Nos. 17-1609 & 17-1629

IN THE

United States Court of Appeals for the Eighth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant/Cross-Appellee,

– v. –

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF ARKANSAS,

Defendant-Appellee/Cross-Appellant.

On Appeal From a Final Judgment of the United States District Court for the Eastern District of Arkansas (Miller, C.J.)

BRIEF OF ARKANSAS PHARMACISTS ASSOCIATION AND NATIONAL COMMUNITY PHARMACISTS ASSOCIATION AS *AMICI CURIAE* SUPPORTING DEFENDANT-APPELLEE/CROSS-APPELLANT, AND AFFIRMANCE IN PART AND REVERSAL IN PART

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amici curiae* state as follows:

1. The Arkansas Pharmacists Association has no parent corporation, and no publicly-traded company owns 10% or more of its stock.

2. The National Community Pharmacists Association has no parent corporation, and no publicly-traded company owns 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

FEDERAL STATUTES AND REGULATIONS:

STATE STATUTES AND REGULATIONS:

OTHER AUTHORITIES:

STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici curiae are trade associations that represent independent, community pharmacists and pharmacies: the Arkansas Pharmacists Association (APA) and the National Community Pharmacists Association (NCPA). Founded in 1882, APA represents over 2,400 members consisting of pharmacists, pharmacy students, and members of the industry located within Arkansas. NCPA was founded in 1898 and represents the interests of the owners, managers, and employees of more than 22,000 independent community pharmacies across the United States. NCPA's members employ over 250,000 individuals on a full or part-time basis and dispense nearly half of the nation's retail prescriptions.[1]

As state and national representatives of independent pharmacists, including many of the pharmacists serving communities throughout Arkansas, *amici* have a significant interest in the outcome of the parties' cross-appeals. These appeals focus on whether federal law preempts Act 900, a State law that the Arkansas General Assembly enacted to: (i) regulate pharmacy benefit managers (PBMs) in their reimbursement of pharmacies for providing pharmaceutical goods and services to covered patients in the State of Arkansas, (ii) protect pharmacists against PBMs' deceptive business practices, and (iii) promote transparency in cost reimbursement.

[1] All parties consent to the filing of this brief. No counsel for any party in this case authored this brief in whole or in part. No person or entity—other than *amici*, their members, or their counsel—made a monetary contribution specifically for the preparation or submission of this brief.

All of these are areas of traditional State concern. As such, Act 900 is subject to a strong presumption against preemption by the two federal statutes at issue here: the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Employee Retirement Income Security Act of 1974 (ERISA).

Because *amici* are comprised of members who the Arkansas General Assembly sought to protect, they can offer a unique perspective on the need for State-level regulation of PBMs. In addition, because *amici*'s members are subject to a host of State-level laws and regulations, they can provide insight into how this Court's interpretation of the preemptive force of the MMA and ERISA could affect (and, if erroneously decided, severely limit) the States' exercise of their historic police powers to regulate everything from wages to standards for medical services.

ARGUMENT

Act 900 is not preempted by either the MMA or ERISA. It regulates in areas of traditional State concern, and PCMA has not carried its considerable burden to overcome the starting presumption that Congress does not intend to displace State laws like Act 900. Accordingly, this Court should affirm the portion of the District Court's judgment finding no preemption under the MMA, reverse the portion of the judgment finding preemption under ERISA, and remand with directions for the District Court to enter judgment in favor of the Attorney General on all claims.

I. ACT 900 IS ENTITLED TO A STRONG PRESUMPTION AGAINST PREEMPTION.

Act 900 regulates areas in which the States have historically exercised their police powers. Because courts do not lightly assume that Congress meant to displace fields traditionally occupied by the States, Act 900 is subject to a strong presumption against preemption.

A. Arkansas Pharmacies Were the Victims of Abusive and Deceptive Practices by PBMs, Which Were Threatening Access to Medical Care Throughout the State.

The State of Arkansas was faced with a serious problem: pharmacies were closing their doors throughout the State and this was, in turn, impeding access to medical care. Indeed, the General Assembly had before it evidence that, over the last decade, more than 10% of the State's independent pharmacies had closed. Dkt. No. 77-3, at 8 (West Decl. ¶ 16).[2] "For many Americans, the pharmacy is their most accessible form of healthcare." Pharmacists Care, *The Value of Pharmacy*, https://pharmacistscare.org/access-to-care/the-value-of-pharmacy/. As an example, the parent of a sick child may seek advice from a pharmacist on the use of over-the-counter medication before an appointment is available with the local pediatrician. Other examples include patients who may obtain vaccinations at local pharmacies or seek advice on matters that profoundly affect the public health—from quitting smoking to managing diabetes.

[2] Because the parties have filed their appendices under seal, all record citations are to the publicly-available portions of documents filed in the District Court.

The General Assembly reviewed evidence of the decline of pharmacies and identified a culprit: pharmacy benefit managers or PBMs. These large companies—the three largest, OptumRx (a subsidiary of UnitedHealth Group), CVS Caremark (a subsidiary of CVS Health), and Express Scripts (a subsidiary of Express Scripts Holding), are among the top 25 companies on the Fortune 500, *see* Fortune, *Fortune 500*, http://fortune.com/fortune500/list/—are the quintessential middlemen of the pharmaceutical industry. On the demand side, PBMs enter into contracts with health insurers and plans to deliver insurer- or plan-sponsored prescription drug benefits to beneficiaries. On the supply side, PBMs contract separately with pharmacies to provide reimbursement for the drugs that the pharmacies dispense to beneficiaries.

