IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA

IOWA ASSOCIATION OF BUSINESS AND INDUSTRY, IOWA BANKERS BENEFIT PLAN, IOWA LABORERS DISTRICT COUNCIL HEALTH AND WELFARE FUND, DES MOINES ORTHOPAEDIC SURGEONS PC, and IOWA SPRING MANUFACTURING & SALES COMPANY, *Plaintiffs*, v. DOUG OMMEN, in his official capacity as Insurance Commissioner of Iowa, *Defendant*.	No. 4:25-cv-00211-SMR-WPK **MOTION OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, IOWA PHARMACY ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, AND INDEPENDENT PHARMACY COOPERATIVE FOR LEAVE TO PARTICIPATE AS *AMICI CURIAE* AND TO FILE OVERLENGTH BRIEF**

The National Community Pharmacists Association (NCPA), Iowa Pharmacy Association (IPA), the American Pharmacists Association (APhA), and the Independent Pharmacy Cooperative (IPC) ("Proposed *Amici*") respectfully move for leave to file a brief as *amici curiae* in the above-captioned case in support of Defendant and in opposition to Plaintiffs' Motion for Preliminary Injunction. Proposed *Amici* also seek leave to file an overlength brief. The proposed *amici curiae* brief is attached as Exhibit A. Defendant has consented to the filing of this brief. Counsel for Plaintiffs informed counsel for the Proposed *Amici* that Plaintiffs do not consent to either form of relief requested in this Motion and that they plan to file a resistance.

Amicus participation is appropriate where, as here, an *amicus* can offer "a unique perspective," "expertise," and "helpful information" to the Court. *North Dakota v. Heydinger*, 2013 WL 593898, at *7 (D. Minn. Feb. 15, 2013); *accord ACLU of Minn. v. Tarek Ibn Ziyad Acad.*, 2010 WL 1840301, at *9 (D. Minn. May 7, 2010); *Swinton v. SquareTrade, Inc.*, 2018 WL 8458862, at *8 (S.D. Iowa Sept. 21, 2018), *aff'd*, 960 F.3d 1001 (8th Cir. 2020). "[T]here is no

governing standard" dictating "the procedure for obtaining leave to file an *amicus* brief in the district court," *Auto. Club of N.Y., Inc. v. Port Auth. of N.Y. & N.J.*, 2011 WL 5865296, at *1 (S.D.N.Y. Nov. 22, 2011), and "District Courts have broad discretion in deciding whether to accept *amicus* briefs," *Gulf Underwriters Ins. Co. v. City of Council Bluffs*, 2011 WL 13285400, at *5 (S.D. Iowa Feb. 18, 2011) (citation omitted).

The statute at issue in this litigation, Senate File 383 ("SF 383"), is principally directed to practices of pharmacy benefit managers (PBMs) that 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. Proposed *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 thus the provisions of SF 383 that seek to regulate them.

NCPA represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the country. IPA represents those same interests at the state level. NCPA's members employ over 239,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions, while IPA represents the interests of 293 Iowa pharmacies and 1400 Iowa pharmacists. APhA represents pharmacists, student pharmacists, pharmacy technicians, and pharmaceutical scientists across the entire profession. With over 800,000 professionals in pharmacy, APhA advocates for consumer access to the care services of pharmacists whenever and wherever healthcare is provided, and serves its members with cutting-edge resources designed to advance their professional careers. And IPC is a group purchasing organization and secondary pharmaceutical wholesaler serving community pharmacies

with over 2,000 member pharmacies. Its objective is to help improve the economic environment of independent pharmacies across the nation.

Proposed *Amici* thus possess a deep understanding of and extensive experience in both the pharmaceutical industry as well as the legal and practical context in which SF 383 will operate. They can speak with authority to the struggles independent pharmacies increasingly face, and it has been on the front lines of the efforts to rein in PBMs for nearly a decade. For this reason, NCPA and APhA—along with groups, like IPA and IPC, representing the immediate interests of affected state pharmacies—regularly participate as *amicus curiae* in PBM-driven cases challenging states' efforts to regulate them. *See, e.g.*, Brief of NCPA *et al.* as *Amici Curiae* Supporting Petitioners, *Mulready v. PCMA*, No. 23-1213 (U.S. June 14, 2024), 2024 WL 3069951; Brief of NCPA *et al.* as *Amici Curiae* in Support of Defendants-Appellees and Affirmance, *PCMA v. Mulready*, No. 22-6074 (8th Cir. Oct. 18, 2022), 2022 WL 14849173; Brief of NCPA *et al.* as *Amici Curiae*, *PCMA v. Wehbi*, No. 18-2926 (8th Cir. July 2, 2021), 2021 WL 2879190; Brief of NCPA *et al.* as *Amici Curiae* Supporting Petitioner, *Rutledge v. PCMA*, No. 18-540 (U.S. March 2, 2020), 2020 WL 1372779; Brief of NCPA *et al.* as *Amici Curiae*, *PCMA v. Rutledge*, No. 17-1609 (8th Cir. Mar. 2, 2020), 2020 WL 1372779; Brief of NCPA *et al.* as *Amici Curiae*, *PCMA v. Gerhart*, No. 15-3292 (8th Cir. Feb. 3, 2016), 2016 WL 465472.

Proposed *Amici*'s brief would offer additional context on the economic environment in which PBMs' abusive practices have arisen; the way pharmacies can (and more often cannot) respond to increasing PBM-created pressures; and the legal issues surrounding ERISA preemption, as to which Proposed *Amici* have experience in both legal and practical ways. Their brief will therefore "contribute in clear and distinct ways" to the Court's analysis by "explaining the broader regulatory or commercial context" in which this case arises; "supplying empirical data" informing

the issue on appeal; and "providing practical perspectives on the consequences of particular outcomes." *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, 976 F.3d 761, 763 (7th Cir. 2020).

Nor would allowing Proposed *Amici* to participate result in any prejudice to Plaintiffs or delay resolution of the motion. The proposed brief is being submitted on the same day as Defendant's brief in opposition. *See United States v. Bd. of Educ. of the City of Chi.*, 1993 WL 408356, at *3 (N.D. Ill. Oct. 12, 1993) (explaining that timeliness is one of the relevant factors in determining whether to permit amicus participation). And this Court has frequently permitted *amici* to participate in its proceedings, even where, as here, one of the parties opposes. *See, e.g., United States v. Hart*, 417 F. Supp. 1314, 1316 n.1 (S.D. Iowa 1976) (granting motion for leave to file *amicus* brief over opposition); *Lubavitch of Iowa, Inc. v. Walters*, 684 F. Supp. 610, 615 n.5 (S.D. Iowa 1988) (referring to positions of *amici* and noting that the court "appreciate[s] the able legal briefing of *amici curiae*"); *Lyon v. Grossheim*, 803 F. Supp. 1538, 1553 & n.35 (S.D. Iowa 1992) (relying on facts and data provided in *amicus* briefs).

