No. 25-5416

IN THE

United States Court of Appeals for the Sixth Circuit

MCKEE FOODS CORP.,

Plaintiff-Appellee,

v.

BFP INC.,

Defendant,

&

CARTER LAWRENCE,

Defendant-Appellant.

On Appeal From a Final Judgment of the District Court for the Eastern District of Tennessee, No. 1:21-cv-279

BRIEF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, AND TENNESSEE PHARMACISTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 25-5416 Case Name: McKee Foods Corp. v. BFP Inc.

Name of counsel: Robert T. Smith, Katten Muchin Rosenman LLP

Pursuant to 6th Cir. R. 26.1, National Community Pharmacists Association, American Pharmacists Association, and Tennessee Pharmacists Association
Name of Party

makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

No

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome? If yes, list the identity of such corporation and the nature of the financial interest:

No

CERTIFICATE OF SERVICE

I certify that on August 5, 2025 the foregoing document was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record.

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This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

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STATEMENT OF INTEREST OF *AMICI CURIAE*[*]

Amici curiae represent the interests of independent community pharmacies. The National Community Pharmacists Association represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the country. The American Pharmacists Association is the voice for pharmacists across all practice settings, including its over 40,000 member pharmacists, scientists, student pharmacists, and technicians. And the Tennessee Pharmacists Association represents similar interests at the state level.

This litigation involves a challenge to several provisions of Tennessee law that, like the laws of nearly all states, regulate the goods and services that pharmacy benefit managers (PBMs) may sell to health benefit plans, and how PBMs transact business with pharmacies. Because PBMs profoundly affect patient access to pharmacy care, and because Tennessee's law seeks to regulate certain business practices of PBMs that have restricted patient access, *amici* have a strong interest in the outcome of this case.

[*] No counsel for any party authored this brief in whole or in part. No party, person, or entity except *amici* made a monetary contribution specifically for the preparation or submission of this brief.

INTRODUCTION

McKee Foods Corporation claims that the Employee Retirement Income Security Act of 1974 (ERISA) preempts two types of provisions of Tennessee law. The provisions at issue regulate pharmacy networks that PBMs sell to prescription-drug benefit plans, including both ERISA-regulated and non-ERISA plans: (1) Tennessee's "any willing provider" laws, which prohibit PBMs from denying access to PBM-constructed pharmacy networks for pharmacies that agree to abide by the PBM's generally applicable terms for its networks (AWP Provisions), and (2) Tennessee's laws prohibiting PBMs from offering inducements or penalties to steer customers to certain pharmacies over others (Anti-Steering Provisions) (together, the Challenged Provisions).

In its opening brief, the State explains persuasively why the Challenged Provisions do not "relate to" ERISA-regulated plans within the meaning of ERISA's express preemption clause. State Br. 29-41. In particular, the State explains that the Challenged Provisions do not have any "connection with" ERISA plans because they do not bear on eligibility determinations or force plans to adopt any scheme of substantive coverage. *Id.* at 32-41.

This brief does not repeat those arguments. Instead, *amici* focus on two threshold issues that provide alternative bases for reversing the judgment below—issues that arise from the unique status of PBMs as mere service providers to ERISA-regulated plans:

First, McKee lacks standing to pursue this action. McKee sponsors a self-funded ERISA plan, but the plan does not maintain its own pharmacy network; rather, McKee's plan purchases pharmacy access from a third-party PBM. Yet in this instance, Tennessee's law regulates only the PBM-pharmacy network that McKee purchases from its PBM. McKee's PBM has not challenged the law on its own behalf. And purchasers of regulated services do not have standing to challenge the regulation of those services absent a showing that McKee has not attempted to make here.

Second, even if this Court were to reach the merits, the Challenged Provisions do not "relate to" ERISA plans in the first instance, obviating the need to determine whether the law bears on eligibility determinations or substantive benefits. The Supreme Court has clarified that the state laws that regulate only insurers and other service providers (like PBMs) do not raise any preemption concerns under ERISA: "'laws that regulate only the insurer, or the way in which it may sell insurance,'" do not "relate to" ERISA plans

"'in the first instance.'" *N.Y. Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 663-64 (1995). And that outcome makes sense. ERISA has nothing to say about state efforts to regulate third parties that happen to sell goods and services to ERISA-regulated plans.

Finally, *amici* reinforce the State's position that, even if the Challenged Provisions "relate to" ERISA plans, they are saved from preemption as applied to PBMs under ERISA's insurance-savings clause, 29 U.S.C. § 1144(b)(2)(A). *See* State Br. 43-54. Notably, because ERISA's insurance-savings clause limits the scope of ERISA's preemption clause—a state law that "relates to" an ERISA-regulated plan is preempted "[e]xcept as provided in [the insurance-savings clause]," 29 U.S.C. § 1144(a)—McKee had to prove that the Challenge Provisions both "relate to" ERISA plans and are not covered by the savings clause. McKee did not make that showing, which likewise warrants reversal.

