No. 25-2494

IN THE

United States Court of Appeals for the Eighth Circuit

IOWA ASSOCIATION OF BUSINESS AND INDUSTRY, *et al.*,

Plaintiffs-Appellees,

v.

IOWA INSURANCE COMMISSIONER, Doug Ommen,

Defendant-Appellant.

On Appeal from the United States District Court
for the Southern District of Iowa, No. 25-cv-0211 (Stephanie M. Rose, C.J.)

BRIEF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, IOWA PHARMACY ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, AND INDEPENDENT PHARMACY COOPERATIVE AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT-APPELLANT AND AFFIRMANCE IN PART AND REVERSAL IN PART

Robert T. Smith
Timothy H. Gray
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20006
202-625-3500
robert.smith1@katten.com
timothy.gray@katten.com

Counsel for Amici Curiae

CORPORATE DISCLOSURE STATEMENT

Consistent with Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state that the National Community Pharmacists Association, Iowa Pharmacy Association, American Pharmacists Association, and Independent Pharmacy Cooperative each has no parent company, and no publicly traded company owns ten percent or more of any of *amici*'s stock.

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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 over 18,900 independent community pharmacies across the country; its members employ over 205,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions. The Iowa Pharmacy Association represents those same interests at the state level, including the interests of 293 Iowa pharmacies and 1400 Iowa pharmacists. The American Pharmacists Association represents pharmacists, student pharmacists, pharmacy technicians, and pharmaceutical scientists across the entire profession. And the Independent Pharmacy Cooperative is a group purchasing organization and secondary pharmaceutical wholesaler serving community pharmacies with over 2,000 member pharmacies.

The statute challenged in this litigation, Senate File 383 (SF 383), is principally directed to practices of pharmacy benefit managers (PBMs) that

[*] All parties consent to the filing of this brief. 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.

have harmed patient access and the continuing viability of independent pharmacies. Among other things, SF 383 regulates the services that PBMs may sell to health benefit plans, how PBMs transact business with pharmacies, the costs and rates PBMs may impose, and the information PBMs must disclose. *Amici*'s brief provides a uniquely helpful perspective because it represents the perspectives and interests of independent community pharmacies most directly affected by PBMs' practices and explains the reasons behind many of SF 383's provisions.

BACKGROUND

States have faced a crisis of access to pharmacy care within their borders, and according to numerous independent studies, PBMs are the chief culprits. Fed. Trade Comm'n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024).[1] In the last few decades, the business practices of PBMs have shuttered countless pharmacies—including in rural communities. *E.g.*, Abiodun Salako, *et al.*, *Update: Independently Owned Pharmacy Closures in Rural America,*

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

2003-2018, RUPRI Center for Rural Health Policy Analysis (July 2018)[2]; R.Doc.31-1 (Wiese Decl.) ¶¶ 6, 20-22.

In response, nearly all states have enacted laws regulating PBMs. The Iowa law at issue here regulates a subset of the business practices of PBMs that have inhibited safe, cost-effective, and convenient access to pharmacy care.

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 PBMs have pursued in the absence of meaningful regulation, and the specific subset of abusive practices that SF 383 was enacted to address.

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. *Rutledge v. Pharm. Care*

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

Mgmt. Ass'n, 592 U.S. 80, 83-84 (2020). PBMs deliver this access by contracting separately with pharmacies to create networks through which plan beneficiaries can fill their prescriptions. *Id.*

PBMs also are not "fiduciaries" under ERISA. As a general matter, a person must exercise "discretionary authority," "control," or "responsibility" over the management or administration of a plan or its assets to qualify as an ERISA "fiduciary." 29 U.S.C. § 1002(21)(A). PBMs do none of these things. Federal appellate courts are unanimous in holding that PBMs are not ERISA fiduciaries, because they do not exercise discretion or control over the administration of ERISA plans.[3]

Because PBMs do not qualify as ERISA fiduciaries, they cannot qualify as plan "administrators" under ERISA, either. An ERISA plan "administrator" is a specifically designated fiduciary. 29 U.S.C. § 1002(16)(A). "[A] plan administrator . . . must, [by] the very nature of his position, have 'discretionary authority or discretionary responsibility in the

[3] *Chi. Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463, 473 (7th Cir. 2007); *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 300-01 (1st Cir. 2005); *accord In re Express Scripts/Anthem ERISA Litig.*, 285 F. Supp. 3d 655, 680 (S.D.N.Y. 2018), *aff'd*, 837 F. App'x 44 (2d Cir. 2020); *Bickley v. Caremark Rx, Inc.*, 361 F. Supp. 2d 1317, 1332 (N.D. Ala. 2004), *aff'd*, 461 F.3d 1325 (11th Cir. 2006).