Finally, Proposed *Amici* seek leave to file an overlength brief of 30 pages. SF 383 is comprehensive legislation, and Plaintiffs seek to enjoin all of its provisions. The Complaint is 38 pages, and the Plaintiff's brief in support of its motion for preliminary injunction is 39 pages. An additional ten pages is essential to provide Proposed *Amici*'s vital background understanding of PBM practices in addition to their perspectives on each of the challenged provisions—each of which requires independent assessment informed by Proposed *Amici*'s extensive experience in ERISA-preemption litigation.

CONCLUSION

Proposed *Amici* respectfully request that the Court grant them leave to file their attached Brief as *Amici Curiae* in Support of Defendant and in Opposition to Plaintiff's Motion for a Preliminary Injunction and simultaneously grant them leave to file an overlength brief of 30 pages.

Dated: July 7, 2025

Respectfully submitted,

/s/ Todd M. Lantz
Todd M. Lantz
Jason R. Smith
WEINHARDT & LANTZ, P.C.
2600 Grand Avenue, Ste. 450
Des Moines, Iowa 50312
Tel.: 515-244-3100
tlantz@weinhardtlantz.com
jsmith@weinhardtlantz.com

Robert T. Smith*
Timothy H. Gray*
Neal S. Mehrotra*
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
Tel.: 202-625-3500
Fax: 202-298-7570
robert.smith1@katten.com
timothy.gray@katten.com
neal.mehrotra@katten.com

Counsel for Amici Curiae

* Motions pending for admission *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that, on July 7, 2025, I had the foregoing Motion was served on all parties by filing it using the Court's CM/ECF system.

/s/ Todd M. Lantz
Todd Lantz
Counsel for Amici Curiae

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA

IOWA ASSOCIATION OF BUSINESS AND INDUSTRY, IOWA BANKERS BENEFIT PLAN, IOWA LABORERS DISTRICT COUNCIL HEALTH AND WELFARE FUND, DES MOINES ORTHOPAEDIC SURGEONS PC, and IOWA SPRING MANUFACTURING & SALES COMPANY, *Plaintiffs*, v. DOUG OMMEN, in his official capacity as Insurance Commissioner of Iowa, *Defendant*.	No. 4:25-cv-00211-SMR-WPK

BRIEF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, IOWA PHARMACY ASSOCIATION, AMERICAN PHARMACISTS ASSOCIATION, AND INDEPENDENT PHARMACY COOPERATIVE AS *AMICI CURIAE* IN SUPPORT OF DEFENDANT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Todd M. Lantz
Jason R. Smith
WEINHARDT & LANTZ, P.C.
2600 Grand Avenue, Ste. 450
Des Moines, Iowa 50312
Tel.: 515-244-3100
tlantz@weinhardtlantz.com
jsmith@weinhardtlantz.com

Robert T. Smith*
Timothy H. Gray*
Neal S. Mehrotra*
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue, NW, Suite 800
Washington, DC 20006
Tel.: 202-625-3500
Fax: 202-298-7570
robert.smith1@katten.com
timothy.gray@katten.com
neal.mehrotra@katten.com

Counsel for Amici Curiae

* Motions pending for admission *pro hac vice*.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

FEDERAL STATUTES:

STATE STATUTES

FEDERAL REGULATIONS AND RULEMAKINGS:

COURT FILINGS:

OTHER AUTHORITIES:

STATEMENT OF INTEREST OF *AMICI CURIAE*[*]

Amici curiae represent the interests of independent community pharmacies. The National Community Pharmacists Association (NCPA) represents the interests of the owners, managers, and employees of more than 19,000 independent community pharmacies across the country. The Iowa Pharmacy Association (IPA) represents those same interests at the state level. NCPA's members employ over 239,000 individuals on a full or part-time basis and dispense roughly 40% of the nation's retail prescriptions, while IPA represents the interests of 293 Iowa pharmacies and 1400 Iowa pharmacists. The American Pharmacists Association (APhA) represents pharmacists, student pharmacists, pharmacy technicians, and pharmaceutical scientists across the entire profession. With over 800,000 professionals in pharmacy, APhA advocates for consumer access to the care services of pharmacists whenever and wherever healthcare is provided, and serves its members with cutting-edge resources designed to advance their professional careers. Finally, the Independent Pharmacy Cooperative (IPC) is a group purchasing organization and secondary pharmaceutical wholesaler with over 2000 community pharmacy members. Its objective is to help improve the economic environment of independent pharmacies across the nation.

This litigation involves a challenge to several provisions of Iowa law that, like the laws of nearly all states, regulate the services that pharmacy benefit managers (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. Because PBMs profoundly affect patient access to pharmacy care, and because Iowa's laws seek to regulate certain business practices of PBMs that

[*] Defendant consents to the filing of this brief; Plaintiffs oppose. No counsel for any party authored this brief in whole or in part. No party, person, or entity—except NCPA, IPA, APhA, IPC, and their members—made a monetary contribution specifically for the preparation or submission of this brief.

have restricted patient access to community pharmacies, NCPA, IPA, APhA, and IPC have a strong interest in the outcome of this case.

INTRODUCTION

This case involves Senate File 383 ("SF 383"), bipartisan legislation that was recently enacted by the Iowa Legislature and signed into law by the Governor. SF 383 includes numerous provisions principally directed at the harmful business practices of PBMs.

PBMs are not prescription-benefit plans. Rather, they are intermediaries sitting between prescription-benefit plans and pharmacies. They contract with pharmacies to form networks where patients can access prescription medications. They contract separately with health benefit plans, including plans regulated by the Employee Retirement Income Security Act of 1974 (ERISA), to sell access to those networks.

In the absence of meaningful state or federal regulations, PBMs have used their market power—the three largest PBMs control 80 percent of all covered lives in America—to the detriment of patients, the plans that PBMs purport to serve, and pharmacies across the country. The provisions of SF 383 at issue here were enacted to curb the worst of PBMs' abuses, require them to be transparent about their practices, and help rectify some of the pernicious economic effects that PBMs have imposed on Iowa's pharmacies and patients alike.

Plaintiffs are not PBMs. They are businesses and coalitions of businesses that sponsor benefit plans that rely on PBMs for access to PBM-created, PBM-administered pharmacy networks. Plaintiffs, in other words, purchase access to PBMs' networks. When it comes to how those networks are put together (and gatekept) and the costs imposed on pharmacies, the Plaintiffs are buying what the PBMs are selling.