As the District Court noted, the contracts between PBMs and pharmacies are ones of adhesion. PCMA Add. 18; Dkt. No. 77-3, at 11 (West Decl. ¶ 24). Due to an extreme imbalance in market power, PBMs can impose take-it-or-leave-it terms on small pharmacies and even large retail chains. Dkt. No. 77-3, at 10-12 (West Decl. ¶¶ 21, 24, 29); Dkt. No. 77-4, at 3 (Reed Decl. ¶ 11); Ark. Br. 14.

Although nearly every PBM agrees to "reimburse" pharmacies for dispensing generic drugs based on "market forces," using so-called Maximum Allowable Cost (MAC) lists, Dkt. No. 75-3, at 35 (Kracke Decl. ¶¶ 17, 20); *id.* at 46 (Bricker Decl. ¶ 19), the reality is that PBMs reserve for themselves unilateral authority to select the amount of reimbursement based on their own confidential and proprietary formulae, PCMA Add. 18. In addition, PBMs maintain multiple MAC lists for pharmacies that

can vary for a variety of undisclosed reasons. Dkt. No. 75-3, at 35 (Kracke Decl. ¶ 15); *id.* at 64 (Hyman Decl. ¶ 21). As the State's expert testified, and PCMA's own expert did not dispute, a PBM could unilaterally decide that the MAC reimbursement is a penny for a drug that cost a pharmacy $1000 to procure. Dkt. No. 77-3, at 12 (West Decl. ¶ 28).

Over the last decade, PBMs have expanded the use of so-called "negative reimbursements"—that is, they reimburse at less than the cost for which a pharmacy could acquire a given drug. Dkt. No. 77-3, at 6 (West Decl. ¶¶ 10-11). This, in turn, distorts the meaning of the PBMs' obligation to "reimburse," which is synonymous with "mak[ing] restoration or payment of an *equivalent*" value. Merriam-Webster Dictionary, *Reimburse*, https://www.merriam-webster.com/dictionary/reimburse (emphasis added); *accord* PCMA Add. 16.

Adding to the unfairness, pharmacies do not learn what they will be reimbursed for a given drug until the point of sale. Dkt. No. 77-3, at 12 (West Decl. ¶ 30). That is because PBMs do not disclose their MAC lists to pharmacies and instead treat them as proprietary and confidential. Dkt. No. 75-3, at 34 (Kracke Decl. ¶ 13); *id.* at 44-45 (Bricker Decl. ¶¶ 10, 14).

PBMs often do not disclose their MAC lists to payors, and over 90% of the time, they maintain two sets of lists—one that reflects the prices at which they will agree to reimburse pharmacies, and a second that reflects prices that they charge payors each time that a drug is dispensed to a covered beneficiary. Dkt. No. 75-3, at

282 (Hayes Rpt. ¶ 21). PBMs then keep for themselves this undisclosed spread, *id.*, which raises concerns about self-dealing, Katherine Eban, *Painful prescription: Pharmacy benefit managers make out better than their customers*, Fortune, Oct. 10, 2013 (*available as reprinted at:* http://katherineeban.com/2013/10/23/painful-prescription-fortune-com/) (discussing conflicts among PBMs and their customers).

The District Court cogently summarized the reality facing the General Assembly: "It is undisputed that the Arkansas pharmacies were in economic distress, that MAC lists are confidential and unregulated, and that contracts allow PBMs to reimburse pharmacies for generic drugs in any manner they see fit." PCMA Add. 18.

B. The General Assembly Responded by Enacting Act 900, Which Regulates the Cost of Medical Goods, Promotes Transparency, and Curbs Abusive and Deceptive Business Practices.

In response to dwindling access to pharmacies, the Arkansas General Assembly enacted Act 900. The Act includes a half dozen provisions designed to curb the abusive practice of PBMs.

At the centerpiece of the legislation are provisions designed to place reasonable limits on the practice of so-called "negative reimbursements." Under Act 900, a pharmacy may appeal a negative reimbursement on the ground that it was below the pharmacy's cost of acquisition. Ark. Code § 17-92-507(c)(4)(A)(i). The burden then shifts to the PBM to demonstrate that the drug could have been purchased at a lower amount through a wholesaler who does business in Arkansas. *Id.* § 17-92-507(c)(4)(C)(ii). If the PBM cannot meet this burden, then it must reimburse the

pharmacy at its cost of acquisition. *Id.* § 17-92-507(c)(4)(C)(i). In the alternative, the Act empowers a pharmacy to decline to dispense a drug, rather than appeal, if doing so would result in a negative reimbursement. *Id.* § 17-92-507(e).

As the District Court recognized, these provisions serve a variety of purposes. They ensure that reimbursements are fair and market-driven, rather than arbitrary and capricious. PCMA Add. 16. In addition, by allowing a PBM to deny an appeal based on the availability of a drug at less than an appealing pharmacy's cost of acquisition, Act 900 still encourages pharmacies to seek the best deal for their customers. *Id.*; *see also* Dkt. No. 77-3, at 16 (West Decl. ¶¶ 38, 40). At the same time, the Act's substantive standards ensure that PBMs cannot arbitrarily deny contractually-available appeals when no pharmacy could procure a drug at the PBM's stated amount of reimbursement. PCMA Add. 16.

Faced with evidence that PBMs were notoriously slow in updating MAC lists when market forces would have justified increasing their reimbursements to pharmacies for particular drugs, *see, e.g.*, Dkt No. 77-3, at 15 (West Decl. ¶ 37), the General Assembly also required PBMs to update their MAC lists within "seven (7) calendar days from an increase of ten percent (10%) or more in the pharmacy acquisition cost from sixty percent (60%) or more of the pharmaceutical wholesalers doing business in the state or a change in the methodology on which the Maximum Allowable Cost List is based or in the value of a variable involved in the methodology." Ark. Code § 17-92-507(c)(2). PCMA has not challenged the District

Court's conclusion that PBMs have access to the information necessary to comply with this provision. *See* PCMA Add. 21-22.