administration' of the plan." 29 C.F.R. § 2509.75-8(D-3) (citation omitted). PBMs, by contrast, are third-party service providers that may perform only "ministerial functions" on behalf of a plan. *Id.* § 2509.75-8(D-2). PBMs' status as non-fiduciaries means they "have no power to make any decisions as to plan policy, interpretations, practices or procedures." *Id.*

ERISA does not regulate the business practices of third-party providers that, like PBMs, sell goods and services to ERISA plans. Otherwise, ERISA would displace state laws regulating everything from doctors, accountants, and lawyers, to hospitals and insurers. *Cal. Div. of Lab. Standards Enforcement v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 329 (1997) ("[I]f ERISA were concerned with any state action—such as medical-care quality standards or hospital workplace regulations—that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, we could scarcely see the end of ERISA's pre-emptive reach, and the words 'relate to' would limit nothing.").

"[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. Herdrich*, for example, the Supreme Court held an HMO-employed physician who cared for an ERISA beneficiary was not

liable under ERISA because he was not a fiduciary; state malpractice law applied instead. 530 U.S. 211, 231, 236 (2000).

Similarly, some lower courts have held a non-fiduciary may be liable under ERISA if it violates ERISA 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 preemption cases. For example, 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 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.

The business model of some PBMs involves maximizing the difference between what they charge plans and what they pay pharmacies for access to prescription drugs. This so-called "spread-pricing" model has incentivized PBMs to engage in business practices that harm plans, patients, and pharmacies.

On the plan side, PBMs have exploited undisclosed conflicts of interest, which have resulted in conduct that harms plans and the patients that PBMs purport to serve. *E.g.*, Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale Law & Pol'y Rev. 360 (2020). For example, PBMs have used their market power to demand hidden rebates from pharmaceutical manufacturers to place drugs on the PBMs' lists of approved medications. *Id.* at 361-62. This has led some PBMs to favor more-expensive drugs, because the hidden rebates generate greater profits for PBMs, even though those drugs are more costly to plans and patients. *Id.* Relatedly, pharmaceutical manufacturers have claimed PBMs have punished them for

lowering drug costs, because it means less room for PBMs to demand hidden rebates from manufacturers. *Id.* at 362.

Pharmacies are particularly hard-hit by PBMs' abuses. Given PBMs' colossal market power, pharmacies have little to no leverage when negotiating with them. Refusing to accept a PBM's contract could mean the inability to serve most patients in a pharmacy's community. Thus, PBM-pharmacy contracts generally grant PBMs unilateral authority to dictate the amount of reimbursement paid to pharmacies, allowing PBMs to reimburse pharmacies less than any pharmacy can purchase drugs at wholesale. *Rutledge*, 592 U.S. at 83-84; Fed. Trade Comm'n at 53-59, *supra* at n.1.

PBMs have also leveraged their market power to capture a share of the retail pharmacy market *for themselves* by giving preferences to their own affiliated pharmacies. PBMs have deliberately limited access to their networks—not out of considerations of safety or costs to their prescription-benefit-plan clients, but to ensure patients use pharmacies that PBMs own and control. PBMs steer patients to PBM-affiliated pharmacies by offering lower copayments and other inducements, and this is particularly true for more-costly specialty medications. Fed. Trade Comm'n, *Specialty Generic*

Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers, at 2 (Jan. 2025).[4]

PBMs have accomplished this by prohibiting their network pharmacies from distributing "specialty drugs," which are typically higher-cost drugs that require special handling, and by simultaneously expanding the designation of "specialty drugs" to include non-specialty medications that PBMs view as the most profitable. *E.g.*, Marty Schladen, *Report: "Specialty" drugs are by far the most expensive, but classification seems arbitrary*, Ohio Capital Journal, May 15, 2023.[5] PBMs may then require patients to obtain those drugs through mail-order pharmacies owned by the PBMs. *E.g.*, Joseph Walker, *Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them*, Wall St. J., Sept. 11, 2023[6]; *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 82 Fed. Reg. 56,336, 56,410 (Nov. 28, 2017) (expressing concern that PBMs are using pharmacy contracts

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

[5] https://ohiocapitaljournal.com/2023/05/15/report-specialty-drugs-are-by-the-most-expensive-but-classification-seems-arbitrary/.

[6] https://www.wsj.com/health/healthcare/generic-drugs-should-be-cheap-but-insurers-are-charging-thousands-of-dollars-for-them-ef13d055.

"in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies").