BACKGROUND

Because this brief focuses on the unique role of PBMs in selling pharmacy-benefit services to benefit plans, it provides critical background on why PBMs are not subject to regulation under ERISA, the abusive business practices that PBMs have pursued in the absence of meaningful

regulation, and the specific subset of abusive practices that the Challenged Provisions were enacted to address. It also highlights aspects of the record that show McKee is pursuing claims on behalf of its third-party PBM, which is in turn relevant to the legal issues discussed below.

A. The federal government generally does not regulate PBMs.

Through ERISA, the federal government regulates certain private-employer and union-sponsored benefit plans. 29 U.S.C. § 1003. But because of their unique status, PBMs are not subject to regulation under ERISA.

PBMs are *not* benefit plans. Rather, benefit plans hire PBMs as service providers that sell plans access to prescription drugs through separate contracts that PBMs maintain with pharmacies. *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 83-84 (2020).

Although ERISA regulates plan "administrators" and "fiduciaries," PBMs are neither. An ERISA administrator is a specifically designated fiduciary. 29 U.S.C. § 1002(16)(A); 29 C.F.R. § 2509.75-8(D-3). And as a general matter, an ERISA fiduciary must exercise "discretionary authority," "control," or "responsibility" over the management or administration of a plan or its assets. 29 U.S.C. § 1002(21)(A). But PBMs do none of these things, leading every court to consider the issue to hold that PBMs are not

fiduciaries (and hence, not administrators). *E.g.*, *Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 473 (7th Cir. 2007) (holding that PBMs are not ERISA fiduciaries); *PCMA v. Rowe*, 429 F.3d 294, 300-01 (1st Cir. 2005) (same), *cert. denied*, 547 U.S. 1179 (2006).

Rather, PBMs are service providers that "have no power to make any decisions as to plan policy, interpretations, practices or procedures." 29 C.F.R. § 2509.75-8(D-2). They are governed by state law—like every other service provider that sells goods or services to ERISA and non-ERISA plans.

"[S]ervice providers" become "liable" under ERISA only "when they cross the line from advisor to fiduciary." *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993). In *Pegram v. Herdich*, for example, the Supreme Court held that an HMO-employed physician who cared for an ERISA beneficiary was not liable under ERISA because he was not a fiduciary, but that physician could be held liable through a state-law malpractice action. 530 U.S. 211, 231, 236 (2000).

Similarly, some lower courts have held that a non-fiduciary may be liable under ERISA if it violates that statute while acting as an agent of an ERISA plan. *E.g.*, *Kollman v. Hewitt Assocs., LLC*, 487 F.3d 139, 148 (3d Cir. 2007). But in that situation, the agent is held accountable for actions it has

taken on behalf of its principal, an ERISA fiduciary, in violation of ERISA. *Id.* A PBM, in contrast, does not act as an agent of an ERISA fiduciary in the "administration of its own business as a PBM." *Moeckel v. Caremark, Inc.*, 622 F. Supp. 2d 663, 677 (M.D. Tenn. 2007).

The Supreme Court has extended this logic to ERISA's preemption clause. Thus, in *Rutledge*, which involved an ERISA challenge to an Arkansas law that regulates PBMs, the Court emphasized that "state law" governs the goods and services that plans, as market participants, purchase for their beneficiaries. 592 U.S. at 89-91. In contrast, in *Gobeille v. Liberty Mutual Insurance Co.*, the Court held that ERISA preempted a state law that compelled a third-party ERISA plan "administrator" to disclose "detailed information about claims and plan members" on behalf of an ERISA plan. 577 U.S. 312, 317, 323 (2016).

B. PBMs have engaged in business practices that harm plans, patients, and pharmacies.

Because PBMs owe fiduciary duties only to their shareholders, not the plans that they purport to serve, PBMs have incentives to engage in business practices that can harm plans, patients, and pharmacies. In the absence of regulation, PBMs have done just that.

PBMs have leveraged their market power—the three largest PBMs cover nearly 80% of all Americans with prescription-drug benefits, *see* Fed. Trade Comm'n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* 13 (July 2024)[1]—to capture a share of the retail pharmacy market by giving preferences to their own affiliated pharmacies. For example, PBMs have steered patients to PBM-affiliated pharmacies by offering lower copayments and other inducements—and this is particularly true for more-costly specialty medications. *See* Fed. Trade Comm'n, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers*, at 2 (Jan. 2025).[2] These PBM practices may cost beneficiaries less out of pocket in the form of copayments and coinsurance, but the PBMs make up for this by charging plans substantially more. The three largest PBMs reimbursed their affiliated pharmacies more than 100 percent over their estimated acquisition cost on 63 percent of the specialty medications they dispensed, and for 22

[1] https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.