Plaintiffs nonetheless seek to enjoin SF 383 in its entirety. But the provisions Plaintiffs urge the Court to enjoin principally regulate only the practices of PBMs—and under binding Supreme Court and Eighth Circuit precedent, ERISA has nothing to say about that conduct.

This Court should deny a preliminary injunction for any of three reasons:

First, Plaintiffs lack standing to the extent they seek an injunction barring enforcement of SF 383's PBM-directed provisions against non-party PBMs. Plaintiffs purchase pharmacy access from a third-party insurer which then hires a PBM to manage the prescription drug coverage. But none of their PBMs have challenged the law on their own behalf. And purchasers of regulated services do not have standing to challenge the regulation of those services absent a showing that Plaintiffs have not attempted to make here.

Second, the PBM-directed provisions do not "relate to" ERISA plans within the meaning of ERISA's preemption clause. Those provisions regulate PBMs, not ERISA plans, and none of them govern central matters of plan administration.

Finally, even if certain of the provisions "relate to" ERISA plans, they are saved from preemption under ERISA's savings clause. The law is specifically directed towards entities engaged in insurance, and it substantially affects risk pooling by regulating the bargains that may be struck between PBMs and plans.

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 of this crisis of care. *See generally* Fed. Trade Comm'n, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024)[1]; Jenny S. Guadamuz, *et al.*, *More US Pharmacies*

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

Closed Than Opened in 2018–21; Independent Pharmacies, Those in Black, Latinx Communities Most at Risk, 43 Health Aff. 1703, 1709-10 (2024). In the last few decades, the business practices of PBMs have shuttered countless pharmacies—a trend that disproportionately affected rural communities. *See, e.g.*, Abiodun Salako, *et al.*, *Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018*, RUPRI Center for Rural Health Policy Analysis (July 2018).[2]

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. Importantly, as explained below, these provisions operate in a space unoccupied by federal law.

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 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—a fact that Plaintiffs' declarants expressly acknowledge. *See* Decl. of Bradley W. Bartle ¶ 9, Dkt. No. 6-1; Decl. of Paul Karow ¶ 7, Dkt. No. 6-3. 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. And federal appellate

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

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). As the Department of Labor has made plain, "a plan administrator . . . must, [by] the very nature of his position, have 'discretionary authority or discretionary responsibility in the 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). Or put differently, because of their status as non-fiduciaries, PBMs "have no power to make any decisions as to plan policy, interpretations, practices or procedures." *Id.*

Critically, ERISA does not regulate the business practices of third-party providers that, like PBMs, sell goods and services to ERISA plans. That makes sense. Otherwise, ERISA would displace state laws regulating everything from doctors, accountants, and lawyers, to hospitals and insurers. *California Div. of Lab. Standards Enforcement v. Dillingham Const., N.A., Inc.*, 519 U.S. 316, 329 (1997) (explaining that "if 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

[3] *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); *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), *cert. denied*, 142 S.Ct. 2867 (2022); *Bickley v. Caremark Rx, Inc.*, 361 F. Supp. 2d 1317, 1332 (N.D. Ala. 2004), *aff'd*, 461 F.3d 1325 (11th Cir. 2006).

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 that an HMO-employed physician who cared for an ERISA beneficiary was not liable under ERISA because he was not a fiduciary, but such a doctor 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 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 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.

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. Known as a spread-

pricing model, this incentivizes PBMs to engage in business practices that can harm plans, patients, and pharmacies. In the absence of regulation, PBMs have done just that.

On the plan side, PBMs have exploited undisclosed conflicts of interest, which have resulted in actions that are harmful to the plans and 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. It is an inherently lopsided bargain. Refusing to accept a PBM's contract could mean the inability to serve most patients in a pharmacy's community. As a result, 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. *See 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 pharmacy 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. *See* 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 have been on the market for a long time. *See, 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. *See, e.g.*, Joseph Walker, *Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them*, Wall Street Journal, 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 "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

[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.

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]

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. According to an interim staff report by 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 mark up of more than 1,000 percent. Fed. Trade Comm'n at 2, *supra* at n.4; *see also* Walker, *supra* at n.6. 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 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.[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 at 1, *supra* at n.1. Over 200 Iowa pharmacies have closed since 2014, with 29 of those coming in 2024 alone. *See* Iowa Pharmacy Ass'n*, 29 Iowa Pharmacies Closed in 2024 – PBM Reform Needed to Save Our Pharmacies* (Jan. 20, 2025).[9]

---

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

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

[9] https://www.iarx.org/blog_home.asp?Display=185.

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. These fall into four categories:

First, SF 383 directly regulates costs and rates. It requires that PBMs: (1) reimburse all pharmacies at a rate no lower than that it uses for its own affiliated pharmacies, SF 383 § 5 (amended Iowa Code § 510B.8B.1.); (2) reimburse retail pharmacies at the published national average acquisition cost or, alternatively, the wholesale acquisition cost (WAC) of the drug, SF 383 § 5 (amended Iowa Code § 510B.8B.2.); (3) pay a dispensing fee to retail pharmacies of $10.68 per prescription, SF 383 § 5 (amended Iowa Code § 510B.8B.3.); (4) pass all rebates received to the health carrier or the employee plan sponsor, SF 383 § 4 (amended Iowa Code § 510B.8.4.); and (5) implement "pass-through pricing" as a mandatory term in their contracts with plans, SF 383 § 6 (amended Iowa Code § 510B.8D.1., .2.) (collectively, the "Cost-Regulation Provisions").

Second, SF 383 prohibits PBMs from imposing pharmacy accreditation requirements inconsistent or more stringent than those established by Iowa, SF 383 § 3 (amended Iowa Code § 510B.4B.1.c.)—a provision substantively identical to a North Dakota law the Eighth Circuit upheld in *PCMA v. Wehbi*, 18 F.4th 956 (8th Cir. 2021)—and bars PBMs from unreasonably deciding certain drugs are "specialty" drugs in order to limit access to them within health carrier networks, SF 383 § 3 (amended Iowa Code § 510B.4B.1.d.).

Third, SF 383 requires PBMs to disclose and publish certain information about *their own business practices*, including "all drugs reimbursed at 10 percent or more below the national average acquisition cost," as well as those at "ten percent or more above," SF 383 § 5 (amended Iowa Code § 510B.8B.4.a.); to include in that report "month and quantity" of the drug, whether the dispensing pharmacy was a PBM affiliate, and if the drug was dispensed pursuant to a

"government health plan," SF 383 § 5 (amended Iowa Code § 510B.8B.4.b.); and to publish that report on the internet, SF 383 § 5 (amended Iowa Code § 510B.8B.4.d.).