Finally, the General Assembly included a provision that requires PBMs to disclose to Arkansas pharmacies updates to MAC lists. Ark. Code § 17-92-507(c)(3). This, in turn, ensures price transparency related to economic transactions occurring within the State.

C. Act 900 Regulates in Areas Traditionally Occupied by the States and is Therefore Subject to a Strong Presumption Against the Displacement of State Law.

Act 900 operates in areas of traditional State concern. As the Supreme Court has repeatedly recognized, "the regulation of health and safety matters is primarily and historically a matter of local concern." *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 719 (1985); *accord DeBuono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997). For that reason, courts have deemed "[t]he regulation of public health and the cost of medical care [as] virtual paradigms of matters traditionally within the police powers of the state." *Med. Soc'y of N.Y. v. Cuomo*, 976 F.2d 812, 816 (2d Cir. 1992); *accord Boyle v. Anderson*, 68 F.3d 1093, 1109 (8th Cir. 1995) ("The passage of MinnesotaCare was an exercise of the state's inherent police powers in the area of health care, in which states have traditionally enacted legislation.").

In addition, the regulation of pharmacists and pharmacies has largely been treated as a matter of State concern. For example, pharmacists and their wholesalers are licensed and regulated by the States, *see, e.g.*, Ark. Code §§ 17-92-101 *et seq.*, and

their operations are subject to State oversight—typically by a Board of Pharmacy, *id.* § 17-92-801. States appropriately dictate when pharmacists may (or must) decline to dispense drugs in certain situations—such as when a pharmacist reasonably believes that a patient is abusing an addictive medication. *See, e.g.*, Ark. Code § 5-64-1102(b)(1) (providing that it is unlawful to sell "any product containing ephedrine, pseudophedrine, or phenylpropanolamine . . . if the person" does so "with reckless disregard as to how the product will be used"); *id.* § 5-64-1103 (placing limits on retail quantities of ephedrine, pseudophedrine, or phenylpropanolamine that a pharmacist may sell); *see also* Ark. Code R. § 07-04-0006(c) (providing that a "pharmacist should not dispense a Schedule V exempt product or Pharmacist Authorized Drug if the pharmacist is aware of information indicating that the patient is inappropriately self-medicating"); *cf.* Ark. Code § 20-16-304(4) (providing that a pharmacist may refuse to furnish "contraceptive procedures, supplies, and information when the refusal is based upon religious or conscientious objection"). And the vast majority of States, Arkansas included, have provided pharmacists with autonomy to determine which drugs they will stock, taking into account the financial, moral, and ethical obligations of the pharmacist. *See, e.g.*, Erica L. Norey, *Duty to Fill? Threats to Pharmacists' Professional and Business Discretion*, 52 N.Y.L. Sch. L. Rev. 95, 105-06 (2007) (discussing variations among the States in providing pharmacists with stocking discretion) (*available at* http://www.nylslawreview.com/wp-content/uploads/sites/16/2013/11/52-1.Norey-Note.pdf); *see* Jody Feder, *Federal and State Laws Regarding Pharmacists Who*

Refuse to Dispense Contraceptives, CRS Report for Congress 6 (2005) (same) (*available at* http://digital.library.unt.edu/ark:/67531/metacrs7544/m1/1/high_res_d/RS22293_2005Oct07.pdf).

In areas like these, where the States have traditionally regulated, the Supreme Court has "addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995). Thus, federal courts work "on the 'assumption that the historic police powers of the states were not to be superseded by the Federal Act unless that was the *clear and manifest purpose* of Congress.'" *Id.* at 655 (emphasis added).

The operation of the presumption has the same vitality in assessing claims of preemption under ERISA and the Medicare Act. For example, in *DeBuono*, the Supreme Court explained that, "[r]ather than warranting pre-emption" by ERISA, the fact that a State law targets the healthcare industry "supports the application of the 'starting presumption' against pre-emption." 520 U.S. at 814 n.10; *Express Scripts, Inc. v. Wenzel*, 262 F.3d 829, 834 (8th Cir. 2001) (explaining that, in evaluating preemption by ERISA, the presumption that Congress does not intend to displace State law operates with particular force "in the case of general health care regulation, where a clear and manifest purpose of Congress is required to overcome the presumption"). As another example, the Second Circuit has applied the presumption against

preemption in evaluating whether the Medicare Act displaced a State law that regulated (and limited) physician billing practices. *Med. Soc'y of N.Y.*, 976 F.2d at 816.

Because Act 900 is an exercise of the historic police powers of the State of Arkansas, PCMA bears "the considerable burden of overcoming 'the starting presumption that Congress does not intend to supplant state law.'" *DeBuono*, 520 U.S. at 814. It has failed to meet that burden here.

II. THE MEDICARE MODERNIZATION ACT AND ERISA DO NOT DISPLACE ACT 900.

There is no clear statement in either the MMA or ERISA that overcomes the strong presumption against the preemption of Act 900.

As explained below, in enacting the MMA, Congress expressly proclaimed that the federal government could "not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i). By precluding federal regulation of price, Congress did not enact (or permit) any substantive, federal price standard that could be said to displace State law on this topic. *Id.* § 1395w-26(b)(3) (providing for the preemption of State law only where that law acts "with respect to" federal "standards established under this part").