[2] https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

percent of medications they reimbursed their affiliated pharmacies at a markup of more than *1,000 percent*. *Id.* at 10. For this and other reasons, the First Circuit recognized that "'[w]hether and how a PBM actually saves an individual benefits [plan] money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits [plan].'" *Rowe*, 429 F.3d at 298 (citation omitted).

In addition, PBMs have deliberately limited access to their pharmacy networks—not out of considerations of safety or costs to their prescription-benefit-plan clients, but to further steer patients to their affiliated pharmacies. The Centers for Medicare and Medicaid Services (CMS), for example, has long expressed concern that PBMs are using pharmacy contracts "in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies." *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 82 Fed. Reg. 56,336, 56,410 (Nov. 28, 2017).

The net result is decreased access to retail pharmacies, which, for many Americans, are their most accessible form of healthcare. *See* Reed Abelson & Rebecca Robbins, *The Powerful Companies Driving Local Drugstores Out of*

Business, N.Y. Times, June 21, 2024.[3] An independent study found abusive PBM practices drove more than 16% of independent rural pharmacies out of business. Abiodun Salako, *et al.*, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis 5 (July 2018).[4] That same study found from 2003 to 2018, PBM practices caused eight zip codes in Tennessee to lose their only pharmacy; one zip code to lose *all* its pharmacies; and another four zip codes to drop to a single pharmacy. *Id.*

C. Tennessee's laws address a subset of abusive PBM conduct.

Facing PBMs' growing threats to accessible care for Tennessee's citizens, the Tennessee Legislature enacted several anti-discrimination provisions in 2021 and 2022 to address a subset of abusive PBM business practices:

First, the AWP Provisions forbid PBMs from excluding a pharmacy from a preferred or non-preferred network "as long as the pharmacy is . . . willing to accept the same terms and conditions that the [PBM] has

[3] https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html.

[4] https://rupri.org/wp-content/uploads/2018-Pharmacy-Closures.pdf.

established for other pharmacies participating within the network." Tenn. Code Ann. § 56-7-3121(b); *id.* § 56-7-3121(a) (similar requirement).

Second, the Anti-Steering Provisions prohibit PBMs from "[o]ffer[ing] financial or other incentives" to "persuade [a] patient, participant, or beneficiary to utilize a pharmacy owned by or financially beneficial to" the PBM, *id.* § 56-7-3120(b)(2), and from charging a "different copayment obligation or additional fee, or provid[ing] any inducement or financial incentive, for using any pharmacy within a given network of pharmacies," *id.* § 56-7-3121(c).

D. McKee seeks relief on behalf of itself and its PBM.

McKee moved to enjoin enforcement of the Challenged Provisions, claiming ERISA preemption. Am. Compl., R.83 at 1078-79. But McKee's plan does not administer its own pharmacy network, *id.* at 1073; rather, McKee purchases access to a customized pharmacy network through a third-party PBM, MedImpact Healthcare Systems, *see* Plan Summary, R.118-1 at 1588, 1605-06, which is not a party to this litigation. Nevertheless, McKee sought declaratory relief and an injunction prohibiting the Commissioner of the Tennessee Department of Commerce and Insurance from enforcing the law

either as applied to McKee's plan or through its PBM. Am. Compl., R.83 at 1083.

The district court granted that relief. Opinion & Order, R.142 at 2232. It held ERISA preempts the Challenged Provisions as applied to self-funded plans *and* their PBMs and enjoined enforcement of the statutes to that extent. *Id.* at 2223 n.8, 2232.

ARGUMENT

I. McKee lacks standing to challenge the AWP and Anti-Steering Provisions.

The district court's injunction should be vacated because McKee does not have standing to support the relief it obtained. Although the Challenged Provisions apply to both third-party PBMs and self-insured plans, McKee does not maintain its own pharmacy network. Plan Summary, R.118-1 at 1588, 1605-06. Rather, its plan contracts with a third-party PBM to provide pharmacy access to the plan's beneficiaries. *See id.* Thus, the Challenged Provisions affect McKee's plan only indirectly; those provisions would apply to the PBM that services McKee's plan, and it is the PBM, not McKee, that would be subject to penalties for noncompliance.

Where, as here, "the plaintiff is not [it]self the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). "Under the rarely applicable 'third-party standing' exception," a plaintiff "rais[ing] a claim on behalf of a third party" may do so only "if [it] can prove '(1) injury-in-fact to the plaintiff, (2) a close relationship between the plaintiff and the third party whose rights he asserts, and (3) a hindrance preventing the third party from raising his own claim.'" *Lathfield Invs., LLC v. City of Lathrup Vill.*, 136 F.4th 282, 294 (6th Cir. 2025) (citation omitted).