Fourth, SF 383 regulates PBMs' attempts to pick and choose favorites—usually their own affiliates—among similarly situated Iowa pharmacies. SF 383's blanket anti-discrimination provision, SF 383 § 1 (amended Iowa Code § 510B.1.4.) forbids PBMs and third-party payors from "discriminat[ing] against a pharmacy or a pharmacist with respect to participation, referral, reimbursement of a covered service, or indemnification."

Other provisions target specific mechanisms PBMs use to accomplish these goals. SF 383: (1) bars PBMs from restricting patients' choice of pharmacy or "impos[ing] a monetary advantage or penalty" to induce them to use certain pharmacies, SF 383 § 3 (amended Iowa Code § 510B.4B.1.a.); (2) requires PBMs to accept "any willing provider" into their networks, prohibiting them from "[d]eny[ing] a pharmacy or pharmacist the right to participate as a contract provider under a health benefit plan" so long as the pharmacy agrees to meet the PBMs' terms and conditions, SF 383 § 3 (amended Iowa Code § 510B.4B.1.b.) (the "AWP Provision"); and (3) prohibits PBMs from requiring that only mail-order pharmacies be used to fill prescriptions, SF 383 § 3 (amended Iowa Code § 510B.4B.1.e.).

SF 383 also prohibits discrete "steering" practices to induce patients to use certain pharmacies or kinds of pharmacies by: (4) mandating that cost-sharing rules be uniform across all pharmacies, SF 383 § 4 (amended Iowa Code § 510B.8.3.), and prohibiting any costs or conditions on retail pharmacy prescriptions more costly or restrictive than those of a mail-order pharmacy, SF 383 § 3 (amended Iowa Code § 510B.4B.1.f.). In addition, SF 383: (5) requires that PBMs include all amounts paid by patients when calculating their contribution toward cost-sharing, SF 383 § 4 (amended Iowa Code § 510B.8.5.) (collectively, the Anti-Discrimination Provisions).

Plaintiffs now bring a pre-enforcement challenge to these provisions, alleging that SF 383 is wholly preempted by ERISA and that certain of its provisions violate the First Amendment. They seek to enjoin the State from enforcing the law against them *and* the PBMs whose pharmacy networks and administration services they purchase. On June 30, 2025, this Court granted a temporary restraining order, *see* Order Granting Plaintiffs' Motion for Ex Parte Temporary Restraining Order (Dkt. No. 17) (the "TRO Order"), after determining that at least one provision of SF 383 is likely preempted and another likely impinges on Plaintiffs' First Amendment rights. *See id.* at 12-19. It temporarily enjoined enforcement of the statute in its entirety, declining to undertake a severability analysis pending further briefing. *See id.* at 19-20.

ARGUMENT

Plaintiffs lack standing to challenge SF 383, and ERISA does not preempt SF 383 in its entirety in any event. Notably, because none of the Plaintiffs self-administers its own pharmacy benefits and all instead work with PBMs, *see* Compl. ¶¶ 8-12, *amici* focus their analysis on the permissibility of SF 383's provisions as applied to third-party PBMs. Further, although *amici* disagree that enforcement of SF 383 would violate the First Amendment, they address in this brief only Plaintiffs' ERISA preemption arguments.

I. Plaintiffs lack standing to challenge regulations applicable to PBMs.

The Court should not enter an injunction barring enforcement of SF 383 because Plaintiffs do not have standing to seek one. None of the Plaintiffs maintain their own pharmacy network or administer the dispensing of prescription drugs. *See* Compl. ¶¶ 8-12. As a result, Plaintiffs do not have standing to challenge SF 383 as applied directly to them because none engage in conduct—or plan to engage in conduct—subject to direct regulation under the law. Accordingly, there is no

"credible threat of enforcement" to which they can point. *See, e.g.*, *Hershey v. Jasinski*, 86 F.4th 1224, 1231 (8th Cir. 2023).

Equally problematic for Plaintiffs, the bulk of SF 383's provisions apply *explicitly and exclusively* to PBMs, and they regulate PBMs' conduct and practices. But Plaintiffs 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.

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 it "hindered in [its] ability to protect [its] own interests." *Hodak v. City of St. Peters*, 535 F.3d 899, 904 (8th Cir. 2008). "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)).

PBMs face no such hindrance. Indeed, 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. *See, e.g.*, *PCMA v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023); *Wehbi*, 18 F.4th 956 (8th Cir. 2021); *Rutledge*, 592 U.S. 80 (2020); *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017). Accordingly, Plaintiffs may not seek any injunctive relief prohibiting enforcement of the PBM-directed provisions at issue insofar as they apply to regulate the conduct of third-party PBMs that maintain and administer their plans' pharmacy networks.

II. Even if Plaintiffs had standing, ERISA does not preempt SF 383 in its entirety.

ERISA regulates the "administration of benefit plans" for certain private-employer and union-sponsored plans. *N.Y. Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 651 (1995). "ERISA does not guarantee substantive benefits." *Gobeille*, 577 U.S. at 320-21. "The statute, instead, seeks to make the benefits promised by an employer more secure," *id.*, by establishing "reporting and disclosure mandates, participation and vesting requirements, funding standards, and fiduciary responsibilities for plan administrators," *Travelers*, 514 U.S. at 651 (citations omitted).

As noted above, PBMs are neither plans nor plan "administrators," and they are not fiduciaries, either. Plaintiffs nevertheless claim that ERISA preempts SF 383's provisions in their entirety, including those provisions that apply solely to 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.* With a single exception—set forth in a footnote and addressed below—Plaintiffs assert only "connection with" preemption. *See* Pl. Br. 22 n.13 (Dkt. No. 16).

"A state law has an impermissible 'connection with' ERISA plans if and only if (1) it 'governs . . . a central matter of plan administration'; (2) it 'interferes with nationally uniform plan administration'; or (3) 'acute, albeit indirect, economic effects' of the law 'force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.'" *Wehbi*, 18 F.4th at 968 (quoting *Gobeille*, 577 U.S. at 320). "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"—"especially . . . if a law merely affects costs." *Rutledge*, 592 U.S. at 87. 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.* at 86-87 (citations omitted); *accord Wehbi*, 18 F.4th at 958.

A. SF 383's Cost-Regulation Provisions are not preempted.

ERISA does not preempt SF 383's Cost-Regulation Provisions, and it is not a particularly close call. As Plaintiffs acknowledge, "cost regulation[s] [are] the sort of state-law provision that ERISA, under *Rutledge*, usually permits." Pl. Br. 23. So it is with SF 383's reimbursement, dispensing-fee, and pass-through provisions. Indeed, Plaintiffs do not even address several of these in their briefing—and their Complaint does not even *allege* that one of them is preempted.

