United States Court of Appeals
for the Eighth Circuit

No. 17-1609

Pharmaceutical Care Management Association

Plaintiff - Appellant

v.

Leslie Rutledge, in her official capacity
as Attorney General of Arkansas

Defendant - Appellee

Arkansas Pharmacists Association;
National Community Pharmacists Association

Amici on Behalf of Appellee(s)

No. 17-1629

Pharmaceutical Care Management Association

Plaintiff - Appellee

v.

Leslie Rutledge, in her official capacity
as Attorney General of Arkansas

Defendant - Appellant

National Community Pharmacists Association;
Arkansas Pharmacists Association

Amici on Behalf of Appellant(s)

Appeals from the United States District Court
for the Eastern District of Arkansas – Little Rock

Submitted: January 9, 2018
Filed: June 8, 2018

Before LOKEN, BEAM, and KELLY, Circuit Judges.

BEAM, Circuit Judge.

In this dispute between a pharmacy trade association, Pharmaceutical Care Management Association (PCMA) and the State of Arkansas, PCMA appeals the district court's ruling that an Arkansas state statute is not preempted by Medicare Part D, 42 U.S.C. § 1395w-26(b)(3), and the State of Arkansas appeals the district court's ruling that the statute *is* preempted by ERISA, 29 U.S.C. § 1144(a). Because the state statute in question is preempted by both ERISA and the Medicare Part D statutes, we affirm in part, reverse in part, and remand.

I. BACKGROUND

In 2015, the Arkansas General Assembly passed a state law which attempted to govern the conduct of pharmacy benefits managers ("PBMs")–the entities that verify benefits and manage financial transactions among pharmacies, healthcare payors, and patients. PBMs are intermediaries between health plans and pharmacies, and provide services such as claims processing, managing data, mail-order drug sales, calculating benefit levels and making disbursements. Pharmacies acquire their drug inventories from wholesalers. The patient buys the drug from the pharmacy, but often at a lower price due to participation in a health plan that covers part of the price. Further, the PBMs create a maximum allowable cost ("MAC") list which sets reimbursement rates to pharmacies dispensing generic drugs. Contracts between PBMs and pharmacies create pharmacy networks. Based upon these contracts and in order to participate in a preferred network, some pharmacies choose to accept lower reimbursements for dispensed prescriptions. Thus, unfortunately, a pharmacy might actually lose money on a given prescription transaction.

In an attempt to address the trend in Arkansas of significantly fewer independent and rural-serving pharmacies in the state, the state legislature adopted Act 900, Arkansas Code Annotated § 17-92-507, an amendment to the state's then-existing MAC law, to "Amend the Laws Regarding Maximum Allowable Cost Lists; to Create Accountability in the Establishment of Prescription Drug Pricing." 2015 Ark. Laws Act 900,

S.B. 688 (Ark. 2015). The Act mandates that pharmacies be reimbursed for generic drugs at a price equal to or higher than the pharmacies' cost for the drug based on the invoice from the wholesaler. It did this by defining "pharmacy acquisition cost" as the amount charged by the wholesaler as evidenced by the invoice. Ark. Code Ann. § 17-92-507(a)(6). The Act further imposes requirements on PBMs in their use of the MAC lists by making them update the lists within at least seven days from the time there has been a certain increase in acquisition costs. Id. § 17-92-507(c)(2). The Act also contains administrative appeal procedures, id. § 17-92-507(c)(4)(A)(i), and allows the pharmacies to reverse and re-bill each claim affected by the pharmacies' inability to procure the drug at a cost that is equal to or less than the cost on the relevant MAC list where the drug is not available "below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale." Id. § 17-92-507(c)(4)(C)(iii). Finally, the Act contains a "decline-to-dispense" option for pharmacies that will lose money on a transaction. Id. § 17-92-507(e).

PCMA brought this action on behalf of its members, the nation's leading PBMs, claiming Act 900 is preempted by both ERISA and Medicare Part D, and also that it is unconstitutional on a number of other grounds not at issue on appeal (because PCMA did not appeal the district court's adverse ruling on these claims). The district court agreed that the pertinent portions of Act 900 were preempted by ERISA based

upon controlling Eighth Circuit case law. See Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017). However, the district court found that Medicare Part D did *not* preempt Act 900, nor was the law unconstitutional on any of the several bases advanced by PCMA. PCMA appeals the Medicare Part D ruling, and the state cross-appeals the ERISA ruling.

II. DISCUSSION

We review de novo the district court's preemption/statutory interpretation rulings. Id. at 726.

A. ERISA Preemption

ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plans." 29 U.S.C. § 1144(a). The breadth of this section is well known. See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995). A state law is preempted if it "'relates to'" an ERISA plan by having "'a connection with or a reference to such a plan.'" Express Scripts, Inc. v. Wenzel, 262 F.3d 829, 833 (8th Cir. 2001) (quoting Travelers, 514 U.S. at 656). In Gerhart, we held that an Iowa statute, similar in purpose and effect to Act 900, was preempted by ERISA because it had a prohibited "reference to" ERISA, and because it interfered with national uniform plan administration. 852 F.3d at 729, 731. The district court found that Gerhart controlled the outcome of the ERISA preemption claim in the instant case. We agree. The Iowa statute in Gerhart

required PBMs to provide information regarding their pricing methodologies to Iowa's insurance commissioner at the commissioner's request. Id. at 727. The statute further limited the types of drugs to which a PBM could apply MAC pricing and limited the sources from which a PBM obtained pricing information. Id. Finally, the statute required PBMs to provide information regarding their pricing methodologies in their contracts with pharmacies and to provide procedures by which pharmacies could comment on and appeal MAC price lists or rates, with potential retroactive payment to pharmacies for incorrect pricing. Id. We held that the Iowa statute both explicitly and implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits, and also had a connection with ERISA. It was therefore preempted. Id. at 729-30.

The state argues that Gerhart should be limited to its consideration of the Iowa Act's "express reference" to ERISA, and that Gerhart's "implicit reference" analysis is dicta inconsistent with Supreme Court precedent. We disagree. In addition to finding that Iowa Code § 510B.8 had a prohibited express reference to ERISA, the Gerhart court found that the "Iowa law also makes implicit reference to ERISA through regulation of PBMs who administer benefits for 'covered entities,' which, by definition, include health benefit plans and employers, labor unions, or other groups 'that provide[ ] health coverage.' These entities are necessarily subject to ERISA regulation." 852 F.3d at 729. None of the state's arguments convince us that we are

not completely bound by a prior panel's reasoning on the exact question before us. Nor do we believe Gerhart to be inconsistent with the Supreme Court's precedent in Travelers or De Buono v. NYSA-ILA Medical and Clinical Services Fund, 520 U.S. 806 (1997). While both cases indicate there is generally a presumption against preemption, De Buono, 520 U.S. at 813; Travelers, 514 U.S. at 654, where, as here, the state law both relates to and has a connection with employee benefit plans, the presumption is gone and the law is preempted. Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324-25 (1997). The district court correctly found that Act 900 was preempted by ERISA.