In evaluating preemption under ERISA, the Supreme Court has repeatedly held that States may enact neutral laws that regulate the costs of goods and services without triggering a finding of preemption—even where those laws cause an employer-sponsored plan to pay higher costs. *E.g.*, *DeBuono*, 520 U.S. at 816 ("Any

state tax, or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is preempted by the federal statute."). This attribute of Act 900—that it simply regulates cost and price transparency—is fatal to PCMA's claim of preemption.

A. Act 900 Does Not Operate with Respect to Any Standard Established By or Promulgated Under the MMA.

PCMA argues that there are two "standards" under the MMA that preempt Act 900: (1) the purported "negotiated prices" standard, and (2) the "network" provision. PCMA Br. 12, 24-26, 37-39. The preemption clause governing Medicare Part D provides:

> The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D plans] which are offered by [Part D sponsors] under this part.

42 U.S.C. § 1395w-26(b)(3). Thus, to overcome the presumption against preemption, PCMA must show that Act 900 plainly regulates "with respect to" a "standard[] established under" Part D. *Id.* The District Court correctly held that PCMA had failed to do so.

1. The MMA's "negotiated prices" provision does not displace State law regulating economic transactions between PBMs and pharmacies.

PCMA's initial argument is premised on demonstrating that the purported "negotiated prices" provision operates as a substantive regulation of pharmaceutical

prices. Indeed, PCMA proclaims that "Congress and [the Centers for Medicare and Medicaid Services (CMS)] have created *a detailed regulatory scheme* to determine the price paid to a pharmacy for a Part D covered drug." PCMA Br. 12 (emphasis added). This argument fails for two reasons: (a) Congress expressly provided that the federal government *cannot* enact Part D standards for drug pricing, and (b) even if the "negotiated prices" provision operated as a substantive regulation (as the District Court assumed), Act 900 does not regulate in that sphere.

a. Congress and CMS have stated that the "negotiated prices" provision is not a substantive regulation of the prices paid to pharmacies for Part D drugs.

Contrary to PCMA's argument, the federal government has not established "the method for determining the retail price for Part D covered drugs." PCMA Br. 16. Just the opposite, Congress *barred* the federal government from doing so through the enactment of a noninterference clause, which provides in full:

> (i) Noninterference: In order to promote competition under this part and in carrying out this part, the Secretary—
>
> (1) may not interfere with the negotiations between drug manufacturers and pharmacies and [part D plan] sponsors; and
>
> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

42 U.S.C. § 1395w-111(i).

Viewed in the proper light, the provision of the MMA mentioning "negotiated prices," *id.* § 1395w-102(d)(1)(A), has nothing to do with regulating the method for determining the prices paid to pharmacies for Part D covered drugs, because those

prices are set outside Part D's regulatory framework, *id.* § 1395w-111(i). Indeed, Congress barred the federal government from regulating the prices paid to pharmacies and, instead, simply meant to require that Part D plan sponsors provide their *beneficiaries* with access to the same prices that the Part D sponsors pay "for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit." *Id.* § 1395w-102(d)(1)(A).

The absence of a federal pricing "standard" defeats PCMA's claim of preemption. After all, the MMA only preempts State law if it acts "with respect to" a "standard[] established under" Part D. 42 U.S.C. § 1395w-26(b)(3). It defies logic to suggest that the absence of a standard somehow constitutes a standard established under Part D. The MMA-preemption cases cited by PCMA are not to the contrary. As explained by the State of Arkansas in its brief, those cases all involved State law claims relating to marketing standards set by CMS. Ark. Br. 29-30.

PCMA, for its part, acknowledges the existence of the noninterference clause recounted above. PCMA Br. 18-19. It therefore appears to argue that, when Congress enacted the MMA, it *implied* that the prices of Part D drugs must be free from any governmental interference—federal or State. *Id.* at 17-18 (claiming that Congress meant to employ a "market-based model" for Part D drug pricing); *see also id.* at 26 (claiming that "the Negotiated Prices Standard requires retail pricing to be a product of the market-based negotiation between the pharmacist and Plan Sponsor").

But the MMA does not say that. It provides only that the *federal* government shall not regulate price. 42 U.S.C. § 1395w-111(i). If Congress had also meant to bar the States from regulating drug prices—an historic police power—it knew it clearly had to say so. *Cf. Travelers*, 514 U.S. at 654 (holding that a clear and manifest statement is required to overcome the presumption against preemption).

As a fallback, PCMA argues that the regulatory definition of "negotiated prices" operates as a substantive regulation of price. PCMA Br. 24. This argument fails for two reason.

First, as discussed above, the noninterference clause bars the Secretary of Health and Human Services and, in turn, CMS from promulgating any regulation that would dictate the method for determining the prices to be paid to pharmacies for Part D-covered drugs. Indeed, as PCMA acknowledges elsewhere, CMS has rejected regulatory proposals that would require it to dictate a pricing methodology precisely because the federal government "'cannot intervene in negotiations between pharmacies and Part D plans.'" PCMA Br. 28 (quoting Dep't of Health & Human Servs., CMS, *Medicare Program; Medicare Prescription Drug Benefits*, 70 Fed. Reg. 4194, 4245 (Jan. 28, 2005)).

Second, CMS dispelled the notion that the definition of "negotiated prices" operates as a substantive regulation of price. In CMS's words, that definition does "not interfere" with how prices are set. Dep't of Health & Human Servs., CMS, *Final Rule, Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated*

Pricing and Remaining Provisions, 74 Fed. Reg. 1494, 1506 (Jan. 12, 2009). Instead, the definition of "negotiated prices" is synonymous with "the price *ultimately received by the pharmacy* or other dispensing provider." *Id.* (emphasis added). The definition is then used for two limited purposes. First, Part D plan sponsors are required to disclose to CMS the price received by the pharmacy. 42 C.F.R. § 423.104(g)(3)(i). Second, as noted above, the regulations require Part D plan sponsors to give their beneficiaries access to the same prices received by pharmacies, regardless of whether the beneficiary has met his or her deductible or co-payment obligations. *Id.* § 423.104(g)(1); *see also* 42 U.S.C. § 1395w-102(d)(1)(A).