These practices negatively affect patients by requiring them to go through mail-order pharmacies for medications that should be available at their corner drugstore. And these practices can lead to negative health consequences—whether because patients do not receive refills in a timely fashion or because the medication is spoiled by temperature extremes. Adiel Kaplan, *et al.*, *Millions of Americans receive drugs by mail. But are they safe?*, NBC News (Dec. 8, 2020).[7]

Moreover, although these PBM practices may cost beneficiaries less in the form of copayments and coinsurance, the PBMs make up for this by charging plans substantially more, driving up premiums. According to the Federal Trade Commission, 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 22 percent of the time they reimbursed their affiliated pharmacies at a *markup of more than 1,000 percent*. Fed. Trade Comm'n at 2, *supra* at n.4; *accord* Walker,

[7] https://www.nbcnews.com/specials/millions-of-americans-receivedrugs-by-mail-but-are-they-safe/.

supra at n.6; R.Doc.31-1 ¶¶ 17-18. For similar 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).

The net result is decreased access to retail pharmacies, which, for many Iowans, are their most accessible form of healthcare. Reed Abelson & Rebecca Robbins, *The Powerful Companies Driving Local Drugstores Out of Business*, N.Y. Times, Oct. 19, 2024.[8] "In some rural and medically underserved areas, local community pharmacies are the main healthcare option for Americans, who depend on them to get a flu shot, an EpiPen, or other lifesaving medicines." Fed. Trade Comm'n, *supra* at n.1. Over 200 Iowa pharmacies have closed since 2014, with 34 of those in 2024 alone. R.Doc.31-1 ¶¶ 20-23.

[8] https://www.nytimes.com/2024/10/19/business/drugstores-closing-pbm-pharmacy.html.

C. SF 383 addresses a subset of abusive PBM conduct.

Facing PBMs' growing threats to accessible care for Iowans, the Iowa Legislature enacted SF 383 to address the worst of PBMs' abusive business practices. The PBM-directed provisions fall into four general categories: (1) straightforward cost and rate regulations, including a flat dispensing fee, Iowa Code §§ 510B.8.5, 510B.8.7, 510B.8B.1.-.3, 510B.8.4, 510B.8D.1.-.2; (2) restrictions on PBMs' imposition of pharmacy accreditation standards and specialty-drug designations, *id.* §§ 510B.4B.1.c.-.d; (3) PBM disclosure requirements, *id.* §§ 510B.8B.4.a.-.b, .d; and (4) provisions prohibiting PBMs from discriminating among similarly situated pharmacies using exclusionary network practices and patient "steering," including an "any-willing-provider" provision, *id.* §§ 510B.1.4., 510B.4B.1.a.-.b, .e, .f, 510B.8.3 (the "anti-discrimination provisions"). The statute includes an explicit severability provision, which incorporates Iowa's general severability provision. *Id.* § 510B.12 (incorporating Iowa Code § 4.12).

Plaintiffs brought a pre-enforcement challenge, alleging that SF 383 is wholly preempted by ERISA and that certain of its provisions violate the

First Amendment.[9] None of the Plaintiffs are PBMs or represent the interests of PBMs. Nonetheless, they sought to enjoin Iowa from enforcing the law against them *and* the PBMs whose pharmacy networks and administration services they purchase. Plaintiffs initially sought and obtained a temporary restraining order, R.Doc.17, which was superseded by a preliminary injunction ("Op.").

D. The district court rightly allowed much of SF 383 to stand but erroneously enjoined certain PBM-directed provisions.

Citing controlling precedent—chiefly *Rutledge* and *Pharmaceutical Care Management Association v. Wehbi*, 18 F.4th 956 (8th Cir. 2021)—the district court rejected Plaintiffs' claims that ERISA preempted SF 383 in its entirety. It recognized that PBMs "operate outside ERISA's governance structure entirely." Op.54. But it allowed Plaintiffs to seek injunctive relief on behalf of PBMs, holding that Plaintiffs' alleged injuries downstream from enforcement sufficed to confer standing to do so. Op.13-17.

Following *Rutledge*, the district court held that requiring PBMs to use "pass-through pricing" for rebates was "permissible cost regulation that does not dictate plan structure or interfere with central matters of plan

[9] *Amici* take no position on Plaintiffs' First Amendment claims.

administration," and the reimbursement-rate and dispensing fee provisions were likewise "supported by *Rutledge*." Op.42-50. Provisions governing how PBMs credit payments similarly "affect[] administrative processing of existing cost-sharing obligations without compelling plans to restructure their coverage schemes." Op.51-53. Applying *Webhi*, it also held that SF 383's pharmacy-accreditation provision was a permissible PBM regulation. Op.39-42. And it held the "quarterly reporting and internet publication requirements escape ERISA preemption because they target PBMs alone." Op.54.

The district court, however, enjoined a number of PBM-directed provisions as preempted by ERISA. *Amici* focus in this brief on a subset.

First, it held preempted provisions requiring certain pass-through pricing terms in PBM contracts because they "impermissibl[y] restrict [] fiduciary discretion in contracting arrangements." Op.56-60.

