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

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

LESLIE RUTLEDGE, in her official capacity as Attorney General of Arkansas,

Defendants.

Civil Action No. 4:15cv510-BSM

This case assigned to District Judge Miller
and to Magistrate Judge Deere

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiff Pharmaceutical Care Management Association ("PCMA"), on behalf of its members, for its complaint against Leslie Rutledge ("Rutledge") in her official capacity as Attorney General of Arkansas, asserts as follows:

INTRODUCTION

1. On April 2, 2015, Arkansas Senate Bill 688 was signed into law as Act 900 of the Arkansas General Assembly's 90th General Session. Act 900 amends the state's existing Maximum Allowable Cost ("MAC") law, Arkansas Code § 17-92-507, to impose additional requirements on the pharmacy benefit managers ("PBMs") that develop, maintain and use maximum allowable cost or "MAC" lists for generic drugs. Act 900 will go into effect on July 22, 2015, 91 days after the April 22, 2015 *sine die* adjournment of the 90th General Assembly.

2. Act 900 mandates that pharmacies be reimbursed for the generic pharmaceuticals they dispense at or above the cost invoiced by wholesalers or manufacturers, regardless of whether the pharmacies could have acquired the drugs for less, and regardless of whether the

pharmacies receive rebates or discounts not reflected on the wholesaler's or manufacturer's invoice. In essence, Act 900 guarantees Arkansas pharmacies a profit on every MAC script filled. In so doing, the act will cause higher prices for prescription drugs and thereby cause significant and substantial harm to consumers, senior citizens, health plan payers including employee benefit plans, employers and insurers, and pharmacy benefit managers ("PBMs").

3. In addition, as the PBMs do not know the acquisition cost of the pharmaceuticals dispensed by the different pharmacies in Arkansas, the statute sets a trigger point for PBM compliance using information to which PBMs have no access.

4. This lawsuit seeks a declaration that 1) Act 900 imposes an excessive burden on interstate commerce in violation of the Dormant Commerce Clause of the United States Constitution; 2) Act 900 substantially impairs existing contracts between PCMA's members and their customers, health insurance carriers and employers, and between PCMA's members and pharmacies, in violation of the Contract Clauses of the United States Constitution and the Constitution of the State of Arkansas; 3) Act 900 imposes obligations on PBMs but fails to provide fair notice of when their actions are likely to become unlawful and thereby violates the Due Process Clauses of the United States Constitution and the Constitution of the State of Arkansas; 4) to the extent that Act 900 affects the prices paid for pharmaceuticals by consumers insured through their employers, the act "relate[s] to" employee benefit plans and is thereby pre-empted by the Employee Retirement Income Security Act ("ERISA") of 1974, 29 U.S.C. §1001, et seq.; and 5) to the extent that Act 900 affects the prices paid for pharmaceuticals by consumers insured through a Medicare Part D Plan, and to the extent that Act 900 purports to permit the disruption of a PBM's contracted pharmacy network for a Part D plan sponsor, the act is a state law "with respect to" a Part D Plan and is thereby pre-empted by the Medicare

Prescription Drug, Improvement, and Modernization Act ("MMA"), Pub. L. No. 108-173 § 232, 117 Stat. 2066, 2208 (Dec. 8, 2003). The Court should enjoin the Defendant from enforcing Act 900.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this case raises questions arising under both federal law and the Constitution of the United States. The Court also has jurisdiction over claims seeking relief under the Arkansas Constitution pursuant to 28 U.S.C. § 1367, because the state claims are so closely related to the federal claims as to form part of the same case or controversy.

6. This Court has personal jurisdiction over Defendant because Defendant resides within the Eastern District of Arkansas.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because most of the events giving rise to these claims occurred in this district and the Defendant resides within the State of Arkansas.

THE PARTIES

8. PCMA is the national trade association representing PBMs with a principal place of business in Washington, D.C. Its PBM member companies administer prescription drug benefit plans for more than 236 million Americans covered by ERISA and non-ERISA (including Medicare Part D) health plans. The ERISA-covered health plans include both insured and self-funded plans sponsored by employers and labor unions. The non-ERISA covered health plans include plans sponsored by state and local governments that contract directly for PBM services, as well as plans sold in the individual health insurance market. None of the PBMs which are members of PCMA are incorporated in the state of Arkansas or have their principal places of business in the state of Arkansas.