Here, there is "no indication that [PBMs] face any obstacle in litigating their rights themselves." *Id.* Indeed, the PBMs' trade association, the Pharmaceutical Care Management Association (PCMA), is a serial litigant that typically takes the front line in seeking to nullify state PBM laws. *See, e.g.*, *PCMA v. Mulready*, 78 F.4th 1183 (10th Cir. 2023); *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021); *Rutledge*, 592 U.S. 80. Accordingly, McKee could not seek—and the district court should not have ordered—injunctive relief prohibiting enforcement of the provisions at issue as applied to the third-party PBM that services McKee's plan.

Although the district court concluded that "regulating PBMs functions as a regulation of an ERISA plan itself," Opinion & Order, R.142 at 2232 n.8. (cleaned up)—which is wrong on the merits, as discussed below—that reasoning would still fail to establish McKee's *standing* to enjoin enforcement against its non-party *PBM*. The "functional regulation" argument is deployed by PBM plaintiffs, as in *Mulready*, when PBMs are asserting their own rights but need to show some downstream relation to ERISA plans. 78 F.4th at 1195-96. PBMs are not plans, nor are they ERISA administrators or fiduciaries. McKee purchases services from MedImpact. Even if those services are bespoke, the relationship is one of vendor and vendee. And in this case, the State would be regulating the vendor, not the vendee.

Nor is this case like *Gobeille*. There, Vermont sought to subpoena *plan information* from the plan's third-party administrator. 577 U.S. at 318. The Second Circuit held that the plan had standing to challenge the subpoena. *Liberty Mut. Ins. Co. v. Donegan*, 746 F.3d 497, 502 (2d Cir. 2014). But in that situation, the State was regulating the plan through its third-party agent, and the plan had a duty to indemnify the administrator for any ensuing civil penalties for noncompliance. *See id.* Here, in contrast, the State is regulating the goods and services that PBMs can sell to plans, and there is no evidence

that McKee has any duty to indemnify MedImpact for any reason, let alone for how MedImpact has elected to structure its business as a PBM. In this way, McKee, as a customer of MedImpact, has no more standing to challenge PBM-directed laws than a customer of a cell phone carrier would have standing to challenge FCC regulations of that carrier's coverage network.

McKee also lacks standing to challenge the law as applied directly to its plan. Because McKee does not administer its own pharmacy network, Am. Compl., R.83 at 1073; Plan Summary, R.118-1 at 1588, 1605-06, and it has offered no evidence it plans to do so in the immediate future, McKee has not proven that it faces a "credible threat of enforcement" of the Challenged Provisions. *Davis v. Colerain Twp.*, 51 F.4th 164, 172 (6th Cir. 2022).

II. Even if McKee had standing, the Challenged Provisions, as applied to PBMs, do not "relate to" ERISA-regulated plans in the first instance.

Even assuming McKee could properly obtain relief on behalf of nonparty PBMs, however, the district court erred in concluding that, as applied to PBMs, the Challenged Provisions "relate to" ERISA-regulated plans in "'the first instance.'" *Travelers*, 514 U.S. at 663-64 (citation omitted).

As noted above, PBMs are neither plans nor plan "administrators," and they are not fiduciaries, either. This appeal concerns whether

Tennessee's laws nonetheless fall within the scope of ERISA's preemption clause, 29 U.S.C. § 1144(a), when they regulate PBMs as providers of pharmacy networks and other services.

ERISA's preemption clause provides that the provisions of ERISA supersede "'any and all State laws insofar as they may now or hereafter relate to any employee benefit plan' covered by ERISA." *Rutledge* 592 U.S. at 86 (quoting 29 U.S.C. § 1144(a)). As a gloss on this text, the Supreme Court has held that ERISA preempts state laws that have a "connection with" or "reference to" ERISA plans. *Id.* The Challenged Provisions are not preempted under either standard as applied to PBMs.

A. As applied to PBMs, the Challenged Provisions do not have an impermissible "connection with" ERISA plans.

A state law has a "connection with" ERISA plans when it "governs a central matter of plan administration or interferes with nationally uniform plan administration." *Rutledge*, 592 U.S. at 87 (citation omitted). "Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan." *Id.* As the Supreme Court has explained, ERISA is "primarily concerned" with preempting state laws that require employers to "structure

benefit plans in particular ways," such as by requiring employers to offer "specific benefits or by binding plan administrators to specific rules for determining beneficiary status." *Id.* (citations omitted).

The district court held that the Challenged Provisions satisfy this standard, relying heavily on *Mulready*, a recent Tenth Circuit decision. Both *Mulready* and the decision below, however, embrace a position that would substantially expand ERISA's preemptive reach into "areas where ERISA has nothing to say"—a prospect the Supreme Court has twice rejected as "'unsettling.'" *Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A.*, 519 U.S. 316, 330 (1997) (quoting *Travelers*, 514 U.S. at 665).