1. Reimbursement Rate Regulations.

Start with §§ 510B.8B.1 and 510B.8B.2, which directly regulate the rates at which PBMs may reimburse pharmacies. "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. That is precisely what these two provisions do.

Sections 510B.8B.1 and 510B.8B.2 bar PBMs from reimbursing their own affiliated pharmacies at a higher rate and setting reimbursement rates no higher than either the average acquisition cost or WAC. Plaintiffs' brief does not address the substance of these reimbursement-rate provisions *at all*, presumably because they recognize that *Rutledge* forecloses a finding of preemption. Among other things, the law at issue in *Rutledge* required PBMs to "tether reimbursement rates to pharmacies' acquisition costs" and, if necessary, "increase [their]

reimbursement rate[s] to cover the pharmacy's acquisition cost"; ERISA had nothing to say about these forms of cost regulation. 592 U.S. 84-85.

Plaintiffs' Complaint, for its part, alleges only that *§ 510B.8B.1* is preempted, saying nothing about § 510B.8B.2. *See* Compl. ¶ 24 (identifying both provisions as parts of SF 383); *id.* ¶ 55(m) (only arguing that 8B.1 is preempted). Plaintiffs assert that § 510B.8B.1 "dictates the design of an ERISA plan's prescription drug benefits by prohibiting ERISA plans from adopting terms that incentivize participants and beneficiaries to utilize pharmacy options that may be more cost-effective to the ERISA plan." *Id.* ¶ 55(m). But this is precisely the argument the Supreme Court considered and rejected in *Rutledge*. There, PCMA argued that "a plan might prefer that PBMs reimburse pharmacies using a MAC list constructed with an eye toward containing costs and ensuring predictability." *Rutledge*, 592 U.S. at 90. But the Supreme Court held that "[r]equiring PBMs to reimburse pharmacies at or above their acquisition costs does not require plans to provide any particular benefit to any particular beneficiary in any particular way." *Id.* The same is true of what—and how—PBMs ultimately charge plans for their services. As in *Rutledge*, Iowa's provisions "do not directly regulate health benefit plans at all," *id.* at 88-89 let alone force them to provide any particular benefits in any particular way.

2. Dispensing Fee.

Plaintiffs do address the dispensing fee, Iowa Code § 510B.8B.3, but do not articulate reasonable grounds for finding it preempted. Their quarrel is not with the law itself—a dispensing fee is a cost regulation, after all—but with how soon the law is implemented. Pl. Br. 23. Specifically, they contend that, "when considering SF 383's abrupt onset beginning July 1, 2025," the dispensing fee "constitutes an 'acute' measure that 'will effectively dictate plan choices.'" *Id.* (quoting *Rutledge*, 592 U.S. at 88).

As the Eighth Circuit observed, however, the preemption question is whether "'acute, albeit indirect, economic effects' of the law 'force an ERISA plan to *adopt a certain scheme of substantive coverage* or effectively restrict its *choice of insurers*.'" *Wehbi*, 18 F.4th at 968 (emphasis added) (quoting *Gobeille*, 577 U.S. at 320). And as the Supreme Court has observed, laws that merely mean "PBMs may pass along higher pharmacy rates to plans with which they contract" are not preempted. *Rutledge*, 592 U.S. at 89. Plaintiffs nowhere argue—much less prove—that the effects of a dispensing fee will force ERISA plans to adopt a specific scheme of substantive coverage or effectively restrict their choice of insurers. That alone dooms their challenge to this provision.

In effect, Plaintiffs are attempting to recharacterize a pure form of cost regulation as bearing on a central matter of plan administration. But they do not identify, as they must, what "scheme of substantive coverage" or "choice of insurers" a July 1 effective date requires them to adopt. *Wehbi*, 18 F.4th at 968. Instead, they speculate about any number of possible "self-help measures" plans may *choose* to embrace "to contain [passed-along] costs." Pl. Br. 23. *Rutledge*, however, makes clear that ERISA is not concerned with laws resulting in passed-along costs, regardless of what PBMs or plans do about them. 592 U.S. at 89.

A more fundamental problem with Plaintiffs' argument is that it fails on its own terms. These "self-help measures," which Plaintiffs admit would be up to each PBM and plan to determine, are not "dictated" by the dispensing fee provision or the effective date. They may be a *result*, but they are not *required* in law or in effect. The dispensing-fee provision, in other words, does not entail "economic effects" that result in *mandating* "a certain scheme of substantive coverage." *Gobeille*, 577 U.S. at 320. Discretionary measures that PBMs and plans may (or may

not!) choose to implement cannot justify preempting a duly enacted State rate regulation. *See Rutledge*, 592 U.S. at 89.

3. Rebate Pass-Through.

Section 510B.8.4 requires that PBMs "pass[] through" 100% of all rebates to "the employee benefit plan sponsor as permitted by" ERISA. This, too, regulates costs and rates. The only difference between it and a provision permissibly "pass[ing] along higher pharmacy rates to plans," *Rutledge*, 592 U.S. at 89, is that it requires PBMs to pass along rebates—in effect, credits. Plaintiffs' brief challenges this provision by lumping it in with provisions addressing the terms PBMs may include in contracts, arguing that it "intru[es] into…fiduciary obligations." Pl. Br. 22. As discussed below, that argument is meritless when it comes to the contract provisions; here, it is bewildering. Section 510B.8.4 is a straightforward and direct regulation of what PBMs do with costs—a "pricing methodology" that "does not directly regulate health benefit plans at all," *Rutledge*, 592 U.S. at 88-90—with no plausible connection to a plan's fiduciary obligations.

Plaintiffs' Complaint takes a different approach, arguing that § 510B.8.4 "limit[s] how an ERISA plan may choose to compensate a PBM" and "forc[es] ERISA plans and ERISA-plan sponsors . . . to adopt alternative compensation arrangements with their PBMs." Compl. ¶ 55(k). But this just tries to reframe a quintessential "form of cost regulation," *Rutledge*, 592 U.S. at 88, in terms of what "a plan might prefer that PBMs" can offer, *id.* at 90. *Rutledge* rejected this reasoning: it "is just a long way of saying" that the provision regulates costs. *Id.* Because the rebate pass-through provision may, at most, "increase costs or alter incentives for ERISA plans without requir[ing] plans to provide any particular benefit to any particular beneficiary in any particular way," it is not preempted. *Id.*

Finally, Plaintiffs argue that § 510B.8.4 is preempted because it contains a "reference to" ERISA plans, arguing that "ERISA plans are essential to [its] operation because, without ERISA plans, this part of the provision has no effect or application." Pl. Br. 22 n.13. But reference-to preemption is not triggered whenever a law mentions the ERISA statute, as this one does. Rather, "the existence of ERISA plans is essential to a law's operation only if the law cannot apply to a non-ERISA plan." *Wehbi*, 18 F.4th at 969. This law "applies to PBMs whether or not they manage an ERISA plan," *Rutledge*, 592 U.S. at 88; *accord Wehbi*, 18 F.4th at 970, and requires PBMs to pass-through rebates to *either* the "health carrier" *or* the "employee plan sponsor." § 510B.8.4. On its face, it does not apply *exclusively* to ERISA plans, and it would have "effect and application," Pl. Br. 22 n.13, even if there were *zero* ERISA plans in Iowa.