9. PCMA brings this lawsuit on behalf of its members, which include PBMs that administer prescription drug benefits on behalf of their customers including health plans and their participants, individual consumers and their families, who reside or purchase pharmaceuticals in Arkansas and, as such, are affected by Act 900.

10. PCMA is a non-profit 501(c)(6) corporation duly organized under the laws of the State of Delaware. PCMA is a national trade association whose members include the following PBMS: Aetna Pharmacy Management; Catamaran Corporation; Cigna Pharmacy Management; CVS Health Corporation; Express Scripts; Human Pharmacy Solutions; LDI; MedImpact Healthcare System; Optum Rx; Prime Therapeutics; and USScript (collectively, the "Members"). PCMA's purposes include advancing the common interest of the Members, including in litigation. The claims in this Complaint serve the Members' common interests. PCMA accordingly has Article III standing to sue on behalf of the Members under the doctrine of associational standing. Neither the claims asserted, nor the relief requested, requires the participation of individual Members in this lawsuit.

11. The injury to the Members will commence immediately upon Act 900's effective date on July 22, 2015. Defendant Rutledge's office already has indicated to PCMA's members that it will begin enforcement of Act 900 on that date, including retroactive enforcement for pharmacy claims dating back two years. Such injury to the Members would make out a justiciable case had the Members themselves brought suit.

12. In addition, in order to comply with Act 900, PCMA members will be forced to immediately revise their business practices, including their pricing methodologies, the frequency with which they update them, and their appeals procedures in contravention of their existing Pharmacy Contracts.

13. PCMA members will also immediately be caused harm by provisions of Act 900 that allow pharmacists to refuse to fill prescriptions, as this could result in a breach of some of PCMA's members' customer contracts, and could cause some of PCMA's members to become out of compliance with regulations promulgated by the federal Medicare agency.

14. Act 900 injures PBMs and their customers in various ways, including the following: (1) PBMs will be forced to abandon their market-driven MAC methodology and adopt a new methodology whereby they reimburse pharmacies for their purported "acquisition cost." This greatly diminishes the value of the MAC methodology to the PBM business model. The effects will be felt in PBMs' nationwide business, because their customer contracts are not limited to employees in any particular state, including Arkansas; (2) PBMs will suffer substantial impairments to their contracts with pharmacies and with customers; and (3) PBMs are subject to a considerable risk of sanctions, including civil damages, criminal prosecution and the loss of their license to practice in Arkansas, because they do not have access to information that is critical for their compliance with the Act.

15. Defendant Leslie Rutledge is the Attorney General of the State of Arkansas. The Attorney General is a resident of Little Rock, Arkansas, and is being sued solely in her official capacity.

16. Defendant, and those subject to Defendant's supervision, direction, and/or control, are responsible for the enforcement of Act 900, including the specific ERISA and Medicare preempted and unconstitutional provisions at issue here.

FACTS

A. The Prescription Drug Market and PBMs' Role

17. Many Arkansas residents receive their prescription drug benefits through health plans, including self-funded and insured ERISA-governed employee health benefit plans, health

plans offered by non-profit hospital or medical services corporations, health insurers, and health maintenance organizations, as well as health plans sponsored by unions, federal and state government plans, and other benefit plans (collectively "health plans").

18. Health plans contract with PBMs to administer and manage their prescription drug benefits and, in particular, to employ particular methods to keep the cost of prescription drugs down.

19. One of a PBM's most critical tools to contain prescription drug costs is its proprietary MAC methodology and MAC list(s). PBMs each develop and administer their own unique and confidential MAC list(s), which are used to set reimbursement rates for pharmacies filling prescriptions for generic drugs. PBMs also use MAC lists to guarantee pricing terms to their customers, the health plans and self-insured employers.

20. PBMs enter into contracts with both chain and independent retail pharmacies ("Pharmacy Contracts"), in every state, including Arkansas. The Pharmacy Contracts operate to create pharmacy networks.

21. These networks are crucial to PBM contracts with their customer health plans ("Customer Contracts"), because they allow PBMs to guarantee that its customers' members, individual consumers and their families, will receive adequate service, including accessibility at the level required by the Centers for Medicare and Medicaid Services ("CMS") for Part D participants.