B. Medicare Part D and Preemption

Medicare Part D is a comprehensive statutory and regulatory scheme for prescription drugs, which aims to balance cost with access to those drugs. The Part D program funds prescription drug benefits through payments from the Medicare government trust fund, and beneficiaries generally get prescriptions through a Part D network provider. See 42 C.F.R. §§ 423.120, 423.124. The statute prohibits both federal and state interference in negotiations between Part D sponsors and pharmacies (known as the "non-interference" clause, 42 U.S.C. § 1395w-111(i)). The federal scheme preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established "standards" in the area regulated by the state law; and (2) the state law acts "with respect to" those

standards. Id. § 1395w-26(b)(3) Conflict between the state law and the federal standard is unnecessary. PCMA argues the district court erred in holding that Act 900 was not preempted by Medicare Part D. It contends that Act 900 acts "with respect to" two standards created by Congress and CMS for Medicare Part D–the Negotiated Prices Standard, and the Pharmacy Access Standard.

1. Negotiated Prices Standard

42 U.S.C. § 1395w-102 sets forth several requirements for standard prescription drug coverage and access to negotiated prices. Most specifically, the regulation defines "negotiated prices" for Part D drugs as the price: "the part D sponsor (or other intermediary contracting organization) [such as a PBM] and the network dispensing pharmacy . . . have negotiated as the amount such network entity will receive, in total, for a particular drug." 42 C.F.R. § 423.100. Negotiated prices are "inclusive of all price concessions from network pharmacies" but "exclude[] contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale." Id.

Act 900 acts "with respect to" the Negotiated Price Standard, first and most obviously by regulating the price of retail drugs. Act 900 effectively replaces the negotiated MAC price with the pharmacy acquisition cost when the MAC rate is below the pharmacy's invoice cost, Arkansas Code Annotated § 17-92-507(b)(4)(A)(i)(b),

and requires that the price paid by pharmacy customers be no less than the price negotiated by the pharmacy with its wholesaler, id. § 17-92-507(c)(4)(C)(iii). The appeals process which allows the pharmacy to reverse and re-bill the claim, eliminates "negative reimbursements" for the pharmacies, resulting in an increase in the retail price of prescription drugs. Id. The state's efforts to change the pricing model from PBMs negotiating with pharmacies to pharmacies negotiating with wholesalers easily acts "with respect to" the Part D standard.

The state argues the district court correctly found that Act 900 did not act "with respect to" the Negotiated Price Standard because Part D's "negotiated prices" provisions are not a substantive standard,[1] and in any event these provisions exclude Act 900's contingent amounts from its meaning. Further it argues the CMS did not mean to control prices by regulating, but instead merely meant to provide transparency and to control entities such as the PBMs. The district court cursorily reasoned that Act 900 was not preempted, in part because it did not affect negotiated prices. The court found that Act 900 would only act to increase prices, leading to an appeal, and the resulting price after the appeal would fall into the category of a "contingent" amount, which Part D expressly excludes from

[1] It is, in fact a standard, as a standard within the meaning of the preemption provision is either a statutory provision or a regulation duly promulgated and published in the Code of Federal Regulations. Do Sung Uhm v. Humana, Inc., 620 F.3d 1134, 1148 n.20 (9th Cir. 2010).

its standard, 42 C.F.R. § 423.100. PCMA points out that the appeal process does not make the price "contingent" because even after the appeal, the resulting price could be one of three pre-determined amounts– the MAC price, the invoice price, or the best price from the wholesaler higher than the MAC. All three amounts can be determined at the point of sale. We agree that the appeal provisions do not render the price "contingent."

2. Pharmacy Access Standard

Medicare Part D also sets forth requirements with regard to Medicare recipients' access to pharmacies. 42 U.S.C. § 1395w-104(b)(1)(C) provides that a 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)." The regulations in 42 C.F.R. § 423.120(a) further spell out the need for assuring pharmacy access. Thus, the Pharmacy Access Standard requires that networks be structured so that a certain percentage of beneficiaries live within a certain distance to a network pharmacy.

The district court found that because the decline-to-dispense provisions do not render a pharmacy as out-of-network, Act 900 did not act "with respect to" the standard. We disagree, and find that Act 900 indeed acts "with respect to" the Pharmacy Access Standard, because a pharmacy that refuses to dispense

drugs becomes, in effect, an out-of-network pharmacy. Act 900's decline-to-dispense clause could conceivably, and likely would, lead to a beneficiary being unable to fill a prescription in his or her geographical location. This would actually interfere with convenient access to prescription drug availability, which is more than is required for preemption. Again, if the state law in question merely acts "with respect to" the standard, it is preempted. It clearly does in this instance. Accordingly, we find that Act 900 is preempted by Medicare Part D.

III. CONCLUSION

We affirm the district court's ERISA ruling, reverse the Medicare Part D ruling, and remand for entry of judgment in PCMA's favor.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION **PLAINTIFF**

v. **CASE NO. 4:15-CV-00510 BSM**

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

ORDER

Plaintiff Pharmaceutical Care Management Associations's [sic] (PCMA) motion for summary judgment [Doc. No. 75] is granted in part and denied in part, and defendant Leslie Rutledge's (State of Arkansas) motion for summary judgment [Doc. No. 77] is granted in part and denied in part. The joint motions to extend time [Doc. Nos. 103, 104] are denied as moot, and this case is dismissed with prejudice.

I. BACKGROUND

Independent community pharmacies have had to eliminate employees during the last five to ten years due to the financial hardships they have faced. Pl.'s Resp. Def.'s Statement Material Fact ¶¶ 18, 22–24, 28, 44, Doc. No. 85-1. The Arkansas legislature passed and amended Arkansas Code Annotated section 17-92-507 *et seq*. in an attempt to address this issue. Act 1194 was passed in 2013 to "Provide for the Transparency of Maximum Allowable Cost Lists for Prescription

Drugs," S.B. 1138, 89th Gen. Assemb., Reg. Sess. (Ar. 2013), and Act 900 was passed in 2015 to "Amend the Laws Regarding Maximum Allowable Cost Lists; and to Create Accountability in the Establishment of Prescription Drug Pricing." S.B. 688, 90th Gen. Assemb., Reg. Sess. (Ar. 2015).

A. Act 900 of 2015

Act 900 amended Act 1194 in a number of ways. First, it defines "[p]harmacy acquisition cost" as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice." Ark. Code Ann. § 17-92-507(a)(6). Second, it provides that a pharmacy benefits manager ("PBM") must:

> [u]pdate its Maximum Allowable Cost List on a timely basis, but in no event longer than 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 wholesaler 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.

Id. § 507(c)(2). Third, it requires a PBM to:

> Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as: (a) not meeting

> the requirement of this section or (b) being below the pharmacy acquisition cost.