The fundamental failing of the district court's decision is conflating PBMs, which are *service providers*, with the *plan*. First, it held that the AWP Provisions are preempted because "the scope of an ERISA plan's provider network (in this case a pharmacy network) is a key aspect of plan administration: how the plan structures and designs its benefits." Opinion & Order, R.142 at 2219-20. These provisions "forc[e] *ERISA plans* to accept, as the name suggests, any willing provider" and function as a "*direct regulation* of benefit structure," *id.* at 2220 (emphasis added)—even to the

extent they apply to PBMs who are selling pharmacy-network access to plans, *id.* at 2223 n.8 (emphasis added).

Second, it held that the Anti-Steering Provisions "functionally mandate that ERISA plans charge plan participants the same copays and/or fees at all pharmacies in a given network"; "prevent an ERISA plan from designing and providing benefits in a way that the plan determines best serves participants"; and "dictate how the [McKee] Health Plan's copay obligations must be structured." Opinion & Order, R.142 at 2220-21.

Finally, it held that "[a]n[y] injunction must encompass action taken against McKee's PBM" because "regulating PBMs" is the "function[al]" equivalent of regulating "an ERISA plan itself." *Id.* at 2223 n.8 (quoting *Mulready*, 78 F.4th at 1188) (cleaned up). In support, it invoked *Mulready*'s belief that "[a] plan's choice between self-administering its benefits and using a PBM 'is in reality no choice at all[.]'" 78 F.4th at, 1195–96 (quoting *PCMA v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010)).

This analysis is wrong. As the Supreme Court recognized in *Rutledge*, a state law that regulates third-party PBMs does "*not directly regulate* health benefit plans at all, ERISA or otherwise." 592 U.S. at 88-89 (emphasis added). And there are good reasons for this distinction.

As discussed below, ERISA does not regulate the providers of goods and services to plans. It also does not purport to regulate the relationships between third-party providers—in this case, PBMs—and *other third parties*—in this case, pharmacies. And it certainly does not displace generally applicable state laws in areas, like these, "where ERISA has nothing to say." *Dillingham*, 519 U.S. at 330.

1. ERISA does not regulate third-party PBMs selling pharmacy-network services to plans.

The Supreme Court has held repeatedly that ERISA does not preempt state laws regulating the standards that apply to third parties who sell goods and services to ERISA plans. Instead, state law governs this relationship.

In *Travelers*, for example, the Court made clear that state laws that regulate only insurers—a common service provider to ERISA plans—do not raise any preemption concerns under ERISA: "'laws that regulate only the insurer, or the way in which it may sell insurance,'" do not "relate to" ERISA plans "'in the first instance.'" 514 U.S. at 663-64.

More recently, in *Rutledge*, the Court emphasized that an Arkansas law that regulates only PBMs—another service provider to ERISA plans—"d[id] not directly regulate health benefit plans at all, ERISA or otherwise." 592 U.S.

at 88-89. Just as importantly, the Court held that regulating the relationship between PBMs and pharmacies "does not require *plans* to provide any particular benefit to any particular beneficiary in any particular way." *Id.* at 90 (emphasis added).

As applied to PBMs, the Challenged Provisions are not meaningfully different from the Arkansas law at issue in *Rutledge*. True, Tennessee's provisions, like Arkansas's, limit the services "a plan might prefer that PBMs" are permitted to offer. *Rutledge*, 592 U.S. at 90. But insofar as they regulate the pharmacy networks that *PBMs sell* to plans, Tennessee's laws, like Arkansas's, do "not require *plans* to provide any particular benefit to any particular beneficiary in any particular way." *Id.* (emphasis added). They do not "force[] [ERISA] plans" to make any specific choices about which benefits to offer or who is eligible for coverage. *Id.* Rather, they regulate which services a PBM may offer and the rates a PBM may charge.

Ignoring this aspect of *Rutledge*, the district court followed *Mulready*'s lead in invoking *District of Columbia* to hold that state laws regulating PBMs "function[ally]" regulate ERISA plans. Opinion & Order, R.142 at 2223 n.8. In *District of Columbia*, the D.C. Circuit reasoned this was so because operating without a PBM is "a practical impossibility" that "would mean

forgoing the economies of scale, purchasing leverage, and network of pharmacies only a PBM can offer." 613 F.3d at 188.

This reasoning misses the mark for at least two reasons:

First, *District of Columbia* was decided before *Rutledge*, which emphasized that state PBM laws do "not directly regulate health benefit plans at all, ERISA or otherwise." 592 U.S. at 88-89. And although *District of Columbia* relied upon *dicta* from *Travelers* for its core conflation of PBMs and plans, it ignored the *holding* in *Travelers* that regulating third-party service providers like PBMs would not ordinarily give rise to ERISA preemption "'in the first instance.'" *Travelers*, 514 U.S. at 663-64. For this reason, in *Rowe*, the First Circuit reached a result opposite the D.C. Circuit's, holding that a Maine law that regulated PBMs did "'not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere.'" 429 F.3d at 301 (citation omitted).