The standards cited by PCMA have nothing to do with a methodology for PBMs to reimburse pharmacies. As such, they do not preempt Act 900.

b. Even if the "negotiated prices" provision acted as a substantive regulation of drug prices, the District Court correctly found that Act 900 operates outside its orbit.

The District Court did not need to consider any of the above issues, because it held that, even if the "negotiated prices" provision regulated the methodology for reimbursing pharmacies, Act 900 fell within an exception to the regulatory definition of that phrase. *See* PCMA Add. 7-9. PCMA is critical of this decision, claiming that the District Court focused only on the appeal provisions of Act 900. PCMA Br. 27-28. But, as explained above, the regulatory definition of "negotiated prices" does not act as a standard for regulating the methodology that PBMs use to reimburse

pharmacies. As a result, there was nothing improper about focusing on the appeal provisions of Act 900.

More importantly, the District Court's analysis of the appeal provisions is consistent with the presumption against preemption. Courts do not lightly assume that Congress meant to displace State laws. Here, the District Court correctly found that, even if the regulatory definition of "negotiated prices" regulated reimbursement methodology (it does not), that definition excludes "'additional contingent amounts'" that "'increase prices and cannot reasonably be determined at the point of sale.'" PCMA Add. 9 (quoting 42 C.F.R. § 423.100). Because the result of a pharmacist's appeal under Act 900 would "increase the price, and because the increase would be contingent on the outcome of a MAC appeal," Act 900 plainly operates outside of standards promulgated under Part D. *Id.*

Thus, even assuming the definition of "negotiated prices" operates as a substantive regulation of the methodology for reimbursing pharmacies, Act 900 operates exclusively within the definition's exception for "additional contingent amounts." Act 900 therefore does not operate "with respect to" any standard established by Part D. There is no error in this reasoning.

2. The network provision that CMS applies to Part D plan sponsors does not relate to a pharmacy's discretion to stock and dispense medications.

PCMA also argues that Act 900's decline-to-dispense provision operates with respect to federal standards that require Part D plan sponsors to establish pharmacy

networks. PCMA Br. 37-45 (citing 42 C.F.R. § 423.120(a)(1); *see also* 42 U.S.C. § 1395w-104(b)(1)(C)(i)-(ii)). But this argument fails for three reasons: (a) the network provision applies to Part D plan sponsors, not PBMs; (b) even if the provision applied to PBMs, it does not impose any obligations on pharmacies to stock and dispense drugs; and (c) a finding of preemption would invalidate a host of State laws that Congress did not intend to preempt.

a. The network provision applies to plan sponsors, not PBMs.

As an initial matter, PCMA's argument distorts a critical distinction regarding Part D's network provision—that it applies to plan "*sponsor[s]*," not PBMs. 42 U.S.C. § 1395w-104(b)(1)(C)(i) (providing that the "PDP *sponsor* of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary)") (emphasis added); *see also* 42 C.F.R. § 423.120(a)(1) (same).

PCMA ignores the full import of this key limitation of the network provision. Instead, it argues in a footnote that reading the regulations in the manner in which they were written would allow a Part D sponsor to avoid the in-network requirement "simply by contracting pharmacy management services to a PBM." PCMA Br. 43-44 n.13. But PCMA never explains why this is so. The regulations hold plan sponsors responsible for creating a network of pharmacies. 42 U.S.C. § 1395w-104(b)(1)(C)(i).

There is nothing in the statute or its implementing regulations that allows plan sponsors to shirk that responsibility through contracts with PBMs.

This alone defeats PCMA's claim. Whereas Act 900 regulates PBMs, the MMA's network provisions do not establish any standards for those entities.

b. Even if the network provision applied to PBMs, it does not impose any obligations on pharmacies to stock and dispense drugs.

PCMA's argument suffers from a second fallacy—it distorts *what* is being regulated through the network provision. By its plain terms, that provision requires Part D plan sponsors to establish a "network" of pharmacies, *id.* § 1395w-104(b)(1)(C)(i), where the plan "may," but is not required to, "reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required," *id.* § 1395w-104(b)(1)(B).

Act 900, in contrast, does not alter or even relate to a plan sponsor's obligation to establish a network of pharmacies. Instead, the decline-to-dispense provision merely allows a pharmacy to decline to dispense a drug where a PBM would pay the pharmacy less than what it cost to acquire the drug in question. Ark. Code § 17-92-507(e). The District Court properly recognized that the unavailability of any given drug does not remove a pharmacy from a sponsor's network. PCMA Add. 9. Moreover, PBMs regularly remove pharmacies from a network after a plan year has begun without any concern that this might implicate a plan sponsor's network-adequacy requirements. Ark. Br. 15, 44-45.

c. A finding of preemption would call into question a host of State laws that Congress surely did not intend to preempt when it enacted the MMA.

Perhaps because the decline-to-dispense provision has nothing to do with plan networks, PCMA spends little time discussing the substance of the MMA's network provision. Instead, it focuses on one of the stated *purposes* of the provision—requiring Part D plan sponsors to "secure participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees." 70 Fed. Reg. at 4247; *see* PCMA Br. 39 (quoting a portion of the same).

But this broad purpose—access to drugs—cannot be construed as establishing a standard that preempts State laws unrelated to pharmacy networks that might be said to affect drug access. If that were the case, then the MMA would preempt a host of State laws that Congress did not intend to displace.