Id. § 507(c)(4)(A)(i). Fourth, it requires PBMs to permit the challenging pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the cost on the relevant maximum allowable cost ("MAC") list where the drug is not available "below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale." *Id.* § 507(c)(4)(C)(iii). Fifth, it provides that a

> pharmacy or pharmacist may decline to provide the pharmacy services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

Id. § 17-92-507(e) (commonly known as the "decline-to-dispense" provision).

B. PCMA, MAC Lists, and Pharmaceutical Reimbursement Scheme

PCMA is a national trade association representing the eleven largest PBMs in the country. Def.'s Resp. Pl.'s Statement Material Fact ¶ 1, Doc. No. 89. None of PCMA's member PBMs are incorporated in Arkansas, but they have contracts covering beneficiaries in Arkansas. *Id.* ¶ 19.

PBMs act as intermediaries between health plans and pharmacies. Generally, when a patient is prescribed a drug by a physician, the patient presents the prescription to a pharmacist. The pharmacist, who buys drugs from wholesalers, dispenses the drug to the patient. Often, the patient does not pay the full price that the pharmacist receives for the drug but instead pays a portion, or copay, if the patient is a member of a health plan that covers part of the drug's cost.

The market for purchasing prescription drugs is national, *id.* ¶ 21, and PBMs perform such services as processing claims, generating reports and data, and managing clinical and financial information as well as retail and mail-order drug sales. Pl.'s Resp. Def.'s Statement Material Fact ¶ 5. PBMs also calculate benefit levels and make disbursements. Def.'s Resp. Pl.'s Statement Material Fact ¶ 2. To carry out these services, PBMs aggregate market data to create confidential maximum allowable cost ("MAC") lists. MAC lists are used to set reimbursement rates for pharmacies filling generic prescriptions. Wholesaler pricing information is one type of data used by PBMs to create MAC lists. Pl.'s Resp. Def.'s Statement Material Fact ¶ 69. This information is available through pricing guides such as Medispan and, in some cases, is made available by wholesalers. *Id.* ¶¶ 69–71.

Contracts between PBMs and pharmacies create pharmacy networks. Def.'s Resp. Pl.'s Statement Material Fact ¶ 12. These contracts generally require pharmacies to fill prescriptions and dispense prescription medications regardless of the amount that the

pharmacy will be reimbursed. Pl.'s Resp. Def.'s Statement Material Fact ¶ 81. These contracts also allow pharmacies to appeal unfavorable reimbursement decisions. *Id.* ¶ 75. PBMs often select pharmacies willing to take lower reimbursements in exchange for being placed in a preferred network and receiving patronage from beneficiaries of the plans serviced by the PBMs. *Id.* ¶ 80; Def.'s Resp. Pl.'s Statement Material Fact ¶ 13.

C. PCMA's Challenge to Act 900

PCMA challenges Act 900 claiming that it (1) is preempted by ERISA; (2) is preempted by Medicare Part D; (3) violates the Commerce Clause of the United States Constitution; (4) violates the Contract Clauses of the United States Constitution and the Arkansas Constitution; and (5) is so vague as to violate the Due Process Clauses of the United States Constitution and the Arkansas Constitution. Both parties move for summary judgment on all claims.

II. LEGAL STANDARD

Summary judgment is appropriate when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 249–50 (1986). Once the moving party demonstrates that there is no genuine dispute of material fact, the nonmoving party may not rest upon the mere allegations or denials in the pleadings. *Holden v.*

Hirner, 663 F.3d 336, 340 (8th Cir. 2011). Instead, the nonmoving party must produce admissible evidence demonstrating a genuine factual dispute that requires resolution at trial. *Id.* Importantly, when considering a motion for summary judgment, all reasonable inferences must be drawn in a light most favorable to the nonmoving party. *Holland v. Sam's Club*, 487 F.3d 641, 643 (8th Cir. 2007). When both parties move for summary judgment, all justifiable inferences must be drawn in favor of the losing party. *Murphy Expl. & Prod. Co. v. Oryx Energy Co.*, 101 F.3d 670, 673 (Fed. Cir. 1996). The evidence is not weighed, and no credibility determinations are made. *Jenkins v. Winter*, 540 F.3d 742, 750 (8th Cir. 2008).

III. DISCUSSION

A. ERISA Preemption

PCMA's motion for summary judgment is granted on its claim that Act 900 is ERISA preempted, and the State of Arkansas's motion is denied because Act 900 is invalid as applied to PBMs in their administration and management of ERISA plans.

Initially, a decision consistent with that reached by the Southern District of Iowa in *Pharmaceutical Care Management Association v. Gerhart*, No. 4:14-CV-000345, 2015 WL 10767327 (S.D. Iowa Sept. 8, 2015) was reached. The Southern District of Iowa and this court independently reached the same conclusions when analyzing similar statutes. Iowa Code section

510B.8 is similar to Act 900 in a number of ways, and the Northern District of Iowa held that the Iowa statute was not preempted by ERISA. While preparing this order, however, the Eighth Circuit Court of Appeals reversed the Southern District of Iowa. *See Pharm. Care Mgmt. Ass'n v. Gerhart*, No. 15-3292, 2017 WL 104467 (8th Cir. Jan. 11, 2017) *reh'g denied.* In that the Eighth Circuit's opinion controls, this ruling has been revised to conform to that opinion.

In *Gerhart*, the Eighth Circuit held that Iowa Code section 510B.8, which is similar to Act 900 in many of the ways that it regulates PBMs and MAC pricing, is preempted by ERISA because it interferes with nationally uniform plan administration. *Gerhart* held that the Iowa statute interferes with uniform plan administration by requiring PBMs, as third-party administrators, to provide a procedure by which pharmacies can contest and appeal MAC reimbursements because doing so restricts an administrator's control in the calculation of drug benefits and removes the ability to conclusively determine final drug benefit payments and monitor funds. *See id.*, 2017 WL 104467 at *5. Similarly, section 507(c)(4) of Act 900 requires PBMs to provide a "reasonable administrative appeal procedure" that allows pharmacies to challenge MAC costs and to reverse and rebill the claim in question.

Gerhart also held that the Iowa law interferes with uniform plan administration by restricting the class of drugs PBMs may place on MAC lists and by restricting the sources from which PBMs may obtain pricing information because both restrictions interfere

with the calculation of benefit levels and with making disbursements. 2017 WL 104467 at *5. Section 507(b) of Act 900, likewise, restricts the class of drugs PBMs may place on its MAC lists. Act 900 does not limit the sources from which PBMs may obtain pricing information *per se*, but sections 507(c)(2) and (c)(4) set "pharmacy acquisition cost" as the standard by which PBMs must update MAC lists and grant appeals, which is as intrusive with MAC methodology as the Iowa statute.

Finally, *Gerhart* held that the Iowa statute interferes with uniform plan administration by requiring PBMs to report or disclose to pharmacies the economic bases of its MAC lists. 2017 WL 104467 at *5. Section 507(c) of Act 900 requires PBMs to provide their MAC lists to pharmacies, to promptly notify pharmacies when MAC lists are updated, and to disclose to pharmacies certain sourcing and pricing information when an appeal is denied.