Second, *District of Columbia*'s reasoning approaches the issue exactly backwards. The logic of that decision, which both *Mulready* and the district court adopted, reduces to this: because PBMs have grown in power and influence to become, in the view of some, indispensable to employee benefit plans, ERISA preemption now renders them *untouchable* by otherwise

permissible exercises of traditional state regulatory power. In effect, it allows PBMs to use the very thing whose consequence states are trying to regulate—excessive market power and extraordinary scale—to bootstrap themselves into immunity. That cannot be right, and indeed it is not.

The district court's reframing of *PBM* regulation as a regulation of *plans' "choices"* is fundamentally misguided and would lead to limitless preemption of generally applicable state regulations. For this reason, courts have wisely refused to measure ERISA preemption in these terms—otherwise, there would be no end to ERISA's preemptive reach.

In *Rutledge*, for example, the Supreme Court rejected PCMA's challenge to a law authorizing a pharmacy to decline to dispense a drug if a PBM is going to reimburse the pharmacy less than the pharmacy's cost to acquire the drug. 592 U.S. at 91; *see* Ark. Code § 17-92-507(e). The PBMs argued this provision "effectively denies plan beneficiaries their benefits" and rendered the pharmacy out of network for a particular drug. *Rutledge*, 592 U.S. at 91. But the Court held the law did not regulate "plan design" in any impermissible way, and it emphasized that "state-law mechanisms" govern the relationship between PBMs and pharmacies. *Id.* at 90-91.

And in *Rowe*, the First Circuit held that Maine could impose upon PBMs a fiduciary duty to the plans that they serve without triggering preemption by ERISA. 429 F.3d at 301. Because that law regulated PBMs, not plans, it did "'not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere.'" *Id.* (citation omitted).

Rutledge and *Rowe* defeat McKee's challenge here. If anything, the Challenged Provisions are less onerous than the state laws at issue in those cases. Arkansas dictated the amounts PBMs reimburse pharmacies. Maine imposed fiduciary obligations upon PBMs. Here, in contrast, PBMs are free to establish multi-tiered pharmacy networks, and they can require pharmacies to meet PBM-imposed standards to participate in those networks. They cannot, however, *discriminate* among pharmacies when inviting them to participate on the PBMs' terms, whether by denying access to the network or by showing special treatment to PBM-favored pharmacies.

To be sure, there are narrow circumstances where state laws regulating third-party providers have been found to "bear[] indirectly but substantially on all insured benefit plans" and thereby lead to a holding that they "relate[d] to" ERISA plans. *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724,

739 (1985); *see also Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 365 (2002). But those cases are critically distinguishable, and in each case, the law was saved from preemption in any event under the insurance-savings clause.

In *Metropolitan Life*, a Massachusetts "[m]andated-benefit law[]," which "require[d] an insurer to provide a certain kind of benefit to cover a specified illness or procedure," 471 U.S. at 728, was deemed to "relate to" ERISA plans as applied to insurance companies selling coverage to ERISA plans—but it was ultimately saved from preemption, *id.* at 739-47. The law "relate[d] to" ERISA because it "require[d] plans to purchase [] mental-health benefits . . . when they purchase[d] a certain kind of common insurance policy." *Id.* at 739. The plan could not choose what to cover and what not to cover—the law made that choice for them.

Here, by contrast, the Challenged Provisions make no substantive coverage decisions on plans' behalf, whether directly or indirectly. They regulate how PBMs interact and transact business with pharmacies and place restrictions on the services a PBM may offer a plan.

In *Rush*, the Court held that an Illinois law that regulated HMOs "relate[d] to" ERISA where it required plans "to submit to an extra layer of

review for certain benefit denials if they purchase medical coverage from any of the common types of health care organizations." 536 U.S. at 365. Notably, the parties did not seriously dispute whether the law "relate[d] to" ERISA-regulated plans; the primary issue was whether the law was saved by the insurance-savings clause—and the law was so saved. *Id.* at 365-73. In any event, because denying benefits is an action the *plan* ultimately takes with respect to its beneficiaries, the law "relate[d] to" ERISA because the HMO was effectively acting in its capacity as the plan's agent. And imposing an "extra layer of review" intruded directly into the plan's eligibility determinations—indisputably "a central matter of plan administration." *Rutledge*, 592 U.S. at 87.

The Challenged Provisions do nothing of the sort; they "regulate[ ] PBM administration, not ERISA plan administration." U.S. Pet.-Stage *Amicus* Br. 15, *Rutledge v. PCMA*, No. 18-540 (U.S. Dec. 4, 2019), 2019 WL 6609430. They therefore do not "relate to" ERISA in the first instance.