As an initial matter, most States have given pharmacists significant discretion in deciding which drugs they will stock and dispense. *Supra* at 8-10. This discretion reflects a practical reality: "no pharmacy can stock everything." Susan Alverson, *Managing Inventory in a Pharmacy*, J. Pharm. Soc'y of Wis. 59 (Jan./Feb. 2011); *see also* FDA, *Orange Book*, Appendix A – Product Name Index, https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071118.pdf (listing thousands of brand-name drugs, not including interchangeable generics). Nor does Medicare require pharmacies to do so. Dkt. No. 75-3, at 289 (Hayes Rpt. ¶ 49).

Yet, under PCMA's broad interpretation of a Part D plan sponsor's network obligations, States could not regulate pharmacies in any way that might limit access to prescription drugs. This would override State laws that provide pharmacists with discretion over what drugs to stock. For example, in the wake of the opioid epidemic, some pharmacists have declined to stock prescription narcotics, because they do not want to deal with the hassle, expense, and security risk associated with these drugs. Abby Goodnough, *Pharmacies Besieged by Addicted Thieves*, N.Y. Times, Feb. 6, 2011, at http://www.nytimes.com/2011/02/07/us/07pharmacies.html. PCMA's reading of the MMA would not only preempt State laws granting pharmacies this discretion, but it also could be construed to displace State laws that make these drugs more difficult to acquire. *See, e.g.*, Ark. Code § 5-64-308(b) (requiring a written prescription for some controlled substances except in situations of emergency).

In addition, under PCMA's argument, State laws that require (or permit) pharmacists to decline to dispense medication—when, for example, a pharmacist suspects abuse or diversion—would be preempted by the MMA. *Supra* at 8-10. There is no evidence that when Congress established network requirements for Part D plan sponsors, it intended to preempt State regulations of pharmacies and pharmacists.

Finally, PCMA's argument would have far-reaching consequences—beyond State laws that directly regulate the stocking and dispensing of pharmaceuticals. If, for example, the MMA preempts State laws that could be said to affect access to

drugs, then federal law would displace State laws regulating everything from business hours to commercial zoning, because those laws would places limits on where and when pharmacies can dispense prescription medications.

* * *

Because Act 900 does not operate with respect to any standard established under Part D, it is not preempted by the MMA. Accordingly, the Court should affirm this portion of the District Court's judgment.

B. Act 900 is Not Preempted by ERISA.

PCMA also pursued a claim of preemption under ERISA. ERISA's express preemption clause displaces State laws "insofar as" they "relate to" an ERISA plan. 29 U.S.C. § 1144(a). The Supreme Court has cautioned against applying "uncritical literalism" when interpreting the meaning of this clause, because "[i]f 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for really, universally, relations stop nowhere." *Travelers*, 514 U.S. at 655 (alterations and second set of quotation marks omitted). Instead, the Supreme Court has held that a "'law "relates to" an employee benefit plan, in the normal sense of that phrase, if it has a connection with or reference to such a plan.'" *Id.* at 656.

The District Court believed that PCMA's claim of ERISA preemption was without merit, *see* PCMA Add. 5-6—and for good reason. The Supreme Court has repeatedly held that ERISA does not preempt State laws simply because they might

impose costs that are borne by ERISA plans or require incidental reporting. *See DeBuono*, 520 U.S. at 816; *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A.*, 519 U.S. 316, 329 (1997); *Travelers*, 514 U.S. at 649.

But while PCMA's claims were still pending before the District Court, a panel of this Court decided *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017) (Perry, J., sitting by designation). In that case, the Court held that ERISA preempted an Iowa law that sought to regulate PBMs.

The District Court held that *Gerhart* "control[led]," and that it required a finding that ERISA preempts Act 900. PCMA Add. 6-7. Respectfully, the District Court was mistaken.

As explained below, the District Court erred in two respects. *First*, it failed to appreciate a critical distinction between Act 900 and the Iowa law at issue in *Gerhart*. *Second*, the District Court treated *dicta* from *Gerhart* as holdings, and it followed these *dicta* even though they run contrary to precedents of the Supreme Court, and even where they were based on prior allegations (*Gerhart* arose on a motion to dismiss) that are contradicted by undisputed evidence now before this Court on review of a ruling at the summary judgment stage.

This Court "need not follow *dicta*." *John Morrell & Co. v. Local Union 304A*, 913 F.2d 544, 550 (8th Cir. 1990). Thus, the State's cross-appeal presents this Court with an opportunity to ensure that its ERISA jurisprudence maintains fidelity with that of the Supreme Court, while acting consistent with the holding in *Gerhart*. Doing so

requires this Court to reverse the portion of the District Court's judgment that deemed Act 900 preempted by ERISA.

1. Because Act 900 includes no express "reference to" ERISA, it is distinguishable from the Iowa statute that was before this Court in *Gerhart*.

The State law at issue in *Gerhart* included a key feature that is not present here: That law made an express reference to ERISA. *See Gerhart*, 852 F.3d at 729 (citing Iowa Code § 510B.1(2)). For its part, PCMA conceded here that, unlike the State law at issue in *Gerhart*, Act 900 makes no express reference to ERISA. Dkt. No. 99, at 2 n.1.

This distinction is critical. In *Gerhart*, this Court held that the Iowa statute's inclusion of an express reference to ERISA was dispositive of PCMA's claim of preemption: "Because of this impermissible reference to ERISA or ERISA plans, Iowa Code § 510B.8 is preempted under 29 U.S.C. § 1144(a)." 852 F.3d at 730. Indeed, the panel emphasized that because of this "prohibited 'reference to' ERISA [and] ERISA plans, we need not reach the question of whether [the Iowa statute] is also preempted under the 'connection with' prong of the analysis." *Id.*

The fact that Act 900 does not make any express reference to ERISA means that *Gerhart*'s holding does not control the outcome of the case here. Instead, this case turns on the Supreme Court's "connection with" jurisprudence.