Because Act 900 regulates PBMs in ways fundamentally similar to the Iowa statute in *Gerhart*, Act 900 is preempted by ERISA. *See* 2017 WL 104467 at *6. Preemption, however, only requires "invalidation of [Act 900] as applied to PBMs in their administration and management of prescription drug benefits for ERISA plans." *See id.* (citing *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (concluding that Vermont's regime is preempted "as applied to ERISA plans")). Thus, the remainder of PCMA's claims must also be evaluated.

B. Medicare Part D Preemption

The State of Arkansas's motion for summary judgment is granted on PCMA's Medicare Part D preemption argument, and PCMA's motion is denied because Act 900 does not act with respect to a standard established under Medicare Part D.

The Medicare statute provides that "[t]he standards established under this part shall supersede any State law or regulation . . . with respect to [Part D] plans which are offered by [Part D] organizations under this part." 42 U.S.C. § 1395w-26(b)(3) (incorporating Part C's preemption provision, 42 U.S.C. § 1395w-112(g)). A "standard" within the meaning of this preemption provision means a statutory provision or a regulation promulgated under Medicare and published in the Code of Federal Regulations. *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010). The meaning of the phrase "with respect to" is broad. For a law to act "with respect to" a Medicare standard, it need not exclusively impact a Medicare standard, and it need not be inconsistent with a Medicare standard. *Id.* at 1149, 1150 n. 25. Ultimately, preemption is found "only where it is the 'clear and manifest purpose of Congress,'" and the plain language of the preemption clause offers the best evidence of Congress's preemptive intent. *Id.* at 1148 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

PCMA asserts that Act 900 acts with respect to Part D's "negotiated prices" standard, which requires beneficiaries to have access to "negotiated prices." 42

U.S.C. § 1395w-102(d). The regulations accompanying this provision define "negotiated prices" as "prices for covered Part D drugs that . . . the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy . . . have negotiated as the amount such network entity will receive, in total, for a particular drug." 42 C.F.R. § 423.100.

Act 900's regulation of MAC pricing does not act with respect to Part D's negotiated prices standard because the standard excludes "additional contingent amounts" that "increase prices and cannot reasonably be determined at the point of sale." *See id.* If Act 900 has any effect on the price of a drug, it would be to increase the price, and because the increase would be contingent on the outcome of a MAC appeal, it is a contingent amount not able to be determined at the point of sale. Thus, Act 900 does not act with respect to Part D's negotiated prices standard because the Part D standard excludes it from its scope.

PCMA also asserts that Act 900's decline-to-dispense provision acts with respect to Part D's "standards for convenient access to network pharmacies." 42 C.F.R. § 423.120(a)(1). These standards require Part D sponsors to structure their networks so that certain percentages of beneficiaries live within certain distances of a network pharmacy. *See id.* Act 900's decline-to-dispense provision does not act with respect to Part D's pharmacy-access standards because a pharmacy that declines to dispense a drug in anticipation of a negative reimbursement is not thereby transformed into an out-of-network pharmacy.

C. The Dormant Commerce Clause

The State of Arkansas's motion for summary judgment is granted on PCMA's Commerce Clause claim, and PCMA's motion is denied because Act 900 does not discriminate against out-of-state economic interests in favor of in-state economic interests and because any burden it imposes on interstate commerce is not "clearly excessive in relation to the putative local benefits." *U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1067 (8th Cir. 2000) (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

The Commerce Clause, intended to create an area of free trade among the states, gives Congress the power to regulate interstate commerce. U.S. CONST. art. I, § 8, cl. 3; *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944). The negative implication of this power, known as the dormant Commerce Clause, prohibits states from unjustifiably discriminating against interstate commerce. *Wyoming v. Oklahoma*, 502 U.S. 437, 453 (1992); *Hampton Feedlot, Inc. v. Nixon*, 249 F.3d 814, 818 (8th Cir. 2001). If a state law overtly discriminates, the state must show, "under rigorous scrutiny, that it has no other means to advance a legitimate local interest." *U & I Sanitation*, 205 F.3d at 1067 (citing *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 392 (1994)). Thus, a state law that overtly discriminates is presumed invalid. *U & I Sanitation*, 205 F.3d at 1063.

Act 900 does not overtly discriminate against interstate commerce. A law discriminates against interstate

commerce when it "favors in-state economic interests over their out-of-state counterparts." *Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality of State of Oregon*, 511 U.S. 93, 93 (1994); *Pete's Brewing Co. v. Whitehead*, 19 F. Supp. 2d 1004, 1010 (W.D. Mo. 1998) (dormant Commerce Clause prohibits "regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors"). Act 900 imposes requirements on PBMs. It does not favor in-state PBMs over out-of-state PBMs or in-state pharmacies over out-of-state pharmacies.

PCMA asserts Act 900 creates impermissible economic protectionism in favor of pharmacies, but "[t]he fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 126 (1978). The Commerce Clause does not protect particular structures or methods of operation in a market. *Id.* at 127–28.

Notwithstanding its facially nondiscriminatory status, Act 900 still may incidentally burden interstate commerce. *See Ben Oehrleins & Sons & Daughter, Inc. v. Hennepin Cty.*, 115 F.3d 1372, 1387 (8th Cir. 1997) (even nondiscriminatory laws may unconstitutionally burden interstate commerce). Even if it is accepted that Act 900 imposes some incidental burden on interstate commerce, PCMA must show that the burden clearly outweighs its putative, or presumed, local benefit. *Pike*, 397 U.S. at 142; *U & I Sanitation*, 205 F.3d at 1067. A state law that discriminates only

incidentally, is presumed valid. *R&M Oil & Supply, Inc. v. Saunders*, 307 F.3d 731, 737 (8th Cir. 2002) ("State statutes passed for the protection of the public's health and safety are generally constitutional despite the incidental burden they may impose on interstate commerce."). Due to the strong presumption of validity, it is not for the courts to second-guess legislative judgment regarding the importance of legitimate safety justifications, *Kassel v. Consol. Freightways Corp. of Delaware*, 450 U.S. 662, 670 (1981), unless "a statute provides little or nothing in the way of demonstrable legitimate local benefit." *Saunders*, 307 F.3d at 737.

Act 900's putative local benefit is legitimate. Independent community pharmacies in Arkansas are in economic distress, Pl.'s Resp. Def.'s Statement Material Fact ¶¶ 18, 22–24, 28, 44, and the parties agree that Act 900's purpose is to protect pharmacies. *See* Pl.'s Mem. Supp. Summ. J., Doc. No. 75-1 at 26; Def.'s Reply Pl.'s Resp. Def.'s Mot. Summ. J. ¶ 14, Doc. No. 92. The parties agree that the Arkansas legislature considered whether unfair MAC methodologies are resulting in pharmacies closing down, especially in rural areas. The parties agree that approximately 44% of Arkansans live in rural areas. Pl.'s Resp. Def.'s Statement Material Fact ¶ 7. The parties agree that 70% to 90% of all prescriptions are for generic drugs, which utilize MAC pricing. *Id.* ¶ 12. They also agree that even large chain pharmacies, which are able to command more favorable contractual terms, report under-reimbursement from PBMs as a primary reason for poor financial

performance. *Id.* ¶¶ 26, 77. Finally, other courts have recognized that states have a legitimate interest in preserving the health of their citizens by increasing access to prescription drugs. *See Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 313–14 (1st Cir. 2005); *Gerhart*, 2015 WL 10767327 at *3–4 (a law designed to preserve the health of citizens was specifically aimed at preventing unfair practices of PBMs from "eroding local pharmacies").