Second, it enjoined the specialty-drug-designation provision, finding it "interferes with central matters of plan administration and fiduciary decision-making" by "preventing PBMs from using specialty drug designations to direct participants to pharmacies with specialized capabilities." Op.31-33.

Third, it enjoined the anti-discrimination provisions, holding that the "Tenth Circuit's analysis in [*Pharmaceutical Care Management Association v.*] *Mulready*[, 78 F.4th 1183 (10th Cir. 2023),] provides the *controlling framework* for" the analysis, Op.30 (emphasis added), and concluding that these provisions governing PBM conduct effectively "require providers to structure benefit plans in particular ways." *id.*; Op.36-39. It did not, however, assess whether these provisions would be subject to ERISA's insurance savings clause and therefore exempt from preemption.

Finally, the district court enjoined the dispensing fee provision, concluding that it was not severable from the anti-discrimination provisions because allowing it as a standalone regulation could produce unintended consequences. Op.80. The parties cross-appealed.

ARGUMENT

I. The district court erroneously found Plaintiffs had standing to challenge PBM-directed provisions, failing to address the test for third-party standing.

The district court erred first in finding that Plaintiffs, who represent plan *sponsors*, had standing to seek injunctive relief on behalf of the *PBMs* against which SF 383's PBM-directed provisions would be enforced. In so doing, the court narrowly focused on whether Plaintiffs made a showing of

injury-in-fact, instead of the central issue—whether Plaintiffs could satisfy the applicable test for third-party standing.

Ordinarily, third parties do not have standing to "assert[] the rights or legal interests of others in order to obtain relief from injury to themselves." *Ben Oehrleins & Sons & Daughter, Inc. v. Hennepin County,* 115 F.3d 1372, 1379 (8th Cir. 1997) (cleaned up). 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).

To assert a claim for relief on behalf of a third party, a plaintiff must show it "suffered an injury in fact"; "ha[s] a close relation to" the third party; and that the third party is "hindered in [its] ability to protect [its] own interests." *Hodak v. City of St. Peters*, 535 F.3d 899, 904 (8th Cir. 2008). Plaintiffs cannot make that final showing here.

"The test for 'hindrance' is a question of 'the likelihood and ability of the third parties . . . to assert their own rights.'" *Id.* (quoting *Powers v. Ohio*, 499 U.S. 400, 414 (1991)). Here, Plaintiffs are asserting the rights of PBMs to claim that SF 383's PBM-directed provisions are preempted. But PBMs obviously face no hindrance bringing their own challenge. 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 states' efforts to regulate them. *E.g.*, *Mulready*, 78 F.4th at 1183; *Wehbi*, 18 F.4th at 956; *Rutledge*, 592 U.S. at 80; *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017); *Rowe*, 429 F.3d at 294.

The district court, however, did not assess whether Plaintiffs had shown entitlement to assert the "rights or legal interests of [PBMs]." *Ben Oehrleins,* 115 F.3d at 1379. Instead, it focused solely on whether the Plaintiffs would suffer "injury to themselves," *id.*, were the law enforced against PBMs. Op.15 ("Plaintiffs have demonstrated substantial financial harm flowing from SF 383's PBM provisions.").

The district court grounded its conclusion that Plaintiffs could stand in for PBMs in "precedent recognizing the functional interdependence between ERISA plans and the intermediaries essential to their operation." Op.14. This reasoning is misguided for two reasons.

First, whether a plaintiff has "suffered an injury in fact" is only one of the factors that must be assessed in evaluating third-party standing. *Hodak*, 535 F.3d at 904. The district court wrongly treated it as dispositive. Op.16 ("The functional relationship between plan sponsors and their

intermediaries create[s] sufficient injury for standing purposes."). The question, however, is whether Plaintiffs could properly seek an injunction barring enforcement of PBM-directed provisions *against non-parties*, given that those non-parties are perfectly capable of seeking such relief themselves. *Hodak*, 535 F.3d at 904. The court failed to answer it.

Second, the "functional regulation" precedents relied upon by the district court address the substantive question of ERISA preemption, not the threshold question of third-party standing. Those precedents in fact illustrate why Plaintiffs do *not* have standing, because the functional-regulation argument is traditionally deployed by PBM plaintiffs (as in *Mulready* and *Wehbi*) when they are asserting their own rights but need to show some downstream "relation to" ERISA plans. Plaintiffs, however, are not PBMs. No PBM or PBM trade association is party to this case. And only PBMs, not Plaintiffs, would be subject to penalties for noncompliance with the PBM-directed provisions.