2. Act 900 does not bear an impermissible "connection with" any ERISA plan.

The Supreme Court has explained that, in determining whether a State law has a forbidden "connection with" an ERISA plan, a reviewing court must look beyond the statute's "unhelpful text," *Travelers*, 514 U.S. at 656, and consider instead "'the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive,' as well as to the nature of the effect of the state law on ERISA plans," *Dillingham*, 519 U.S. at 325. Critically, in conducting this inquiry, the Supreme Court has "unequivocally concluded" that ERISA's preemption clause was not "intended to modify 'the starting presumption that Congress does not intend to supplant state law.'" *DeBuono*, 520 U.S. at 813.

Act 900 does not have an impermissible "connection with" any ERISA plan. As explained below, State laws such as Act 900 are not the kind that Congress meant to preempt.

a. The Supreme Court has repeatedly held that States may regulate economic transactions, including the costs of goods and services, even where such laws apply directly to ERISA plans.

The Supreme Court has clarified repeatedly that when a plan (or its agent) enters the marketplace for goods or services, the State may regulate those transactions like it would anyone else without running afoul of ERISA. *See DeBuono*, 520 U.S. at 816; *Dillingham*, 519 U.S. at 329; *Travelers*, 514 U.S. at 649. Otherwise, ERISA would preempt everything from medical standards to wage laws, because such State-level

regulations would "invariably affect the cost and price of services" ultimately paid for by ERISA plans. *Travelers*, 514 U.S. at 660. Thus, in *Dillingham*, the Supreme Court rejected a preemption claim involving a State law that required ERISA plans to pay a mandatory wage for certain services. 519 U.S. at 329-30. As the Court explained, the wages "to be paid" and "the substantive standards to be applied" in deciding wages are "quite remote from the areas with which ERISA is expressly concerned." *Id.*

Act 900 is no different. It regulates the cost of providing a prescription drug (a benefit) to a beneficiary. It operates in the same way that a State wage law might regulate the amount that a plan-operated clinic would have to pay a nurse who provided medical services (also a benefit) to a beneficiary. Indeed, *DeBuono* addressed this precise situation. There, the Supreme Court rejected a claim by a plan-operated medical center that ERISA preempted a State tax on the income of such centers. 520 U.S. at 814-16. Applying *Travelers* and *Dillingham*, the Court held that, whether direct or indirect, a "state tax, or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted by the federal statute." *Id.* at 816; *accord Boyle*, 68 F.3d at 1101-10 (holding that ERISA did not preempt a State tax on hospital and healthcare providers that allowed those entities to pass the tax to ERISA plans).

In *DeBuono*, the Supreme Court also clarified the types of State laws that Congress intended to displace—such as a State law that dictates "a method of

calculating *pension* benefits that federal law permits" or a law that "required employers to provide certain benefits." 520 U.S. at 815 (emphasis added). Act 900 does none of these things. Unlike a State law that dictates a method for calculating a pension, which interferes with the benefit itself, Act 900 regulates the *cost of a good* that happens to be a benefit in the same way that the wage law at issue in *Dillingham* dictated "the substantive standards" for the *costs of services* that, likewise, happened to be a benefit. 519 U.S. at 329-30. In addition, Act 900 does not require plans to make particular drugs available to beneficiaries. In short, it is agnostic to plan design.

Act 900 likewise does not bear an impermissible "connection with" ERISA simply because it includes incidental reporting and disclosure requirements. In *Dillingham*, the State not only dictated what wages an ERISA plan had to pay for certain services, but it also imposed reporting obligations to ensure compliance. 519 U.S. at 329-30. The Supreme Court held that this law was not of the type preempted by ERISA. Act 900 is no different. It requires PBMs to disclose pricing information like myriad other State laws bearing on price transparency. None of this gives rise to an impermissible "connection with" ERISA.

b. *Gerhart*'s *dicta* on the "connection with" prong of ERISA preemption is owed no deference because it is contrary to Supreme Court precedent and would embrace a view of preemption that knows no limit.

The panel in *Gerhart* acknowledged that, because the Iowa statute made "a prohibited 'reference to' ERISA," it did not need to "reach the question of whether it

[was] also preempted under the 'connection with' prong of the analysis." 852 F.3d at 730. "Nevertheless," it stated that its "review of [the Iowa statute] shows it to have a prohibited connection with ERISA." *Id.*

Gerhart's "connection with" discussion meets the textbook definition of *dicta*. By the panel's own acknowledgement, its "review" of the "connection with" prong was unnecessary to the disposition of the case before it. *Passmore v. Astrue*, 533 F.3d 658, 660-61 (8th Cir. 2008) (stating that *dictum* is a ""judicial comment made while delivering a judicial opinion, but one that is unnecessary to the decision in the case and therefore not precedential"").

Normally, a panel does not lightly disregard a prior panel's *dicta*. *See, e.g.*, *Ehrlich v. Town of Glastonbury*, 348 F.3d 48, 58 n.14 (2d Cir. 2003) (stating that a panel "owes considerable deference" to *dictum* that is a "careful assessment" of the relevant issue). But here, there are two reasons why *Gerhart*'s *dicta* are owed no deference.