4. Contractual Pass-Through Provisions.

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. As with the rebate pass-through provision, these regulations govern pricing and costs; they merely restrict the costs that PBMs may permissibly require plans to pay them. And again, "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 90.

Plaintiffs do not argue that these provisions force them to "adopt any particular scheme of substantive coverage," nor could they colorably do so after *Rutledge*. *Id.* Rather, Plaintiffs argue that—because the statute phrases the cost regulation in terms of how it is embodied in contractual

arrangements—it impinges on their ERISA-imposed "fiduciary obligations." Pl. Br. 22. The logic of this argument is remarkable, and obviously incorrect.[10]

First, the section of ERISA they cite has nothing to do with the regulation of third parties who sell goods or services to ERISA plans. *See id.* (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.* The provision is meant to place limits on self-dealing by ERISA 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.

Plaintiffs nonetheless take the position that the phrase "reasonable compensation" preempts state laws regulating the costs PBMs can require of plans. The argument proves too much. For one thing, it conflicts with the outcome of *Rutledge*. For another thing, if Plaintiffs are right, then an 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). For example, a plan's fiduciaries could decide to disregard a state minimum-wage law that applies to nurses if, in their view, the law would exceed "reasonable compensation." But the Supreme Court has been clear that "if ERISA were concerned with any

[10] In their complaint, Plaintiffs argue that these provisions "limit[] how an ERISA plan may choose to compensate a PBM . . . and forc[e] ERISA plans and ERISA-plan sponsors to alter contracts that allow PBMs . . . to retain increments generated under alternatives to pass-through pricing." Compl. ¶ 55(o). But that gives up the game. The Supreme Court was emphatic in *Rutledge* that states may regulate costs—and even set up contract-dispute mechanisms to resolve appeals associated with those costs—without regulating a "central matter of ERISA-plan administration."

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." *Dillingham Constr.*, 519 U.S. at 329.

All the Cost-Regulating Provisions, in short, are permissible under *Rutledge*. None "forc[e] [Plaintiffs] to adopt any particular scheme of substantive coverage." 592 U.S. at 90. The Court should not enjoin any of them.

B. The accreditation and specialty drug designation provisions are not preempted.

Nor does ERISA preempt Iowa's prohibition of PBMs imposing accreditation requirements beyond the State's regulatory baseline or its restrictions on PBMs' ability to arbitrarily designate certain drugs as higher-cost, limited-distribution "specialty drugs." As with many of the Cost-Regulating Provisions, Plaintiffs' brief does not make a meaningful case for preemption of the accreditation and specialty-drug restrictions.

1. Accreditation Requirements.

The accreditation provision prohibits PBMs from requiring "any course of study, accreditation, certification, or credentialing . . . inconsistent with, more stringent than, or in addition to state requirements for licensure or certification" as a "condition of participation in a third-party payor network." § 510B.4B.1.c. *Wehbi* held that a materially identical provision in North Dakota was not preempted because it "merely limit[ed] the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network," which "constitutes, at most, regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects." 18 F.4th at 968 (quoting *Gobeille*, 577 U.S. at 320).

Wehbi controls here. Indeed, Plaintiffs *concede* that accreditation provisions are not preempted as applied to PBMs' requirements for participating in PBMs' pharmacy networks. *See* Pl. Br. 20 n.11.

Plaintiffs suggest, however, that SF 383 is distinguishable because it "impacts the third-party payor's network directly." Pl. Br. 20 n.11. But this is a distinction without a difference.

None of the Plaintiffs assemble or administer their own pharmacy networks. They buy access to networks PBMs maintain. And the State may regulate the goods and services that third parties happen to sell to ERISA plans without triggering any concerns under ERISA.

By its own terms, SF 383's accreditation provision applies directly and exclusively to PBMs and PBMs' conduct; the reference to "third-party payor networks" necessarily *is* a reference to PBMs' networks. Indeed, PCMA argued in *Wehbi* that North Dakota's accreditation provisions were preempted for this reason—they supposedly "dictate[d] choices concerning the design of *provider networks*," PCMA Replacement Br. 22-27, 31, *PCMA v. Wehbi*, No. 18-2926 (8th Cir. May 11, 2021), 2021 WL 2022000 (emphasis added)—and the Eighth Circuit rejected that argument. *Cf.* Compl. ¶ 55(d) ("pharmacy-accreditation standard . . . dictates how an ERISA plan's pharmacy network is designed and maintained"). SF 383's reference to "third-party payor network[s]" does not alter the analysis—the objects of regulation are *PBMs' networks*, which is why the accreditation provision applies directly and exclusively to PBMs, not ERISA or non-ERISA plans.

2. Specialty Drug Designation.

SF 383's restriction on PBMs' ability to unreasonably designate "specialty drugs," § 510B.4B.1.d, likewise regulates PBMs' conduct and does not "govern . . . central matters of plan administration." *Wehbi*, 18 F.4th at 968 (quoting *Gobeille*, 577 U.S. at 320). The statute is clear:

PBMs cannot "unreasonably" reclassify drugs as "specialty" with the objective of limiting their dispensing to certain pharmacies. What is not clear is why Plaintiffs are concerned about "unreasonable" designations undertaken by PBMs with an ulterior motive, which is all the statute proscribes. It does not affect existing specialty classifications or bar *reasonable* ones. Indeed, Plaintiffs' brief does not offer any particularized basis for finding this provision preempted. Rather, Plaintiffs address it in passing, lumping it in with SF 383's overall anti-discrimination provision, *see* Pl. Br. 18, but not explaining how this restriction on *PBM conduct* with respect to drugs pharmacies dispense is susceptible to preemption by itself.

