to guide

processing of claims and disbursement of benefits." *Id.* But "if a benefit plan is subject to differing regulatory requirements of differing States," the goal of uniformity would be "difficult to achieve." *Id.*; see also *Gobeille*, 136 S. Ct. at 944 ("Requiring ERISA administrators to master the relevant laws of 50 states and to contend with litigation would undermine the congressional goal of minimizing the administrative and financial burden on plan administrators—burdens ultimately borne by the beneficiaries." (alterations omitted) (quoting *Egelhoff*, 532 U.S. at 149–50)); *N.Y. State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U.S. 645, 656–57 (1995) ("[T]he goal was to minimize the administrative and financial burdens of complying with conflicting directives among States … requiring the tailoring of plans and employer conduct to the peculiarities to the law of each jurisdiction." (quoting *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142 (1990))).

Nor is it any answer that—as *amici* the United States and American Medical Association argue—Act 900 applies "only to PBMs, not to ERISA plans." Br. of Am. Medical Ass'n et al., as *Amicus Curiae* 13; see also Br. of United States as *Amicus Curiae* 27 (Act 900 "imposes obligations on PBMs, not plans"). This purported distinction is illusory. To begin, it does not exist in the statute, which governs pharmacy benefit plans administering their own benefits and PBMs alike. See Resp. Br. 46–47. And regardless, a regulation that governs the reimbursement strategies that a PBM may use is neither more nor less than a regulation of the administration of benefits on behalf of a plan. When a pharmacy benefit plan contracts for the administration of its plan by a PBM that uses MAC pricing (or other managed care pharmacy tools), the

plan is selecting the PBM's MAC-based reimbursement system to be *the plan's* "system for processing claims and paying benefits." *Egelhoff*, 532 U.S. at 150; see also Resp. Br. 38. As the D.C. Circuit explained in holding a similar regulation preempted under ERISA, statutes like Act 900 that impose significant restrictions on PBMs "bind plan administrators because the 'choice' they leave an [employee health benefit plan] between self-administration and third-party administration of pharmaceutical benefits is in reality no choice at all." *Pharm. Care Mgmt. Ass'n* v. *District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010).

B. Managed Care Pharmacy Professionals Should Be Permitted To Develop Tools For Patient Outcomes And Management Of Costs Without The Constraint Of Disparate State Regulation.

The state-specific restriction on plan benefit design and administration embodied in Arkansas's Act 900 is an impermissible intrusion into the administration of ERISA-governed pharmacy benefit plans. This Court should make clear that ERISA preemption excludes states from imposing state-specific requirements on the administration of ERISA-governed pharmacy benefit plans—and that managed care pharmacy strategies that plans and PBMs implement to reduce costs while improving population outcomes are free from state regulation. In particular, without ERISA's guarantee of uniform standards, managed care pharmacy professionals would be severely compromised in their ability to develop and deploy evidence-based utilization management tools to improve patients' health outcomes at the lowest possible costs.

The importance of uniformity in benefit plan regulation—and the costs that multifarious state regulation would impose—is particularly clear in connection with the design and deployment of utilization management tools. A critical goal of managed care pharmacy is to improve health at the *population* level as well as the individual level—including through the utilization management programs that marshal population-level evidence to design benefit plans to direct all patients to the drugs that will treat their medical needs most effectively and at the lowest cost. These practices cannot improve population-level outcomes unless they can be designed and deployed as to the entire population. If patients in different states must be treated differently as a result of local regulations, then evidence-based interventions to improve population-level outcomes will be curtailed.

In addition, the guarantee of uniformity that ERISA provides with respect to administration of covered pharmacy benefit plans incentivizes the development of evidence-based utilization management tools. As detailed above, managed care pharmacy professionals must precisely calibrate tools like prior authorization and step therapy based on the unique risks, costs, and benefits of specific medications as they are used by specific populations. See, *e.g.*, Wilkins, *supra*, at 641. To be effective, such tools must be designed based on the managed care pharmacy professionals' continuous evaluation of the evidence of a medicine's effectiveness and side effects, and must carefully balance a medicine's cost and safety risks against the benefit that a medication may provide for an individual patient. See *id.* at 643 (managed care pharmacy organizations "have the responsibility and opportunity to incorporate clinical and technology advancements into these processes with a constant goal of improving

health outcomes and cost-effectiveness"). ERISA's guarantee of uniform rules—free from potentially inconsistent regulations imposed by different state legislatures that may be responding to different economic interests—permits the experimentation and evaluation necessary to develop and improve such programs, and ultimately, improve patient care overall.