2. Neither *Nichols* nor *Miller* hold that an AWP law regulating PBMs' relationships with pharmacies has a forbidden "connection with" ERISA plans.

Having accepted the mistaken premise that regulating PBMs *is* regulating plans, the district court concluded that its hands were tied by this

Court's decision in *Kentucky Association of Health Plans, Inc. v. Nichols*, 227 F.3d 352, 358-61 (6th Cir. 2000), *aff'd sub nom Ky. Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003). That case also concerned an AWP law, but it is readily distinguishable.

As the State notes, *Nichols* ultimately held that Kentucky's AWP law was saved from preemption, so its discussion of whether the law "relates to" ERISA plans is arguably *dicta*. *See* State Br. 36-38. In any event, *Nichols* theorized that Kentucky's AWP law "relates to" ERISA-regulated plans principally because that law treated some ERISA plans differently than non-ERISA plans and therefore made an impermissible "reference to" ERISA plans. 227 F.3d at 358-61. By contrast, its discussion of "connection with" preemption only briefly set forth the standard and stated that, because the AWP law "affect[ed] the benefits available by increasing the potential providers" and "directly affect[ed] the administration of the plans," it effectively "mandate[d] employee benefit structures." *Id.* at 363.

Nichols' reasoning is questionable here—there is a vast leap from "affecting administration" to "mandating structure"—but regardless, *Nichols* did not consider, nor can it be construed to bar, a state's regulation of *third-party PBMs* in their capacity as providers of products and services.

In contrast, as applied to PBMs, the Challenged Provisions speak primarily to the relationships and agreements *between PBMs and pharmacies*. Construing ERISA to preempt this sphere of *PBM activity* would result in extending its preemptive force to a conceptually limitless degree. It ties the hands of state legislatures to regulate contracts, sales, and services within their borders in areas of traditional state concern.

Nor did the Supreme Court address these issues on appeal in *Nichols*: "Neither party sought review of [this Court's 'relate to'] holding." Reply Br. 2, *Ky. Ass'n of Health Plans, Inc. v. Miller*, No. 00-1471 (U.S. Dec. 9, 2002), 2002 WL 31789695. Instead, the parties disputed whether—and the Supreme Court decided only that—Kentucky's law was saved from preemption under ERISA's insurance-savings clause. *Miller*, 538 U.S. at 334-42.

As discussed below, the Challenged Provisions also would be saved by the insurance-savings clause. But in all events, *Nichols* has no bearing on the validity of the Challenged Provisions as applied to third-party PBMs.

3. The district court's reasoning would lead to limitless preemption of state regulation of third-party providers.

Accepting the district court's reasoning leads to radical results illustrating it *cannot* be correct. For example, a health plan may wish to

establish its own clinic or otherwise provide health benefits directly to beneficiaries—and it may decide that it is more cost-effective and efficient for all consultations to be held remotely and centralized at an out-of-state facility. A state, however, may decide that medical care provided within the state's borders must be provided by state-licensed providers, and it may pass a law requiring that remote-care network providers abide by that.

Like an AWP law, such a regulation would indirectly affect "how the plan structures and designs its benefits" by limiting the options available to it from third-party care networks. Opinion & Order, R.142 at 2220. This, too, would limit "plans' discretion to shape benefits as they see fit." *Id.*

But ERISA surely would not preempt the state's efforts to regulate remote health care—just as it would not preempt laws forbidding plans or PBMs from using unlicensed in-state professionals because they are cheaper. Nothing in ERISA empowers benefit plans to override generally applicable State "health care regulation." *Travelers*, 514 U.S. at 661.

There is no principled way to distinguish, on one hand, a state law setting standards for the quality of the care that health plans may purchase for their beneficiaries from, on the other, a state law, like this one, regulating the quality and composition of the pharmacy networks PBMs may sell to

health plans. Neither mandates substantive benefits; neither affects central matters of plan administration.

Nor does it matter that McKee has chosen to purchase a bespoke pharmacy network from its PBM. A state may, for example, regulate "medical-care quality standards" for services that providers offer without triggering preemption, *Dillingham*, 519 U.S. at 329—even if this results in limiting the services "a plan might prefer that PBMs" provide, *Rutledge*, 592 U.S. at 90. Indeed, the Supreme Court has emphasized repeatedly that ERISA does not preempt such generally applicable laws even if they "potentially affect[ ] the choices made by ERISA plans." *Dillingham*, 519 U.S. at 330. Thus, while a benefits plan may have specific *preferences* for a pharmacy network that a PBM cannot by law implement, this does not alter the underlying reality: regulations of network suppliers "do not directly regulate health benefit plans at all," *Rutledge*, 592 U.S. at 88-89, let alone "force[]" them "to provide any particular benefit to any particular beneficiary in any particular way," *id.* at 90.