22. The retail pharmacies in a PBM's network fill the prescriptions of health plan participants with drugs they have purchased on their own directly from wholesalers or manufacturers. When a consumer goes to a pharmacy to fill a prescription, the pharmacy will check with the PBM to confirm the applicable plan design for the health plan member in order to

determine coverage and copayment information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually-agreed negotiated rate minus the co-pay collected by the pharmacy from the plan participant.

B. PBMs' Use of MAC Pricing

23. The methodology for establishing these contracted prices for brand-name drugs (*i.e.*, those still under patent protection) differ from those for generic drugs (*i.e.*, those where the patent has expired and therapeutically equivalent versions are produced by any number of competing manufacturers). This lawsuit involves contracted prices for generic drugs. About 80 percent of prescriptions in the U.S. are dispensed as generic drugs. The considerable savings brought by dispensing generics over brand name pharmaceuticals is key to containing drug costs and maximizing savings to health plans and plan participants.

24. One of the most common methodologies used by PBMs in paying pharmacies for dispensing generic prescription drugs is MAC methodology. Almost four-fifths of private employer prescription drug plans (and 45 state Medicaid programs, including Arkansas Medicaid, as well as Medicare Part D plans) use MAC as a cost management tool. In a recent report, the Office of Inspector General of the U. S. Department of Health and Human Services described the "significant value MAC programs have in containing Medicaid drug costs."[1]

25. MACs specify the allowable reimbursement by a PBM for a particular strength and dosage of a generic drug that is available from multiple manufacturers but sold at different prices. The use of MAC lists is critical due to the lack of price standardization for identical products from different manufacturers.

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[1] Office of Inspector General, Medicaid Drug Pricing in State Maximum Allowable Cost Programs (August 29, 2013), p.21, available at https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp.

26. PBMs and their client health plans use MAC pricing to control the cost of drugs paid by or on behalf of their plan participants by establishing a consistent and reasonable price regardless of the manufacturer. By placing a ceiling on what the PBM will pay the pharmacies under their agreements, MAC pricing motivates and incentivizes pharmacies to seek and purchase generic drugs at the lowest available prices in the marketplace. Based on the extensive and continuous study of market dynamics, PBMs use MAC lists to balance fairly compensating pharmacies, so they continue to be incentivized to dispense generic products, with providing a cost-effect benefit to their health plan customers. .

27. Each PBM develops and maintains multiple of its own confidential MAC pricing lists derived from its proprietary methodologies. Within each PBM, MAC lists may differ by health plan customer. These variations may range from the number of drugs on the list to the maximum allowable cost for each drug. PBMs do not typically maintain lists that are specific to the state in which the prescriptions will be filled. Indeed, many of the PBMs' customers offer prescription drug coverage to beneficiaries throughout the country, and while each of those customers may have several MAC lists associated with its contract, those lists are typically distinguished by what type of health plan the beneficiary is enrolled in, not what state they reside or work in.

28. MAC list development is a time-consuming, resource-extensive investment for each PBM. In order to develop a MAC list, the PBM must first determine which drugs to include on the list. This determination, which may be made on a client-to-client basis, is based upon numerous factors, including whether drugs are approved by the FDA or listed in the FDA's Orange Book, whether the drugs have therapeutic equivalents and how many, whether there are multiple generic versions, and the number of manufacturers supplying the drugs. The number of drugs on a MAC list can range from the hundreds to the thousands.

29. Then, for each drug that is chosen for the list, the PBM must determine the appropriate reimbursement for the drugs. MAC pricing is calculated based on multiple factors aggregated to derive what pharmacies pay, on average, for generic drugs. These factors include published Average Wholesale Prices ("AWP"), MAC lists that are made public from state Medicaid systems, the PBMs' market intelligence based on the prices its in-house mail-order pharmacies are able to negotiate, and subscription-only price compendiums that are provided at a cost to those PBMs that enroll. From those resources, each PBM develops its own pricing benchmarks and explicit formulas used to create its own unique MAC prices and MAC lists of standard reimbursements for generic drugs.

30. The PBMs' pricing methodologies and customer-specific MAC lists are unique to each PBM, and are not generally known or readily ascertainable in the PBM industry. The PBM industry is fiercely competitive. As one of their most valuable tools in providing cost-effective solutions to their customers, PBMs consider both their MAC lists and MAC pricing methodologies to be proprietary trade secrets, and protect them as such.