As for burdens, PCMA asserts that Act 900 forces PBMs to choose between applying a new, uniform business model nationwide; suffering administrative costs by adopting state-specific practices when doing business in Arkansas; or abstaining entirely from conducting business in Arkansas. The possible effects of Act 900 on the administrative costs or on the profits of PBMs is not a cognizable burden under the Commerce Clause, and even if it was, the burden to interstate commerce would not be clearly excessive relative to Act 900's presumed local benefit. *See Rowe*, 429 F.3d at 313. PCMA also asserts Act 900 will ultimately harm the public because it will cause the cost of prescriptions to rise and make prescriptions less accessible, but Act 900 does not require PBMs to pass costs on to consumers. Further, this argument "relates to the wisdom of the statute, not to its burden on commerce." *Exxon Corp.*, 437 U.S. at 127.

PCMA asserts that Act 900's decline-to-dispense provision burdens interstate commerce because it will prevent people who are employed by companies outside the state from buying prescriptions at pharmacies

inside the state. Even if this assertion is accepted as true, PCMA acknowledges that "pharmacies receive less than their acquisition cost in a very small number of prescriptions dispensed." Pl.'s Statement Material Fact ¶ 10; Pl.'s Resp. Def.'s Statement Material Fact ¶ 40 (undisputed that pharmacists experience approximately 10% of reimbursements below cost). Act 900 also requires PBMs to timely update their MAC lists and to provide an appeals procedure, both of which further reduce the likelihood of negative reimbursements. For these reasons, Act 900's burden on interstate commerce does not clearly outweigh its presumed local benefit.

D. State and Federal Contract Clauses

The State of Arkansas's motion for summary judgment is granted, and PCMA's motion is denied because Act 900 does not substantially impair preexisting contractual relations.

The United States Constitution and the Arkansas Constitution prohibit the passing of laws that impair the "obligation of contracts." Consequently, these issues will be analyzed together. U.S. CONST. art. I, § 10; ARK. CONST. art. II, § 17; *see E. Poinsett Cty. Sch. Dist. No. 14 v. Massey*, 866 S.W.2d 369, 371 (Ark. 1993); *Mahurin v. Oaklawn Jockey Club*, 771 S.W.2d 19, 21 (Ark. 1989). Although the Contract Clause is facially absolute, states maintain the right to act pursuant to their inherent police power to promote the public welfare. *Minnesota Ass'n of Health Care Facilities, Inc. v.*

Minnesota Dep't of Pub. Welfare, 742 F.2d 442, 449 (8th Cir. 1984) (quoting *Home Bldg. & Loan Ass'n v. Blaisdell*, 290 U.S. 398, 428 (1934)). One whose rights are subject to legitimate state regulation cannot render such regulation illegitimate by making a contract about them. *Hudson Cty. Water Co. v. McCarter*, 209 U.S. 349, 357 (1908).

To violate the Contract Clause, a state law must substantially impair preexisting contractual relationships. *Equipment Mfrs. Inst. v. Janklow*, 300 F.3d 842, 849–50 (8th Cir. 2002). A law already in effect at the time a contract is entered does not violate the Contract Clause. *Blaisdell*, 290 U.S. at 429–30; *Mahurin*, 771 S.W.2d at 21; *McGuire v. Ameritech Servs., Inc.*, 253 F. Supp. 2d 988, 1006 (S.D. Ohio 2003). Act 900 went into effect July 22, 2015, so, as a matter of law, it cannot impair contracts entered after that date.

PCMA asserts that Act 900 impairs contractual relations between both PBMs and pharmacies and between PBMs and their client health plans in the context of MAC pricing, appeals, and guaranteed dispensing. The record is unclear as to whether any unexpired contracts between PBMs and pharmacies or between PBMs and health plans, which were entered prior to July 22, 2015, still exist. Accordingly, a substantive Contract Clause analysis follows.

Whether a contractual impairment is substantial depends primarily on the nature of the impairment and the extent to which it disrupts reasonable contractual expectations. *Janklow*, 300 F.3d at 854–55;

Minnesota Ass'n of Health Care Facilities, 742 F.2d at 450. Past industry regulation plays a significant role in determining the parties' reasonable contractual expectations. *Id.* The more severe the impairment, the closer the scrutiny applied. *Id.* Even a law that substantially impairs a preexisting contract does not violate the Contract Clause unless it lacks a significant and legitimate purpose or is an unreasonable method of accomplishing its purpose. *See Janklow*, 300 F.3d at 850; *White Motor Corp. v. Malone*, 599 F.2d 283, 287 (8th Cir. 1979), *aff'd, Malone v. White Motor Corp.*, 444 U.S. 911 (1979). In the context of economic regulation, "courts properly defer to legislative judgment as to the necessity and reasonableness of a particular measure." *U.S. Trust Co. of N.Y. v. New Jersey*, 431 U.S. 1, 22–23 (1977).

PCMA asserts that because pharmacy contracts and health plan contracts tie generic drug reimbursements to a specified MAC list, Act 900 substantially impairs those contracts because it requires PBMs to reimburse pharmacies according to the pharmacy's acquisition cost instead of according to MAC lists and because health plans will have to pay a cost-based price rather than a MAC price. Act 900, however, does not require PBMs to reimburse pharmacies for the price listed on their wholesaler invoices rather than MAC. Acquisition cost is the standard by which an appeal may be initiated, but Act 900 provides that an appeal of a negative MAC reimbursement may be denied if certain criteria are met. Acquisition price becomes the reimbursement standard only if a PBM cannot satisfy

section 507(c)(4)(C)(iii). Further, it is undisputed that "pharmacies receive less than their acquisition cost in a very small number of prescriptions dispensed." Pl.'s Statement Material Fact ¶ 10; Pl.'s Resp. Def.'s Statement Material Fact ¶ 40. Accordingly, Act 900 does not substantially impair preexisting contracts.

Additionally, the appeals procedure imposed by Act 900 does not disrupt reasonable contractual expectations because contracts between PBMs and pharmacies generally provide a procedure for appealing MAC reimbursements. Pl.'s Resp. Def.'s Statement Material Fact ¶ 75; Def.'s Resp. Pl.'s Statement Material Fact ¶ 14. Although PBM contracts generally provide that a pharmacist must accept whatever reimbursement a PBM determines is appropriate based on confidential MAC lists, Pl.'s Resp. Statement Material Fact ¶ 81, the parties should have reasonably expected an appeals procedure that offered relief from unfair reimbursements; otherwise, the appeals provisions provided in the parties' contracts would be a nullity. Indeed, the commonly understood meaning of a "reimbursement" supports this notion. Thus, Act 900 attempts to give effect to terms already embraced by PBM contracts, even if only in theory.