Accordingly, the Challenged Provisions do not have a "connection with" ERISA plans. ERISA does not provide PBMs unrestricted license to engage in self-dealing to the detriment of patients, plans, and pharmacies.

B. The AWP and Anti-Steering Provisions do not impermissibly "refer to" ERISA plans.

Because it concluded the Challenged Provisions have a "connection with" ERISA plans, the district court found it unnecessary to reach whether they were preempted under the "reference-to" standard. Should this Court reach that question, however, it is clear the Challenged Provisions do not satisfy that test.

The Challenged Provisions indisputably *mention* ERISA plans. The terms "covered entity" and "pharmacy benefit manager" used in the Challenged Provisions are defined to include "[p]lans governed by the Employee Retirement Income Security Act of 1974," among nearly a dozen other things. Tenn. Code Ann. § 56-7-3102(1), (5). But reference-to preemption requires that a law "act[] immediately and exclusively upon ERISA plans" or "the existence of ERISA plans [be] essential to the law's operation." *Rutledge*, 592 U.S. at 88 (cleaned up). In other words, a "mere reference to an ERISA plan" is not enough unless it "singl[es] them out for different treatment." *Nichols*, 227 F.3d at 360 (citing *Mackey v. Lanier Collection Agency & Service, Inc.*, 486 U.S. 825, 830 n.4 (1988)).

The statutes do not act "immediately and exclusively" on ERISA plans; they merely include ERISA plans in a large category of "covered entities" or "pharmacy benefit managers." This also precludes a finding that "the existence of ERISA plans is essential to" the Challenged Provisions' "operation," because that test is satisfied "only if the law cannot apply to a non-ERISA plan." *Wehbi*, 18 F.4th at 969 (citing *Rutledge*, 592 U.S. at 89).

III. Even if the Challenged Provisions "relate to" ERISA plans, McKee has failed in its burden to show that they are not saved from preemption as applied to third-party PBMs.

Even assuming the Challenged Provisions *could* be said to "relate to" ERISA-regulated plans, however, they *are saved from preemption* as applied to PBMs by virtue of ERISA's insurance-savings clause. A state law "regulates insurance," 29 U.S.C. § 1144(b)(2)(A), if it (1) is "specifically directed toward entities engaged in insurance," and (2) "substantially affects the risk pooling arrangement between the insurer and the insured." *Miller*, 538 U.S. at 342. As the State persuasively explains, the Challenged Provisions do both. *See* State Br. 43-54. Indeed, the federal government took the same position in an *amicus* brief in *Mulready*. *See* U.S. *Amicus* Br. 17-22, *PCMA v. Mulready*, No. 22-6074 (10th Cir. Apr. 10, 2023), 2023 WL 2990378.

Rather than repeat the State's arguments for why the Challenged Provisions are saved from preemption as applied to third-party PBMs, *amici* note McKee's fundamental failure to carry its burden on this score. *See, e.g.*, *Wehbi*, 18 F.4th at 967 (proponent of ERISA preemption "bears the burden of proving preemption"). Contrary to the suggestion of the Tenth Circuit in *Mulready*, ERISA's insurance-savings clause is not an affirmative defense that the State can waive, *see* 78 F.4th at 1204-05; it is a co-equal component of plaintiff's burden to establish ERISA preemption.

Under ERISA's express preemption clause, State laws that "relate to" ERISA-regulated plans are preempted "[e]xcept as provided in subsection (b) of this section." 29 U.S.C. § 1144(a). And subsection (b) provides that, except for "an employee benefit plan" or "trust" subject to regulation under ERISA, "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." *Id.* § 1144(b)(2)(A), (B).

Thus, under the plain text of ERISA's preemption clause, McKee had to show two things: (1) that the Challenged Provisions "relate to" ERISA-regulated plans; and (2) that the Challenged Provisions are not laws "which

regulate insurance" as applied to third-party PBMs. 29 U.S.C. § 1144(a), (b)(2)(A). But McKee did not even attempt to make that latter showing here.

Accordingly, should the Court find that the Challenged Provisions "relate to" ERISA plans, then it should hold that McKee did not carry its burden under the savings clause as applied to third-party PBMs.

CONCLUSION

The Court should reverse the judgment of the district court for lack of standing or on the merits because ERISA does not preempt the Challenged Provisions as applied to McKee's third-party PBM.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure, I hereby certify that this brief is in compliance with the type form and volume requirements. Specifically, the brief is proportionately spaced; uses a Roman-style, serif typeface (Book Antiqua) of 14-point; and contains 6,497 words, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure.

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CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2025, I electronically transmitted a copy of the foregoing Brief to the Clerk of the Court using the Electronic Case Filing (ECF) system for filing. Service will be accomplished electronically through the ECF system to all registered participants.

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