C. Act 900

31. The bill that became Act 900, which amends prior law, was filed on March 2, 2015 and passed by the Arkansas Senate on March 25, 2015 and then by the House on March 26, 2015. The legislative record reflects no reference to or study by a legislative committee regarding the potential consequences of the proposed law's provisions.

32. Act 900 became law on April 2, 2015, one month after it was originally filed. It will become effective on July 22, 2015, 91 days after the April 22, 2015 *sine die* adjournment of the 90th General Assembly.

33. Act 900 makes five significant changes to prior law:

a. It defines "pharmacy acquisition cost" as "the amount that a pharmaceutical wholesaler charges for a pharmaceutical product as listed on the pharmacy's billing invoice." Ark. Code § 17-92-507(a)(6).

b. It requires PBMs to update their MAC lists within seven 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" Arkansas. Ark. Code § 17-92-507(c)(2).

c. It requires PBMs to provide an administrative appeal procedure to allow pharmacies to challenge MAC lists (prospectively) and reimbursements (retrospectively) as being below the "pharmacy acquisition cost." Ark. Code § 17-92-507(c)(4)(A)(i).

d. 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 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." Ark. Code § 17-92-507(c)(4)(C)(iii).

e. It provides that 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. (Italics in the original). Ark. Code § 17-92-507(e).

34. Violation of any provision of Act 900 constitutes a deceptive and unconscionable trade practice subject to Arkansas' consumer protection law (Ark. Code § 4-88-101 et seq.), which subjects the violator to both civil and criminal penalties, including loss of licensure. § 17-92-507(g); §§ 4-88-103, 4-88-113.

35. Act 900 also states that the law does not apply to a MAC list maintained by the Arkansas Medicaid Program or the Employee Benefits Division of the Department of Finance and Administration, provided those programs do not employ a PBM to administer their prescription drug benefits. Ark. Code § 17-92-507(f).

36. In a letter dated July 10, 2015 and sent to many PBMs doing business in Arkansas, Defendant Rutledge's office stated that it interpreted Act 900 to mean "that it is a deceptive trade practice for a PBM to reimburse a pharmacist in an amount below the acquisition cost," even if that pharmacist had not yet appealed a reimbursement.

37. Act 900 does not state that its provisions should be applied retrospectively or retroactively. However, in its July 10, 2015 letter, the Attorney General's Office indicates that it intends to enforce the law retroactively, stating that it "has received numerous 'negative reimbursement' complaints from various Arkansas pharmacies over the past two years," and that its intent is to "forward these [outstanding] complaints to you again and request that you reverse and reprocess such claims in compliance with the law and in order to alleviate the negative claims or 'negative reimbursements' identified by those complaints."

D. Act 900 Harms Arkansas Consumers

38. Act 900's provisions requiring that pharmacists receive at least their acquisition cost for every prescription filled come at a great cost to PBMs, health plans, and, ultimately, Arkansas prescription drug consumers -- including senior citizens.

39. Contrary to the definition of "pharmacy acquisition cost" imposed by the law, the actual cost to a pharmacy for any given prescription drug is *not* simply the price listed on the invoice received from a wholesaler, because that price does not reflect price concessions including bulk discounts and rebates.

40. Payers have historically experienced considerable difficulty in determining the "true" market price for dispensed pharmaceuticals. This is why PBMs and other market participants have employed various strategies to determine the price they will pay when a prescribed pharmaceutical is dispensed. These strategies, which have evolved over the past several decades, have resulted in the widespread adoption of MAC lists.

41. This widespread adoption of MAC lists has had significant positive effects on pharmaceutical markets. MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. In addition, MACs heighten the competition between generic manufacturers. MACs also ensure that pharmacies are not being overpaid for the services they provide. These three factors combine to reduce pharmaceutical costs overall. In addition, the use of MAC lists streamlines the prescription drug reimbursement process, which improves overall system performance.

42. Act 900 will cause both immediate and long term effects. In the short-term, Act 900 will force multi-state employers to modify their employee benefit plans for Arkansas-based employees. More specifically, employers will have to modify their contracts with insurers/PBMs, to ensure their Arkansas-based employees receive benefits that comply with Act 900, including Arkansas-specific MAC lists; Arkansas-specific MAC pricing; and an Arkansas-specific appeals process. Although a number of other states have enacted legislation regulating PBMs, no other state includes a "guaranteed profits" provision like Act 900. Thus, employers

with Arkansas-based employees (and the insurers and PBMs that provide services to them) will have to create an Arkansas-specific employee benefit plan incorporating these disparate elements.