Past industry regulation also suggests that PBMs could not have reasonably expected that their reimbursement practices would escape regulation forever. First, the pharmaceuticals industry is already highly regulated. *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001); *see also Energy Reserves Grp., Inc. v. Kansas Power & Light Co.*, 459 U.S. 400, 413 n. 15

(1983) (noting as significant that the parties are operating in a heavily regulated industry and that other states regulate certain areas of the industry). Second, Act 900 states that it was enacted to "create accountability in the establishment of prescription drug pricing" and was an obvious attempt to mitigate the harmful results of MAC pricing. Although Act 900 imposes more specific standards, Act 1194, Act 900's predecessor, regulated MAC pricing and mandated an appeals process. *See* S.B. 1138, 89th Gen. Assemb., Reg. Sess. (Ar. 2013). PCMA has also been on notice of the national controversy caused by MAC methodology because other jurisdictions have enacted similar laws regulating PBMs. *See Rowe*, 429 F.3d at 298, 312–13 (holding Maine's Unfair Prescription Drug Practices Act was "designed to deal with one of the serious problems of our time," namely the "tremendous market power" of PBMs and a lack of transparency in their dealings with manufacturers and pharmacies, which ultimately affect pharmaceutical access and cost) (quoting *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 80 (1st Cir. 2001), *aff'd sub nom. Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003)); *Gerhart*, 2015 WL 10767327 at *1 (explaining that Iowa law regulates PBMs by overseeing their use of MAC methodology because "pharmacies complain that MAC reimbursements can be so low that pharmacies are forced to sell drugs at a loss or refuse to dispense certain drugs altogether"). As a result, PBMs cannot be surprised by legislative efforts to protect public health and welfare by protecting pharmacies. *Cf. Minnesota Ass'n of Health Care Facilities*, 742 F.2d

at 450 ("Nursing homes could not reasonably expect that the terms of whatever contracts they had with their residents would exempt them from rate regulation by the state.").

Even if Act 900 substantially impairs preexisting contracts, it still does not violate the Contract Clause because its purpose, as previously established, is legitimate. *See id.* at 450–51. It is undisputed that 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. *See* Pl.'s Resp. Def.'s Statement Material Fact, ¶¶ 59, 61, 81. As PCMA asserts, leveling the playing field between contracting parties is not a legitimate purpose, but protecting basic societal interests is. *Energy Reserves Group, Inc.*, 459 U.S. at 412; *Janklow*, 300 F.3d at 861. The fact that Act 900 may incidentally benefit pharmacies in the process of protecting the public's ability to access pharmacies does not render the law an insignificant or illegitimate use of the state's police power. Furthermore, Act 900's regulations on MAC pricing and appeals procedures are not unreasonable methods of combating MAC reimbursement practices deemed harmful to pharmacies and the public.

The decline-to-dispense provision does not change the outcome because "pharmacies receive less than their acquisition cost in a very small number of prescriptions dispensed." Pl.'s Statement Material Fact ¶ 10; Pl.'s Resp. Def.'s Statement Material Fact ¶ 40. Act 900 requires PBMs to timely update their MAC lists and to

provide an appeals procedure, both of which reduce the likelihood of negative reimbursements even further. Given these considerations, the decline-to-dispense provision does not substantially impair preexisting contractual relationships, nor is it an unreasonable way of accomplishing its legitimate purpose of protecting local pharmacies access.

E. Vagueness Under State and Federal Due Process Clauses

The State of Arkansas's motion for summary judgment is granted, and PCMA's motion is denied on PCMA's facial void-for-vagueness challenge because Act 900 gives fair notice of what is required.

No state can "deprive any person of life, liberty or property, without due process of law." U.S. CONST. amend. XIV, § 1; ARK. CONST. art. II, § 8. Statutes violate due process when they fail to sufficiently define prohibited conduct so that a person of ordinary intelligence can understand what conduct is prohibited. *Woodis v. Westark Cmty. Coll.*, 160 F.3d 435, 438 (8th Cir. 1998); *Arkansas Tobacco Control Bd. v. Sitton*, 166 S.W.3d 550, 553 (Ark. 2004). Due process is also violated when statutes establish standards that permit arbitrary or discriminatory enforcement. *Woodis*, 160 F.3d at 438; *Sitton*, 166 S.W.3d at 553. A law imposing criminal sanctions or implicating constitutional rights requires more definiteness than a law regulating economic behavior. *See Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982);

Ferguson v. Skrupa, 372 U.S. 726, 730 (1963) (legislative bodies have broad scope to experiment with economic problems).

Generally, "[w]hen a state statute is challenged on its face as unconstitutionally vague, and no First Amendment interests are imperiled, that assertion is far too broad." *Reprod. Health Servs. of Planned Parenthood of St. Louis Region, Inc. v. Nixon*, 428 F.3d 1139, 1143–44 (8th Cir. 2005). This is because facial challenges "run contrary to the fundamental principle of judicial restraint that courts should neither anticipate a question of constitutional law in advance of the necessity of deciding it nor formulate a rule of constitutional law broader than is required by the precise facts to which it is to be applied." *TCF Nat'l Bank v. Bernanke*, 643 F.3d 1158, 1163 (8th Cir. 2011) (citing *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449–50 (2008)); *U.S. v. Stephens*, 594 F.3d 1033, 1037 (2010) ("Facial challenges threaten to short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution.").

PCMA takes issue with Act 900's "MAC Update Provision," which requires a PBM to

> Update its Maximum Allowable Cost List on a timely basis, but in no event longer than 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 wholesaler [sic] doing business in the state. . . .

Ark. Code Ann. § 17-92-501(c)(2). A "pharmaceutical wholesaler" is "a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy." *Id.* § 501(a)(2).

According to PCMA, "PBMs have no way to know when their obligations under Act 900's MAC Update Provision are triggered" because "the statute does not specify whether sixty percent should be calculated by reference to the volume of drug sales or the number of wholesalers." Pl.'s Mem. Supp. Summ. J., Doc. No. 75-1 at 33. PCMA correctly acknowledges in subsequent briefing, however, that "[t]he plain language of the law requires a PBM to change [its] MAC list when sixty percent of [the] pharmacy wholesalers doing business in Arkansas have an increase in prices" and that the volume of business is "irrelevant" under this language. Pl.'s Opp. Def.'s Mot. Summ. J., Doc. No. 85 at 37. Thus, PCMA seems to have resolved its vagueness issue, and in any case, the language of the MAC Update Provision is reasonably clear.