Thus, while treating regulation of PBMs as the "functional equivalent" of regulating plans may allow *PBMs* to invoke ERISA preemption, it cannot confer upon *plans* the right to enjoin enforcement against *absent PBMs*. Plans may, of course, challenge SF 383 to the extent its provisions apply directly to

them. Plans may also arguably be injured by PBMs' compliance with the provisions applicable to PBMs. For *standing* purposes, though, Plaintiffs are the PBMs' customers. As such, they have 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, even if the effect of those regulations is to cause the customer a cognizable injury. *Ben Oehrleins*, 115 F.3d at 1381 (no standing where "relief due the generator plaintiffs turns on the rights of the *haulers* to be free of the Ordinance's designation requirements," and haulers had "aggressively litigated their own claims"). If "[t]he modern structure" of a given service provider relationship could "create[] a sufficient nexus" to "support federal jurisdiction," Op.17, it would represent a significant shift in the law.

The district court found additional support for Plaintiffs' standing to sue on PBMs' behalf in the "standard indemnification provisions in [Plaintiffs'] PBM contracts," stating they "require [Plaintiffs] to hold their PBMs harmless for regulatory compliance costs." Op.15-16. This, too, was error.

To begin with, it is not clear how the court concluded any "indemnification provision" was "standard," given that only two such

contracts were introduced by the Plaintiffs and only in reply. One of them was publicly docketed, and it says nothing about "regulatory compliance costs." Rather, it requires the sponsor to indemnify the PBM, Caremark, for "any and all Losses incurred arising out of or relating to" the sponsor's "negligence or breach of its obligations or warranties," "any legal defects in the design of the Plan," or "any deficiencies in the [Plan Design Document]." Dkt.No.39-2 at 22-23. None of these would plausibly require indemnification of costs resulting from Iowa's enforcement of SF 383 against Caremark.

Moreover, even assuming the other plan-PBM contract of record (which remains under seal) has a broader indemnification provision, it would not support a finding of standing for all Plaintiffs. There was no showing this indemnification provision was representative or typical of the agreements that other Plaintiffs have with PBMs. Indeed, it stands to reason that most plans—as in the publicly docketed Caremark agreement—would prefer a narrow indemnification clause. A universal, limitless, hold-harmless guarantee seems likely the exception, not the rule.

The district court's reliance on *Liberty Mutual Insurance Co. v. Donegan*, 746 F.3d 497, 502 (2d Cir. 2014), *aff'd sub nom. Gobeille*, 577 U.S. 312, is thus misplaced. Op.15-16. To begin with, the third-party administrator in that

case was acting as the plaintiff's *agent*; the case involved a subpoena issued to obtain *plan* information. *Id.* at 501-02. Here, PBMs are regulated in their own business affairs. *Moeckel*, 622 F. Supp. 2d at 677. And the agreement there "provide[d] that Liberty Mutual w[ould] hold Blue Cross harmless for *any financial charges* 'arising from or in connection with' the Plan." *Donegan*, 746 F.3d at 502 (emphasis added). By contrast, the only agreement in the public record here identifies narrow circumstances where Plaintiffs may need to indemnify PBMs—none of which SF 383 implicates.

The court also cited *Prudential Insurance Co. of America v. National Park Medical Center*, 413 F.3d 897 (8th Cir. 2005), to support its conclusion, but that case says nothing about third-party standing. Rather, the parties had long agreed that, "[b]y its terms[,] the [statute] [wa]s applicable to health care insurers[,] which include[d] the plaintiffs." *Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr.*, 964 F. Supp. 1285, 1290 (E.D. Ark. 1997). Here, Plaintiffs acknowledge that the PBM-directed provisions do not regulate them, and no directly regulated PBM is a plaintiff.

There is, in short, no basis to allow Plaintiffs to act as proxies for deliberately absent PBMs. PBMs know how to sue to protect their rights and interests. For whatever reason, they decided not to do so. That, however,

does not render this the "exceptional case" in which Plaintiffs are entitled to assert PBMs' "rights or legal interests," even if the goal is "to obtain relief from injury to themselves." *Ben Oehrleins,* 115 F.3d at 1379.

II. The district court wrongly enjoined the pass-through pricing, specialty-drug-designation, and anti-discrimination provisions.

As discussed below, *infra* Section V, the district court correctly concluded that many of SF 383's provisions were permissible exercises of state regulatory authority. Its holdings that several PBM-directed provisions were preempted by ERISA, however, were mistaken—assuming Plaintiffs have standing to challenge these provisions.

A. The contractual pass-through provisions are a permissible form of rate regulation.

Sections 510B.8D.1 and 510B.8D.2 require that PBMs' contracts with plans implement "pass-through pricing," which is "a model of prescription drug pricing in which payments made by a third-party payor to a [PBM] for prescription drugs are equivalent to the payments the [PBM] makes to the dispensing pharmacy or dispensing health care provider for the prescription drugs, including any professional dispensing fee." § 510B.1.11B.