First, there is no way to reconcile *Gerhart*'s *dicta* with the Supreme Court's holdings in *Travelers*, *Dillingham*, and *DeBuono*. For example, the *Gerhart* panel opined that the Iowa law was preempted by ERISA because it "restricts the class of drugs to which [PBMs] may establish maximum *reimbursement amounts* and limits the sources from which they may obtain *pricing information*." *Gerhart*, 852 F.3d at 731 (emphasis added). But in *Dillingham*, the Supreme Court held that a State regulation was *not preempted* by ERISA that set the wages "to be paid" and "the substantive standards to be applied" in setting those wages. 519 U.S. at 329-30. There is no reasonable basis

for distinguishing State standards that set the wages paid by an ERISA plan with laws that set the reimbursement amounts for drugs that might get passed along to an ERISA plan.

As another example, the *Gerhart* panel opined that provisions of the Iowa law were preempted under the Supreme Court's recent decision in *Gobeille v. Liberty Mutual Insurance Co.*, 136 S. Ct. 936 (2016). *Gerhart*, 852 F.3d at 731. But the panel did not appreciate the important distinctions between the law at issue in *Gobeille*, which required certain entities to report "detailed information about *claims and plan members*" to further a comprehensive, State-run healthcare database, 136 S. Ct. at 945 (emphasis added), and the Iowa law, which required PBMs to "report to the commissioner and to network pharmacies their methodology for establishing *reimbursement amounts* paid to pharmacies for providing certain generic drugs to plan participants," *Gerhart*, 852 F.3d at 731. Contrary to *Gerhart*'s *dictum*, *Dillingham* approved laws that require incidental reporting of wages, *see* 519 U.S. at 329-33, and *Gobeille* reaffirmed that State laws are not preempted where "the enforcement of which necessitates incidental reporting by ERISA plans," 136 S. Ct. at 946. Thus, the panel did not recognize the fundamental distinction between a State law that dictates detailed reporting on "claims and plan members," which *Gobeille* deemed preempted, and a State law that requires incidental reporting about prices, which *Dillingham* held was not preempted.

As a final example of *Gerhart*'s erroneous *dicta*, the panel opined that the Iowa law had an impermissible, "implicit" reference to ERISA simply because that law

would have regulated ERISA plans. *Gerhart*, 852 F.3d at 729. There is, however, no way to reconcile that statement with prior decisions of the Supreme Court and this Court, which have held that State laws of general applicability may apply equally to ERISA plans. *See, e.g.*, *DeBuono*, 520 U.S. at 815; *Boyle*, 68 F.3d at 1099.

Second, *Gerhart* misapprehended the form of the benefit that was at issue. According to the panel, Iowa's regulation of PBMs implicated "the calculation of drug benefits." 852 F.3d at 731. But, as a factual matter, that was not the case—and it is certainly not the case here either. Like Act 900, the Iowa law does not dictate what drug benefits a plan might ultimately provide to its beneficiaries. *Id.* Instead, the law regulates the cost that a plan might ultimately bear in procuring drugs for its beneficiaries. *Id.* at 727. Thus, the Iowa law is no different than the State laws at issue in *Travelers* and *DeBuono*, which affected the costs that plans might ultimately bear in procuring medical services for their beneficiaries. In those cases, the Supreme Court held that ERISA did not preempt the State laws.

Adhering to *Gerhart*'s *dicta* would call into question State laws that regulate everything from "medical-care quality standards" to "hospital workplace regulations" because they might be said to dictate the manner in which ERISA plans ultimately pay for healthcare services. *Dillingham*, 519 U.S. at 329. The Supreme Court and this Court have firmly rejected such an expansive interpretation of ERISA. *E.g.*, *DeBuono*, 520 U.S. at 815; *Boyle*, 68 F.3d at 1099.

CONCLUSION

For the reasons stated above and in the principal brief of the Attorney General of Arkansas, Act 900 is not preempted by federal law. Accordingly, this Court should affirm the portion of the District Court's judgment finding no preemption under the MMA, reverse the portion of the judgment finding preemption under ERISA, and remand for the District Court to enter judgment in favor of the Attorney General on all claims.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rules 29(a)(4)(G) and 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, this *amici curiae* brief is proportionately spaced; uses a Roman-style, serif typeface (Garamond) of 14-point; and contains **7,646 words**, exclusive of the material not counted under Rule 32(f) of the Federal Rules of Appellate Procedure.

Because this is a cross-appeal, the type-volume limitations of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure do not apply. *See* Fed. R. App. P. 28.1(a). Instead, Rule 28.1(e)(2) of the Federal Rules of Appellate Procedure sets forth the type-volume limitations for the parties' briefs.

This *amici curiae* brief meets the length requirements of Rule 29(a)(5) of the Federal Rules of Appellate Procedure because it is "no more than one-half the maximum length authorized by these rules for a party's principal brief," Fed. R. App. P. 29(a)(5), and, in this cross-appeal, the maximum length for a principal brief is 15,300 words, *id.* 28.1(e)(2)(B)(i). *Accord* 4th Cir., *Appellate Procedure Guide* 2 (Dec. 2016) ("An amicus brief in support of an opening/response brief in a cross-appeal may contain up to 7,650 words.") (*available at* http://www.ca4.uscourts.gov/AppellateProcedureGuide/Briefing/briefapxreq_ca4.pdf).

In addition, pursuant to Rule 28A(h)(2) of the Eighth Circuit Rules of Appellate Procedure, I hereby certify that the electronic version of this brief has been scanned and that the brief is virus free.

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CERTIFICATE OF SERVICE

I hereby certify that I had the foregoing *Amici Curiae* Brief electronically filed by tendering it to the Office of the Clerk of the United States Court of Appeals for the Eighth Circuit on June 21, 2017.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. I further certify that I served paper-copies of the brief on all counsel of record using the addresses listed in the Court's CM/ECF system.

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