To the extent that this language is unclear, no criminal penalties would attach to a PBM in violation of Act 900. This is true because a criminal penalty attaches only if the Arkansas Deceptive Trade Practices Act is violated by a deceptive trade practice that is committed "knowingly and willfully." Ark. Code Ann. § 4-88-103; *see Vill. of Hoffman Estates*, 455 U.S. at 499 (scienter requirement mitigates a law's vagueness,

especially with respect to the adequacy of notice to the complainant that his conduct is proscribed).

PCMA further argues that even if a PBM could determine what constitutes 60% of wholesalers, it still cannot determine what those wholesalers' prices are because PBMs do not have access to wholesaler price lists. Pl.'s Mem. Supp. Summ. J., Doc. No. 75-1 at 33–34. In addition to implicitly admitting that PBMs can reasonably understand what Act 900 requires of them, this argument does not present an issue of vagueness. Instead, it addresses whether a PBM can comply with Act 900. The question of "vagueness" asks whether the law itself defines illegal behavior sufficiently, *Woodis*, 160 F.3d at 439, not whether the law provides access to the external information needed to comply.

PCMA further asserts that it cannot comply with Act 900 because gathering the data needed would be an "insurmountable act." Pl. Resp. Def.'s Statement Material Facts ¶ 72 (undisputed that Optum Rx, a PBM, has not explored the possibility of obtaining a direct data feed with wholesalers). But, MAC "methodologies are based upon the market intelligence that the PBMs have devised as their way of accounting for actual acquisition costs. . . ." *Id.* ¶ 60. PBMs also have access to wholesale pricing information via Medispan and, in some instances, via automated data feed access directly to individual wholesalers. *Id.* ¶¶ 69–71. Whether PBMs have the ability to comply with the law's reasonably clear requirements, though disputed, is not an issue of vagueness and remains to be determined.

IV. CONCLUSION

For these reasons, PCMA's motion for summary judgment [Doc. No. 75] is granted on PCMA's ERISA claim because act 900 is invalid as applied to PBMs in their administration and management of ERISA plans. The government's motion for summary judgment [Doc. No. 77] is granted on all other claims. The joint motions to extend time [Doc. Nos. 103, 104] are denied as moot, and this case is dismissed with prejudice.

IT IS SO ORDERED this 1st day of March 2017.

/s/ Brian S. Miller
UNITED STATES
DISTRICT JUDGE

29 U.S.C. § 1144. Other laws

(a) Supersedure; effective date

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title. This section shall take effect on January 1, 1975.

(b) Construction and application

(1) This section shall not apply with respect to any cause of action which arose, or any act or omission which occurred, before January 1, 1975.

(2)(A) Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.

(B) Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to

regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

(3) Nothing in this section shall be construed to prohibit use by the Secretary of services or facilities of a State agency as permitted under section 1136 of this title.

(4) Subsection (a) shall not apply to any generally applicable criminal law of a State.

(5)(A) Except as provided in subparagraph (B), subsection (a) shall not apply to the Hawaii Prepaid Health Care Act (Haw. Rev. Stat. §§ 393-1 through 393-51).

(B) Nothing in subparagraph (A) shall be construed to exempt from subsection (a) –

> **(i)** any State tax law relating to employee benefit plans, or
>
> **(ii)** any amendment of the Hawaii Prepaid Health Care Act enacted after September 2, 1974, to the extent it provides for more than the effective administration of such Act as in effect on such date.

(C) Notwithstanding subparagraph (A), parts 1 and 4 of this subtitle, and the preceding sections of this part to the extent they govern matters which are governed by the provisions of such parts 1 and 4, shall supersede the Hawaii Prepaid Health Care Act (as in effect on or after January 14, 1983), but the Secretary may enter into cooperative arrangements under this paragraph and section 1136 of this title with officials

of the State of Hawaii to assist them in effectuating the policies of provisions of such Act which are superseded by such parts 1 and 4 and the preceding sections of this part.

(6)(A) Notwithstanding any other provision of this section –

> **(i)** in the case of an employee welfare benefit plan which is a multiple employer welfare arrangement and is fully insured (or which is a multiple employer welfare arrangement subject to an exemption under subparagraph (B)), any law of any State which regulates insurance may apply to such arrangement to the extent that such law provides –
>
> > **(I)** standards, requiring the maintenance of specified levels of reserves and specified levels of contributions, which any such plan, or any trust established under such a plan, must meet in order to be considered under such law able to pay benefits in full when due, and
> >
> > **(II)** provisions to enforce such standards, and
>
> **(ii)** in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement, in addition to this subchapter, any law of any State which regulates insurance may apply to the extent not inconsistent with the preceding sections of this subchapter.

(B) The Secretary may, under regulations which may be prescribed by the Secretary, exempt from subparagraph (A)(ii), individually or by class, multiple

employer welfare arrangements which are not fully insured. Any such exemption may be granted with respect to any arrangement or class of arrangements only if such arrangement or each arrangement which is a member of such class meets the requirements of section 1002(1) and section 1003 of this title necessary to be considered an employee welfare benefit plan to which this subchapter applies.

(C) Nothing in subparagraph (A) shall affect the manner or extent to which the provisions of this subchapter apply to an employee welfare benefit plan which is not a multiple employer welfare arrangement and which is a plan, fund, or program participating in, subscribing to, or otherwise using a multiple employer welfare arrangement to fund or administer benefits to such plan's participants and beneficiaries.

(D) For purposes of this paragraph, a multiple employer welfare arrangement shall be considered fully insured only if the terms of the arrangement provide for benefits the amount of all of which the Secretary determines are guaranteed under a contract, or policy of insurance, issued by an insurance company, insurance service, or insurance organization, qualified to conduct business in a State.

(7) Subsection (a) shall not apply to qualified domestic relations orders (within the meaning of section 1056(d)(3)(B)(i) of this title), qualified medical child support orders (within the meaning of section 1169(a)(2)(A) of this title), and the provisions of law referred to in section 1169(a)(2)(B)(ii) of this title to the

extent they apply to qualified medical child support orders.

(8) Subsection (a) of this section shall not be construed to preclude any State cause of action –

> **(A)** with respect to which the State exercises its acquired rights under section 1169(b)(3) of this title with respect to a group health plan (as defined in section 1167(1) of this title), or
>
> **(B)** for recoupment of payment with respect to items or services pursuant to a State plan for medical assistance approved under title XIX of the Social Security Act which would not have been payable if such acquired rights had been executed before payment with respect to such items or services by the group health plan.

(9) For additional provisions relating to group health plans, see section 1191 of this title.

(c) Definitions

For purposes of this section:

> **(1)** The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.
>
> **(2)** The term "State" includes a State, any political subdivisions thereof, or any agency or instrumentality of either, which purports to regulate,

directly or indirectly, the terms and conditions of employee benefit plans covered by this subchapter.

(d) Alteration, amendment, modification, invalidation, impairment, or supersedure of any law of the United States prohibited

Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.