43. Employers based outside of Arkansas (and the PBMs that serve them) will need to similarly address the likelihood that employees and their covered dependents either live in Arkansas or travel to Arkansas at some point in time, and seek to have a prescription filled within that state. Employers could therefore either take steps to ensure plan compliance with Arkansas-specific provisions, or can ignore the requirements of Act 900 and assume the risk that their employees and covered dependents will not be able to have their prescriptions filled while in Arkansas.

44. In addition, Act 900 takes away the pharmacies' incentive to seek out the lowest price possible for a generic drug, because it promises pharmacies that they will be reimbursed for any acquisition cost they expend, rather than the MAC, which reflects average acquisition cost. Without an incentive for pharmacies to seek out the lowest price possible for a drug, wholesalers will have less incentive to compete. As a result, prescription drug prices will increase.

45. PBMs know that they will need to handle increased appeals from pharmacies that have not recovered their acquisition cost, they will respond by setting higher MACs, which will result in guaranteed profits for pharmacies that purchase the drug for less than the MAC.

46. The increased drug costs caused by Act 900 will be born directly by PBMs and indirectly by the insurers, employers and consumers in Arkansas. For example, those insurers and employers that bear the costs of prescription drug reimbursement through "pass-through" contracts will see an immediate increase in the prices paid under their PBM contracts.

47. Consumers of prescription drugs will bear some of the costs of Act 900 as well. If their prescription benefit plan has a percentage co-payment/co-insurance for pharmaceuticals, an increase in the cost of the pharmaceutical (whether attributable to a successful appeal of a MAC, or increased MACs because of the incentives created by Act 900) will result in a direct increase in the cost borne by the employee, since the co-payment is computed based on the actual cost of the dispensed drug.. If the benefit plan is structured as a high-deductible plan, any increase in the cost of the pharmaceutical will similarly result in a direct increase in the cost borne by the employee, at least as long as the deductible has not been exceeded.

48. There will also be lagged effects of Act 900. The combination of increased pharmaceutical spending and increased administrative costs will cause employers and employee benefit plans (and the insurers that provide services to them) to look for savings elsewhere, including changes in plan design -- such as modifications in covered benefits and the mix of co-payments and deductibles that apply to those benefits. Act 900 will also create pressure to develop new pricing models for handling generic drugs that may not be subject to a MAC – and new pricing models may trigger further changes in plan design.

E. Act 900 Harms PBMs

49. Act 900 places significant restrictions on PBMs and their ability to provide their services to those clients with covered lives in Arkansas. First, PBMs have no way of knowing when their obligation to update their MAC lists based on pharmaceutical wholesaler invoice pricing will be triggered because PBMs do not have visibility into the acquisition costs of individual pharmacies for specific drugs with specific wholesalers.

50. Second, the law requires PBMs to reimburse pharmacies for their acquisition costs or higher. The Attorney General has notified PBMs that it intends to enforce Act 900 to require PBMs to reimburse pharmacies for their acquisition costs or higher even before a pharmacy has

filed an appeal. PBMs have no ability to do this for the same reason that they are unable to update their MAC lists based on pharmacy acquisition cost: they have no visibility into what price any particular pharmacy has negotiated with any particular wholesaler.

51. Third, even if PBMs are able to comply, the law requires that they grant any pharmacy reimbursement or MAC appeal in which a pharmacy can show that the MAC/reimbursement is lower than its acquisition cost as listed on its wholesaler invoice. This will harm the PBMs because it essentially renders MAC lists as they were previously developed valueless in Arkansas.

52. Fourth, the law is in direct conflict with Pharmacy Contracts and Customer Contracts. Under Act 900, PBMs are unable to avail themselves of the bargained-for terms of their Pharmacy Contracts, including those terms related to pricing, guaranteed dispensing, and appeals. As a result, PBMs will themselves fail to meet guarantees in their Customer Contracts and will be subject to penalties as a result.