Like the rebate pass-through provision—which the district court correctly concluded was *not* preempted by ERISA, Op.42-44—these

regulations squarely govern pricing. They restrict the costs that PBMs may permissibly require plans to pay them. As a practical and functional matter, this is rate regulation—it regulates the rate (and method) that PBMs can use to charge health plans—that just happens to be couched in the language of contracts. And "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." *Rutledge*, 592 U.S. at 88. So it is here.

Because the statute phrases this quintessential cost regulation in terms of how it is embodied in PBM contracts, however, the district court concluded it impinges on plans' ERISA-imposed "fiduciary obligations." Op.56-57 (contrasting provisions that "merely require[] PBMs to take specific action regarding rebates they receive" with provisions "directly restrict[ing] what plan sponsors may include in their contracts with PBMs"). The logic of this distinction is untenable.

To begin with, the section of ERISA the court cites has nothing to do with the regulation of third parties who sell goods or services to ERISA plans. Op.57 (citing 29 U.S.C. § 1108(b)(2)(A)). Rather, it is an *exemption* from a general prohibition on transactions between plans and parties in interest

under 29 U.S.C. § 1106. *See* 29 U.S.C. § 1108(b). This provision allows ERISA plans to enter contracts with parties in interest so long as "reasonable compensation" is paid for any services provided to the plan. *Id.* It is meant to place limits on self-dealing by plan fiduciaries. It has nothing to do with state-law regulations of the goods and services that third parties can provide to ERISA plans. And in *Rutledge*, the Supreme Court was clear that state law may regulate this relationship.

The district court nonetheless held that, because 29 U.S.C. § 1108(b)(2)(A) imposes "obligations to enter into contracts with reasonable costs" and "to exercise prudent judgment in selecting and monitoring service providers," Section 510B.8D.1 "limits fiduciary discretion in ways that interfere with [plans'] ability to negotiate arrangements [they] deem most reasonable or beneficial." Op.56-57. This broad conception of fiduciary duties in service-provider transactions is not and cannot be the yardstick for preemption.

For one thing, it squarely conflicts with *Rutledge*, which holds that ERISA is fundamentally unconcerned with the underlying *subject matter* of "rate regulations," like these, that do not "forc[e] plans to adopt any particular scheme of substantive coverage." 592 U.S. at 88. Requiring PBMs

to include cost regulations in contracts does not render them any less cost regulations.

More importantly, if the district court is correct, then this simple exemption from party-in-interest transactions would preempt *any* state law that affects costs under a contract for "services necessary for the establishment or operation of [a] plan." 29 U.S.C. § 1108(b)(2)(A). A plan's fiduciaries could decide to disregard a state minimum-wage law if, in their view, the law would exceed "reasonable compensation." But the Supreme Court has been clear that states may regulate the wages plans pay, *Dillingham Constr.*, 519 U.S. at 329, and it has likewise held that states may entertain "lawsuits" by third-party service providers "against ERISA plans" for breach of contract and other state-law claims, even though those suits "obviously affect[] and involv[e] ERISA plans," *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 833 (1988); *In Home Health, Inc. v. Prudential Ins. Co. of Am.*, 101 F.3d 600, 606 (8th Cir. 1996) (recognizing third-party providers would refuse to do business with ERISA plans if they were immune from generally applicable State-law claims, which would "not serve but rather directly defeat[]" ERISA's purposes).

In short, Sections 510B.8D.1 and 510B.8D.2 are cost regulations, which are unambiguously allowed by *Rutledge*. It was error to enjoin them.

B. The specialty-drug-designation provision regulates PBM conduct, not plan administration.

The district court also erred in enjoining SF 383's restriction on PBMs' ability to designate "specialty drugs," § 510B.4B.1.d., because it misread the statute to bar *all* designations of specialty drugs. Op.32 ("SF 383 eliminates a tool that plans use."). The statute, however, only bars *PBMs* from "*[u]nreasonably* designat[ing] a prescription drug as a specialty drug" to prevent or limit access to that drug. § 510B.4B.1.d (emphasis added).

Properly understood, this is a straightforward regulation of conduct of PBMs (a third party) with respect to drugs that pharmacies (a fourth party) dispense. And a rule governing the reasonableness of PBMs' own drug classification decisions does not and cannot affect "a central matter of plan administration," *Rutledge*, 592 U.S. at 87 (quoting *Gobeille*, 577 U.S. at 320); it does not "requir[e] payment of specific benefits" or "bin[d] plan administrators to specific rules for determining beneficiary status." *Id.* As the federal government put it in *Rutledge*, laws like Iowa's "regulate[] PBM administration, not ERISA plan administration." U.S. *Amicus* Br. 15, *Rutledge*

v. PCMA, No. 18-540 (U.S. Dec. 4, 2019), 2019 WL 6609430; *accord Moeckel*, 622 F. Supp. 2d at 677 (PBM does not act as an agent of an ERISA plan in the "administration of its own business as a PBM").