(e) Automatic contribution arrangements

(1) Notwithstanding any other provision of this section, this subchapter shall supersede any law of a State which would directly or indirectly prohibit or restrict the inclusion in any plan of an automatic contribution arrangement. The Secretary may prescribe regulations which would establish minimum standards that such an arrangement would be required to satisfy in order for this subsection to apply in the case of such arrangement.

(2) For purposes of this subsection, the term "automatic contribution arrangement" means an arrangement –

(A) under which a participant may elect to have the plan sponsor make payments as contributions under the plan on behalf of the participant, or to the participant directly in cash,

(B) under which a participant is treated as having elected to have the plan sponsor make such contributions in an amount equal to a uniform percentage of compensation provided under the plan until the participant specifically elects not to have such contributions made (or specifically elects to have such contributions made at a different percentage), and

(C) under which such contributions are invested in accordance with regulations prescribed by the Secretary under section 1104(c)(5) of this title.

(3)(A) The plan administrator of an automatic contribution arrangement shall, within a reasonable period before such plan year, provide to each participant to whom the arrangement applies for such plan year notice of the participant's rights and obligations under the arrangement which –

(i) is sufficiently accurate and comprehensive to apprise the participant of such rights and obligations, and

(ii) is written in a manner calculated to be understood by the average participant to whom the arrangement applies.

(B) A notice shall not be treated as meeting the requirements of subparagraph (A) with respect to a participant unless –

(i) the notice includes an explanation of the participant's right under the arrangement not to have elective contributions made on the participant's behalf (or to elect to have such contributions made at a different percentage),

(ii) the participant has a reasonable period of time, after receipt of the notice described in clause (i) and before the first elective contribution is made, to make such election, and

(iii) the notice explains how contributions made under the arrangement will be invested in the absence of any investment election by the participant.

A.C.A. § 17-92-507. Maximum Allowable Cost Lists

(a) As used in this section:

(1) "Maximum Allowable Cost List" means a listing of drugs used by a pharmacy benefits manager setting the maximum allowable cost on which reimbursement to a pharmacy or pharmacist may be based;

(2) "Pharmaceutical wholesaler" means a person or entity that sells and distributes prescription pharmaceutical products, including without limitation a full line of brand-name, generic, and over-the-counter pharmaceuticals, and that offers regular and private delivery to a pharmacy;

(3) "Pharmacist" means a licensed pharmacist as defined in § 17-92-101;

(4) "Pharmacist services" means products, goods, or services provided as a part of the practice of pharmacy in Arkansas;

(5) "Pharmacy" means the same as in § 17-92-101;

(6) "Pharmacy acquisition cost" means the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice;

(7) "Pharmacy benefits manager" means an entity that administers or manages a pharmacy benefits plan or program;

(8) "Pharmacy benefits manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefits manager; and

(9) "Pharmacy benefits plan or program" means a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in this state.

(b) Before a pharmacy benefits manager places or continues a particular drug on a Maximum Allowable Cost List, the drug:

(1) Shall be listed as therapeutically equivalent and pharmaceutically equivalent "A" or "B" rated in the United States Food and Drug Administration's most recent version of the "Orange Book" or "Green Book" or has an NR or NA rating by Medispan, Gold Standard, or a similar rating by a nationally recognized reference;

(2) Shall be available for purchase by each pharmacy in the state from national or regional wholesalers operating in Arkansas; and

(3) Shall not be obsolete.

(c) A pharmacy benefits manager shall:

(1) Provide access to its Maximum Allowable Cost List to each pharmacy subject to the Maximum Allowable Cost List;

(2) Update its Maximum Allowable Cost List on a timely basis, but in no event longer than 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;

(3) Provide a process for each pharmacy subject to the Maximum Allowable Cost List to receive prompt notification of an update to the Maximum Allowable Cost List; and

(4)(A)(i) Provide a reasonable administrative appeal procedure to allow pharmacies to challenge maximum allowable costs and reimbursements made under a maximum allowable cost for a specific drug or drugs as:

(a) Not meeting the requirements of this section; or

(b) Being below the pharmacy acquisition cost.

(ii) The reasonable administrative appeal procedure shall include the following:

(a) A dedicated telephone number and email address or website for the purpose of submitting administrative appeals;

(b) The ability to submit an administrative appeal directly to the pharmacy benefits manager regarding the pharmacy benefits plan or program or through a

pharmacy service administrative organization; and

(c) No less than seven (7) business days to file an administrative appeal.

(B) The pharmacy benefits manager shall respond to the challenge under subdivision (c)(4)(A) of this section within seven (7) business days after receipt of the challenge.

(C) If a challenge is under subdivision (c)(4)(A) of this section, the pharmacy benefits manager shall within seven (7) business days after receipt of the challenge either:

(i) If the appeal is upheld:

(a) Make the change in the maximum allowable cost;

(b) Permit the challenging pharmacy or pharmacist to reverse and rebill the claim in question;

(c) Provide the National Drug Code number that the increase or change is based on to the pharmacy or pharmacist; and

(d) Make the change under subdivision (c)(4)(C)(i)(a) of this section effective for each similarly situated pharmacy as defined by the payor subject to the Maximum Allowable Cost List;

(ii) If the appeal is denied, provide the challenging pharmacy or pharmacist the National Drug Code number and the name of the

national or regional pharmaceutical wholesalers operating in Arkansas that have the drug currently in stock at a price below the Maximum Allowable Cost List; or

(iii) If the National Drug Code number provided by the pharmacy benefits manager is not available below the pharmacy acquisition cost from the pharmaceutical wholesaler from whom the pharmacy or pharmacist purchases the majority of prescription drugs for resale, then the pharmacy benefits manager shall adjust the Maximum Allowable Cost List above the challenging pharmacy's pharmacy acquisition cost and permit the pharmacy to reverse and rebill each claim affected by the inability to procure the drug at a cost that is equal to or less than the previously challenged maximum allowable cost.

(d)(1) A pharmacy benefits manager shall not reimburse a pharmacy or pharmacist in the state an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services.

(2) The amount shall be calculated on a per unit basis based on the same generic product identifier or generic code number.

(e) A pharmacy or pharmacist may decline to provide the pharmacist services to a patient or pharmacy benefits manager if, as a result of a Maximum Allowable Cost List, a pharmacy or pharmacist is to be paid less

than the pharmacy acquisition cost of the pharmacy providing pharmacist services.

(f)(1) This section does not apply to a Maximum Allowable Cost List maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration.

(2) This section shall apply to the pharmacy benefits manager employed by the Arkansas Medicaid Program or the Employee Benefits Division if, at any time, the Arkansas Medicaid Program or the Employee Benefits Division engages the services of a pharmacy benefits manager to maintain a Maximum Allowable Cost List.

(g)(1) A violation of this section is a deceptive and unconscionable trade practice under the Deceptive Trade Practices Act, § 4-88-101 et seq., and a prohibited practice under the Arkansas Pharmacy Benefits Manager Licensure Act, § 23-92-501 et seq., and the Trade Practices Act, § 23-66-201 et seq.

(2) This section is not subject to § 4-88-113(f)(1)(B).