For its part, Plaintiffs' Complaint asserts that barring PBMs from arbitrarily reclassifying drugs somehow "*dictates* how an ERISA plan's pharmacy network is designed and maintained, the terms an ERISA plan must offer to pharmacies in its network, and the terms of ERISA-plan coverage." Compl. ¶ 55(e) (emphasis added). But the Supreme Court rejected a similar argument in *Rutledge*. There, Arkansas law authorized pharmacies to decline to dispense medications when a PBM would reimburse the pharmacy less than its cost to acquire the drug. *Rutledge*, 592 U.S. at 91. The PBMs argued this rendered the pharmacy out of network and effectively regulated pharmacy-network design. *See id.* But the Supreme Court held otherwise: "When a pharmacy declines to dispense a prescription, the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement." *Id.*

Rules governing the reasonableness of PBM drug classification do not affect "a central matter of plan administration," *Rutledge*, 592 U.S. at 87 (quoting *Gobeille*, 577 U.S. at 320): they do not "require[e] payment of specific benefits" or "bin[d] plan administrators to specific rules for determining beneficiary status." *Id.* And Plaintiffs identify no "acute, albeit indirect economic effects" from requiring PBMs to be reasonable that would "force an ERISA plan to adopt a certain

scheme of substantive coverage." *Id.* (quoting *Gobeille*, 577 U.S. at 320). 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 (explaining that a PBM does not act as an agent of an ERISA plan in the "administration of its own business as a PBM"). Thus, Iowa's specialty-drug provision is not preempted.

C. The reporting and disclosure provisions are not preempted.

Plaintiffs also challenge SF 383's requirements that PBMs make certain reports and disclosures about the things PBMs do. Pl. Br. 21-22. Plaintiffs' lack of standing is particularly pronounced here, because the three provisions they challenge here are directed to PBMs—§ 510B.8B.4.a., .b., and .d.—and *do not affect Plaintiffs at all*, directly or indirectly.

For similar reasons, the PBM-reporting provisions are not preempted. SF 383 requires PBMs to issue public reports about things PBMs do about drugs, drug prices, and pharmacies. PBMs must identify "all drugs reimbursed at ten percent or more" below or above "the national average drug acquisition cost," and provide date, quantity, and reimbursement rate information. § 510B.8B.4.a., b. This report is comprehensive, not plan-specific; it applies to PBMs' pricing practices across all prescriptions and all drugs dispensed anywhere by anyone under any kind of coverage. It does not require PBMs to disclose anything about plans. It does not require plans to disclose anything, either.

ERISA has nothing to say about this. It is concerned with laws that require plans (or third parties) to disclose *plan* information—for example, "claims data on members, subscribers, and policyholders," or "detailed information about claims and plan members." *Gobeille*, 577 U.S. at 316, 323. For such laws, "[p]re-emption is necessary to prevent the States from imposing novel, inconsistent, and burdensome reporting requirements *on plans*." *Id.* at 323 (emphasis added).

Iowa's provisions do not operate on plans, and they obviously do not "[r]equire[] PBMs to report to [Iowa] the kind of detailed information that ERISA requires plans to report to the Secretary of Labor." *Wehbi*, 18 F.4th at 969; *see Gobeille*, 577 U.S. at 321-22 (describing mandatory ERISA plan disclosures, which do not concern drugs and pharmacies). In all events, "modest disclosure requirements" like these "constitute, at most, regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects and impact on the uniformity of plan administration across states." *Wehbi*, 18 F.4th at 969. And here, there is no effect on "plan administration" at all; PBMs are simply required to tell the State and the public various details of *PBMs' business transactions* with pharmacies. *See Dillingham Constr.*, 519 U.S. at 325 (preemption inquiry looks "to the nature of the effect of the state law on ERISA plans").

Plaintiffs' argument for preemption conflates SF 383's disclosure requirements of *PBMs* (§§ 510B.4B.2.a. & b.) with *plans*. *See* Pl. Br. 21. Their Complaint does much the same thing, asserting that these *PBM* disclosure requirements "enlarg[e] the requirements governing an *ERISA plan's mandated disclosures* in Iowa." Compl. ¶ 55(n) (emphasis added). As noted, however, these provisions do not mandate "plan" disclosures at all, nor does the mandatory report *PBMs* must make include any *plan* information. The reimbursement rates PBMs charge pharmacies are not "fundamental components of ERISA's regulation of plan administration," *Gobeille*, 577 U.S. at 323, just as direct "rate regulations" are not ERISA's concern, *Rutledge*, 592 U.S. at 88.

Finally, Plaintiffs suggest in passing that the PBM reporting and disclosure provisions "resemble the earlier Iowa requirements that *Gerhart* found ERISA to preempt," and that the Court should enjoin them on that basis. Pl. Br. 21-22. *Gerhart* held preempted mandatory disclosure of PBMs' "methodology for establishing reimbursement amounts paid to pharmacies." 852 F.3d at 731. But *Rutledge* held that a state could require PBMs to *timely update* maximum allowable cost

lists because it did not "affect plan design." 592 U.S. at 84, 90 n.3. Thus, it would be anomalous to hold that a *disclosure* requirement concerning essentially the same thing is preempted. And for that reason, *Rutledge* plainly abrogated any reading of *Gerhart* to the contrary.

D. The Anti-Discrimination Provisions are not preempted.

Lastly, Plaintiffs seek to enjoin SF 383's Anti-Discrimination Provisions—including the AWP Provision and cost-sharing provisions—arguing that they effectively dictate "plan design," even to the extent they regulate the relationships only between PBMs and pharmacies. *See* Pl. Br. 17-18, 19-20. Plaintiffs rely heavily on a recent Tenth Circuit decision, *Mulready*, to justify preemption. *See id.* (citing *Mulready,* 78 F.4th at 1198-2000). Likewise relying on *Mulready*, the Court's TRO Order determined Plaintiffs were likely to show ERISA preempts the blanket anti-discrimination provision, § 510B.1.4., because it "either directs or forbids an element of plan structure or benefit design." TRO Order at 16-17 (quoting *Mulready*, 78 F.4th at 1198).

Mulready, however, is fundamentally mistaken to the extent it deems *PBM* network or cost-sharing laws as bearing on a central matter of *plan* design. The Anti-Discrimination Provisions, which govern what PBMs may and may not do with respect to PBM-assembled, PBM-administered pharmacy networks, are regulating *pharmacy network services* that a PBM sells to plans. They tell PBMs they cannot offer certain items on their menus (such as pharmacy networks that arbitrarily exclude some pharmacies based on PBMs' own preferences) or serve their menu items in a certain way (such as by implementing incentives and penalties that direct patients to pharmacies based on PBMs' own preferences). The point of ERISA's preemption provision is to "ensur[e] that plans do not have to tailor *substantive benefits* to the particularities of multiple jurisdictions," *Rutledge*, 592 U.S. at 86 (emphasis added), not to displace regulations restricting certain *ways* a third party may sell services to ERISA and non-ERISA plans alike.