The district court, however, misread the statute to outright "prevent[] PBMs from using specialty drug designations." Op.31. This interpretation reads the term "unreasonably" out of the statute—and indeed, the court's quotation of the provision omits it. *Id.* ("Under Iowa Code § 510B.4B(1)(d), PBMs may not 'designate a drug as a specialty drug . . . .'"). This is incorrect. SF 383 leaves PBMs free to designate drugs as "specialty drugs." It merely places guardrails on their ability to do in an arbitrary or self-serving manner. *Cf.* Schladen, *supra* at n.5.

The district court's misapprehension of the scope of § 510B.4B.1.d informed its preemption analysis, Op.31, meaning the analysis no longer holds. "*[P]reventing* PBMs from using specialty drug designations" is what, it concluded, "interferes with central matters of plan administration and fiduciary decision-making." *Id.* (emphasis added). But the statute will not have that effect. In short, because the provision does not "prevent[]" the practice, it cannot "interfere[]" with plan administration, either.

C. ERISA's savings clause preserves the anti-discrimination provisions as applied to PBMs, even if they "relate to" plans.

The district court concluded the anti-discrimination provisions "relate to" ERISA plans as applied to PBMs that serve those plans. Op.24-30. *Amici* disagree, but do not address that finding here. Rather, *amici* stress that the district court's analysis was incomplete: it failed to assess these PBM-directed provisions under ERISA's insurance savings clause, which would save them from preemption regardless.

ERISA provides that preemption does not "exempt or relieve any person from any law of any State which regulates insurance." 29 U.S.C. § 1144(b)(2)(A). A state law "regulates insurance" if it (1) is "specifically directed toward entities engaged in insurance" and (2) "substantially affect[s] the risk pooling arrangement between the insurer and the insured." *Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329, 342 (2003). The anti-discrimination provisions do both.

The anti-discrimination provisions address core features of insurance coverage—network composition and cost-sharing rules. The federal government took the same position in an *amicus* brief in *Mulready*, arguing the any-willing-provider and anti-discrimination provisions of Oklahoma's

PBM law were saved from preemption as applied to PBMs serving both insured and self-funded ERISA plans. U.S. *Amicus* Br. 11-22, *PCMA v. Mulready*, No. 22-6074 (10th Cir. Apr. 10, 2023), 2023 WL 2990378. Iowa's versions of these provisions likewise satisfy *Miller*'s two-part test.

First, the anti-discrimination provisions are "specifically directed toward entities engaged in insurance." *Miller*, 538 U.S. at 342. The any-willing-provider provisions in *Miller* applied to some "[health maintenance organizations (HMOs)] that d[id] not act as insurers but instead provide[d] only administrative services to self-insured [ERISA health] plans." *Id.* at 336 n.1. Providing these services nonetheless "suffice[d] to bring [third-party HMOs] within the activity of insurance" for purposes of the insurance savings clause. *Id.* The same is true of third-party PBMs; they package, sell, and administer pharmacy networks to Plaintiffs.

Here, the district court held that many PBM-directed provisions are sufficiently substantive to "dictate" or "mandate" certain benefit structures. Assuming this is true, it compels the conclusion, under *Miller*, that PBMs are sufficiently involved in the "activity of insurance" to qualify for the savings clause. *Id.* They cannot "dictate" or "mandate" substantive terms of insurance coverage *without* being involved in the "activity of insurance."

As to *Miller*'s second prong, Plaintiffs acknowledged below that the anti-discrimination provisions (particularly "the any-willing-pharmacy and cost-sharing provisions") "might qualify as substantially affecting risk-pooling between the insurer and the insured." Dkt.No.16 at 25. There is no "might" about it; *Miller* explicitly holds that such provisions satisfy the second prong: "By expanding the number of providers from whom an insured may receive health services, AWP laws alter the scope of permissible bargains between insurers and insureds . . . ." 538 U.S. at 338–39. The cost-sharing regulations similarly prohibit certain trade-offs between insurers and insured—"no longer may [Iowa prescription-drug] insureds seek insurance from [certain pharmacies] in exchange for a lower premium." *Id.* at 339.

This Court can and should hold that the anti-discrimination provisions are saved from preemption as applied to PBMs that serve both insured and self-funded ERISA plans.

IV. The district court's failure to address the savings clause led it to erroneously invalidate the dispensing-fee provision, and in any event, that provision is fully severable.

The district court's failure to address the savings clause, and its resulting finding that the anti-discrimination provisions are preempted, led

it to invalidate the otherwise unproblematic dispensing fee provision. As explained below, it assumed erroneously that the anti-discrimination provisions were unenforceable, which it speculated might lead to unintended consequences related to the dispensing fee. Reversal as to the anti-discrimination provisions therefore requires reversal as to the dispensing fee.