Outside the context of ERISA-governed health plans, states already regulate population-wide utilization management programs. Unlike self-insured health benefit plans, fully insured plans *are* subject to state and local regulations, which in that context *are not* preempted by ERISA. See 29 U.S.C. § 1144(b)(2); *Metro. Life Ins. Co.* v. *Massachusetts*, 471 U.S. 724, 738–47 (1985). This leads to a substantial difference in cost: because self-funded benefit plans do not need to comply with a patchwork of state and local laws restricting potential cost-saving measures, they face lower administrative expenses than fully funded plans. *See* The Alliance, *When You're Considering Self-Funding* 4 (Aug. 2014), https://the-alliance.org/wp-content/uploads/2017/08/WhenYoureConsideringSelf Funding_whitepaper.pdf.

State-level regulation of step therapy provides a clear illustration of the flaws in a scheme whereby states are permitted to engage in disuniform regulation of the administration of pharmacy benefit plans. Several states have enacted legislation directed to the use of step therapy programs outside the context of ERISA-governed plans. See Sharona Hoffman, *Step Therapy: Legal and Ethical Implications of a Cost-Cutting Measure*, 73 Food & Drug L.J. 38, 53 (2018) ("As of mid-2017, 14 states had passed legislation addressing step therapy, and at least 12 others had bills under consideration." (footnote omitted)). But

legislative measures are not well suited to the complex considerations that go into the development of an effective step therapy plan.

As detailed above, step therapy systems are medication- and population-specific: they turn on detailed analysis of the evidence as to safety and effectiveness of available medications as used by particular populations of patients to determine whether more cost-effective or safer, "lower-step" medications should be tried. Thus, to be "[d]one well," step therapy must be based on careful consideration of both medical and economic factors. Fischer & Avorn, *supra*, at 802. Given the complexity of this balance for any particular drug, step therapy is not susceptible to broad-based legislative efforts, especially on a state-by-state basis. That is because "[i]t is unlikely that legislators, by pulling one available lever in a complex system, can improve the rationality and affordability of prescribing. It will be difficult to implement such policies through laws and still respect the clinical and economic nuances that should ideally be driving optimal prescribing." *Id.* Instead, "[l]aws to restrict the use of a single cost-containment approach only add complexity …, without clearly addressing the real problems with prescribing." *Id.* The benefits of step therapy are best achieved when pharmacy benefit plans are "allowed to enact reasonable evidence-based policies to avoid needless expenses incurred by suboptimal prescribing practices, often driven by intense marketing to prescribers and patients (and now, to legislators)." *Id.*

While these laws are not at issue in the instant case, they present another example of the respect in which state-specific regulation can interfere with the design and administration of ERISA-governed self-insured health benefit plans, ultimately harming beneficiaries

in the form of less specialized and effective treatment as well as high costs. Managed care pharmacy professionals that develop and refine step therapy protocols for health benefit plans rely on current scientific, medical, and pharmaceutical treatment evidence and guidelines. They must therefore retain flexibility to make and continuously update judgments based on the evolving body of evidence before them. This is best accomplished by "ongoing efforts and collaboration among payers, prescribers, pharmacists, and patient groups to ensure that solutions meet the needs of all stakeholders." *AMCP Partnership Forum: Optimizing Prior Authorization for Appropriate Medication Selection*, 26 J. Managed Care & Specialty Pharmacy 55, 60 (2020). And these efforts are ongoing. See Patrick P. Gleason, Commentary, *Assessing Step-Therapy Programs: A Step in the Right Direction*, 13 J. Managed Care Pharmacy 273, 274 (2007) (discussing "ongoing assessment … of PBM utilization management programs"). If state legislators impose static regulations that are not targeted to specific medications and populations, the health and cost benefits that step therapy has been shown to provide will be lost.

And the costs of such legislation are exacerbated when different states impose different rules. Significantly worse than bending medication- and population-specific step therapy protocols to meet one set of legislative edicts, managed care pharmacy professionals facing a panoply of state regulations would be compelled to develop and implement different strategies in different states to meet each state's rules. Such a system has inherent administrative inefficiencies: Compliance costs will be significant, offsetting the cost-related benefits of these strategies and ultimately increasing health care costs

overall. Moreover, a patchwork of state regulations also limits the ability to evaluate the effectiveness of any given strategy across a population. Indeed, some states' requirements could even preclude entirely the use of a utilization management program that has been shown both to improve health outcomes and reduce costs—thus depriving patients and pharmacy benefit plans of the most effective tools. This is directly contrary to "[o]ne of the principal goals of ERISA": "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*, 532 U.S. at 148 (quoting *Fort Halifax*, 482 U.S. at 9).

CONCLUSION

To ensure the fulsome development and deployment of managed care pharmacy strategies, this Court should reiterate that ERISA preempts state regulation of ERISA-governed pharmacy benefit plans. The decision below should be affirmed.

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April 1, 2020

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