Put another way, the fact that Iowa plans must purchase access to PBM pharmacy networks that are subject to State laws, and that those networks are conduits through which beneficiaries receive substantive benefits, does not mean that Iowa's PBM laws "govern . . . central matters of plan administration." *Wehbi*, 18 F.4th at 968 (quoting *Gobeille*, 577 U.S. at 320). Laws concerning the composition of PBM networks and the strategies PBMs use to incentivize certain *ways* to receive benefits do not "require providers to *structure benefit plans* in particular ways," "requir[e] payment of specific benefits," or "bind[] plan administrators to specific rules for determining beneficiary status." *Rutledge*, 592 U.S. at 86-87 (emphasis added). The structure of third-party *pharmacy networks* is simply not the same thing as the structure of *plans—i.e.*, what benefits are covered and who is eligible for coverage.

E. Even if the Anti-Discrimination Provisions "relate to" ERISA plans for purposes of preemption, they are not preempted as applied to PBMs by virtue of ERISA's savings clause.

Even assuming the Anti-Discrimination Provisions "relate to" ERISA plans as applied to PBMs that serve those plans, however, they are saved from preemption 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." *Kentucky Ass'n of Health Plans, Inc., v. Miller*, 538 U.S. 329, 342 (2003). The Anti-Discrimination Provisions do both.

Although *amici* believe these provisions are not subject to preemption at all, they indisputably *address* core features of insurance coverage—network composition and cost-sharing rules. Indeed, the federal government took the same position in an *amicus* brief in *Mulready*, arguing that the AWP and anti-discrimination provisions of Oklahoma's PBM law were saved from preemption as applied to PBM serving both insured and self-funded ERISA plans. *See* 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. Plaintiffs suggest that *Miller* imposes a stringent test that requires the overwhelming majority of entities subject to the law actually *be insurers*. Pl. Br. 25. The PBM-directed provisions do not qualify, they say, because "PBMs are administrators, not insurers." *Id.* But the AWP 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 "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. Plaintiffs' position is that the PBM-directed provisions are sufficiently substantive to "dictate" or "mandate" certain benefit structures. Assuming this is true, *Miller* indicates that PBMs are sufficiently involved in the "activity of insurance" to qualify for the savings clause. *Id.* Plaintiffs cannot have it both ways.

As to *Miller*'s second prong, Plaintiffs acknowledge that the Anti-Discrimination Provisions ("the any-willing-pharmacy and cost-sharing provisions") "might qualify as substantially affecting risk-pooling between the insurer and the insured." Pl. Br. 25. There is no "might" about it; *Miller* explicitly holds that such provisions satisfy the second prong. *See* 538 U.S. at 338–39 ("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 . . . ."). 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.

Accordingly, should the Court find that the Anti-Discrimination Provisions satisfy ERISA's "connection with" test, it should nonetheless hold they are saved from preemption as applied to PBMs that serve both insured and self-funded ERISA plans.

III. The challenged provisions of SF 383 are fully severable, and the Court must allow any non-preempted provisions to stand.

As a general matter, where invalid provisions coexist with valid ones, "courts should 'limit the solution' by enjoining enforcement of 'any problematic portions while leaving the remainder intact.'" *Sisney v. Kaemingk*, 15 F.4th 1181, 1194 (8th Cir. 2021) (quoting *Free Enter. Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010)). "[L]egislative intent [i]s 'the touchstone for any decision about remedy,'" including severability. *Advantage Media, L.L.C. v. City of Eden Prairie*, 456 F.3d 793, 800 (8th Cir. 2006) (quoting *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 321 (2006)). The question is, "[w]ould the legislature have preferred what is left of its statute to no statute at all?" *Ayotte*, 546 U.S. at 330.

Here, the Legislature has already provided a definitive answer to that question. SF 383 contains an express severability provision, which operates to preserve the balance of the statute should any of its provisions be deemed invalid. *See* SF 383 § 8 (amended Iowa Code § 510B.12) (invalidity of any provision or application thereof "does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable"). 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); *see Advantage Media*, 456 F.3d at 800 (courts must "be sensitive to such expressions of legislative preference for severance").[11]

Plaintiffs acknowledge SF 383's severability clause. Their response is to assert, in wholly conclusory fashion, that SF 383's "provisions are all intertwined, the remainder cannot workably exist, and determining which parts should live requires intricate legislative work." Pl. Br. 31 n.16; *see* Compl. ¶ 62. The Legislature's decision to include a severability clause, of course, refutes any such argument—the "legislative work" has already been done, and the Legislature's judgment is that it wanted each provision to stand on its own.

At any rate, Plaintiffs' perfunctory argument is obviously wrong. The provisions are not in any sense "intertwined," and each of them can "workably exist" by itself. Reimbursement rate regulations and dispensing fees, for example, do not depend upon the existence of an AWP policy. Restrictions on PBMs' conduct with respect to accreditation requirements and specialty-drug designations do not depend upon cost-sharing requirements. Each provision imposes a different, independent restriction on PBMs, and each is intended to curb specific abusive practices. Whatever may be enjoined, SF 383's other provisions "remain[] complete and capable of execution without" them. *Gresham v. Swanson*, 866 F.3d 853, 855 (8th Cir. 2017).

CONCLUSION

The Court should hold that Plaintiffs are unlikely to succeed in showing the PBM-directed provisions are preempted and decline to enjoin them. Should the Court find that some, but not all, of those provisions are likely to be preempted in law or in application, however, those provisions should be severed from the remainder of SF 383.

[11] Iowa, moreover, has codified a general presumption of severability, *see* Iowa Code § 4.12, and Iowa makes clear courts "have an obligation to preserve as much of a statute as possible within constitutional restraints," *Clark v. Miller*, 503 N.W.2d 422, 424 (Iowa 1993).

Dated: July 7, 2025

Respectfully submitted,

/s/ Todd M. Lantz
Todd M. Lantz
Jason R. Smith
WEINHARDT & LANTZ, P.C.
2600 Grand Avenue, Ste. 450
Des Moines, Iowa 50312
Tel.: 515-244-3100
tlantz@weinhardtlantz.com
jsmith@weinhardtlantz.com

Robert T. Smith*
Timothy H. Gray*
Neal S. Mehrotra*
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue, NW
Suite 800
Washington, DC 20006
Tel.: 202-625-3500
Fax: 202-298-7570
robert.smith1@katten.com
timothy.gray@katten.com
neal.mehrotra@katten.com

Counsel for Amici Curiae

* Motions pending for admission *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that, on July 7, 2025, I had the foregoing Brief of *Amici Curiae* served on all parties by filing it using the Court's CM/ECF system.

/s/ Todd M. Lantz
Todd Lantz
Counsel for Amici Curiae