The district court's severability analysis is also wrong on the merits. As the court recognized, SF 383 contains an *explicit* severability provision, Iowa Code § 510B.12, and operates against a background presumption of severability, *id.* § 4.12. As the court also recognized, severability presents a question of "legislative intent, as indicated by the words employed and the considerations underlying the enactment of the statute." *State v. Monroe*, 236 N.W.2d 24, 35 (Iowa 1975) (en banc); *accord Advantage Media, L.L.C. v. City of Eden Prairie*, 456 F.3d 793, 800 (8th Cir. 2006).

SF 383, however, already provides definitive evidence of legislative intent. Where, as here, "there is a severability clause in the statute itself[,] *the presumption is inescapable* that this was the legislative intent." *State v. Books*, 225 N.W.2d 322, 325 (Iowa 1975) (emphasis added).

The district court held otherwise. Its grounds for invalidating the dispensing fee provision, however, were entirely speculative. It posited *potential* market consequences of a standalone dispensing fee and presumed a legislative desire to avoid this hypothetical outcome: "If anti-discrimination and anti-steering provisions are preempted while the dispensing fee remains," it reasoned, "the fee *could* incentivize plans and PBMs to avoid affected pharmacies entirely." Op.80 (emphasis added). From this, it concluded, "the legislature *would not* have enacted a provision driving business away from the rural pharmacies the statute seeks to protect." *Id.* (emphasis added).

For one thing, this ignores that the dispensing-fee provision appears in the same statutory section as the (permissible) reimbursement rate and PBM-reporting provisions, SF 383 § 5 (Iowa Code § 510B.8B), *not* the anti-discrimination provisions codified elsewhere. Plainly, the Legislature did not conceive of them as linked.

More importantly, speculation about possible unintended practical effects of legislation (suggested by Plaintiffs in their briefing and contested by Iowa) is not evidence of underlying legislative intent sufficient to scrap the severability clause that lawmakers enacted. Absent "[c]ompelling

reasons," *Monroe*, 236 N.W.2d at 36, a court should not override a state's determination, embodied by a severability clause, that the statutory provisions it chooses to make law are each desirable and necessary. *Books*, 225 N.W.2d at 325.

The dispensing-fee provision, like every other provision of SF 383, was meant to stand independently. As in so many other areas of statutory interpretation, judicial conjecture about market dynamics and general legislative intent is not a substitute for statutory text. Legislators are free to revisit and revise the law if the district court's speculation pans out. But "[i]f changes in a law are desirable from a standpoint of policy or mere practicality, it is for the legislature to enact them, not for the court to incorporate them by interpretation." *Monroe*, 236 N.W.2d at 36.

V. Most of SF 383's provisions are straightforwardly permissible under controlling precedent, and there is no colorable argument otherwise.

Plaintiffs have cross-appealed, presumably to challenge some or all of the district court's holdings regarding the rest of SF 383. Because the court's analysis of those provisions faithfully applied controlling precedents, Plaintiffs' arguments will necessarily fail to the extent they seek reversal as to the PBM-directed provisions.

Rutledge explains that "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans." 592 U.S. at 88. SF 383's pass-through rebate, reimbursement rate, and payment-processing and crediting provisions, all of which govern how PBMs pay money to others, are rate regulations—pure and simple. *Id.*

Undeterred, Plaintiffs have claimed a distinction between rate regulations of PBMs and rate regulations of plans, but the distinction is immaterial: "tax[es] or other law[s]" directly applicable to *plans* "that increase[] the cost of providing benefits to covered employees" inevitably "have some effect on the administration of ERISA plans," but they are not preempted. *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 (1997).

The PBM-directed reporting requirements are likewise permissible under *Webhi*, which upheld both PBM *and* plan disclosure requirements because they had a *de minimis* effect on plan administration. 18 F.4th at 969. Moreover, as the district court rightly recognized, PBMs "operate outside ERISA's governance structure entirely," so "reporting requirements imposed upon" them "encounter no preemption barrier." Op.54.

CONCLUSION

The Court should reverse the portion of the judgment enjoining SF 383's PBM-directed provisions because Plaintiffs lack standing. Alternatively, it should reverse the district court's invalidation of the pass-through pricing, specialty-drug-designation, anti-discrimination, and dispensing-fee provisions, while affirming that SF 383 is otherwise not preempted by ERISA.

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Respectfully submitted,

/s/ Robert T. Smith

Robert T. Smith
Timothy H. Gray
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
Tel.: 202-625-3500
robert.smith1@katten.com
timothy.gray@katten.com

Counsel for Amici Curiae

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 6,476 words, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on October 6, 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.

/s/ Robert T. Smith
Robert T. Smith
Counsel for Amici Curiae