53. Fifth, PBMs will also see an increase in administrative costs under Act 900. First, even if PBMs were to gain access to individual wholesaler information, they would be forced to compile this data and calculate any changes on a near-constant basis in order to comply with the MAC list update provision. Second, the amendments to the administrative appeal process mean that PBMs face the constant uncertainty of an increased volume of reimbursement appeals with no statute of limitations. Third, in order to properly consider whether the appeals have merit, in every appeal the PBM would need to collect and analyze data from each appealing pharmacy regarding their wholesale purchasing processes in order to determine whether they purchase the majority of their drugs from a particular wholesaler. Even assuming that those pharmacies are able and willing to provide such information, which the PBMs have no way of accessing on their

own, this presents a large burden to the PBMs in processing all of this information. Fourth, in the event that an appeal is successful, the burden is on the PBM to ensure that all "similarly situated" pharmacies receive the benefit of the change to the MAC. Because this information is not publicly available, the PBMs have no means of ensuring that similarly situated pharmacies are treated similarly, unless all of those pharmacies agree to submit such information during the appeals process. All of these additional tasks add up to an enormous financial burden on PBMs.

CLAIMS FOR RELIEF

COUNT ONE

(ERISA PREEMPTION)

54. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 53 as if fully set forth herein.

55. ERISA is a comprehensive federal statute that regulates employee benefit plans with the purpose of providing for the uniform national treatment of employee benefit plans.

56. ERISA § 514 -- ERISA's express preemption provision -- provides that ERISA preempts state laws related to an employee benefit plan.

57. Act 900 "relate[s] to" an employee benefit plan due to: (1) the requirements imposed on on those PBMs that are serving individuals "living or working in Arkansas;" (2) the direct economic effect that it imposes on ERISA plans; and (3) the changes that it imposes on the structure of the plans.

58. Furthermore, Act 900 is not saved from preemption by ERISA's savings clause, 29 U.S.C. § 1144(b)(2)(A), which saves from preemption a state law that "regulates insurance, banking or securities" because it is not directed towards entities engaged in insurance but rather is expressly directed at PBMs, which do not engage in insurance-related activity.

59. Plaintiff has no adequate remedy at law available against Defendants for the injuries and irreparable harm its members will imminently suffer when Act 900 takes effect on July 22, 2015.

COUNT TWO

(MEDICARE PREEMPTION)

60. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 59 as if fully set forth herein.

61. Medicare Part D expressly preempts any state law "with respect to" a Medicare Part D plan. Social Security Act §§ 1860D-12(g) and 1856(b)(3). The standard for determining whether Part D preempts a law is a three part test. A statute is preempted if (1) the federal government established "standards" in the Medicare Part D program; (2) the state law is one "with respect to" these standards; and (3), the state law does not govern licensure or solvency.

62. The federal government and the Centers for Medicare and Medicaid Services have established a standard that concerns pharmacy drug pricing. For example, the Medicare statute mandates that beneficiaries have access to "negotiated prices," which are defined by accompanying regulations as "prices for covered Part D drugs that (1) the Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug; (2) are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) include any dispensing fees." 42 C.F.R. § 423.100; *see also* 42 U.S.C. § 1395w-102(d)(1)(A) (mandating access to negotiated pricing) and (d)(1)(B)(defining term).

63. The Medicare statute and Medicare regulations also establish strict standards with regard to pharmacy access for Part D enrollees. 42 U.S.C. § 1395w-104(b)(1)(C)(i) and 42 C.F.R. § 423.120(a)(1).

64. Act 900 is a law "with respect to" a Part D plan. To the extent that a state law purports to regulate the prices that a pharmacy can charge or receive for a drug that is a covered Part D drug, it is a state law with respect to a Part D standard. And, to the extent that a state law purports to permit a Part D in-network pharmacy to refuse to dispense a covered Part D drug to a Medicare beneficiary, it is a state law with respect to a Part D standard.

65. Act 900 is not a law regulating licensure or solvency. Therefore, it is preempted by the Medicare Part D and Medicare Advantage statutes.

66. Plaintiff has no adequate remedy at law available against Defendants for the injuries and irreparable harm its members will imminently suffer when Act 900 takes effect on July 22, 2015.

COUNT THREE

(DORMANT COMMERCE CLAUSE, §§ 17-92-507(C)(4)(A)(I)(B); 17-92-507(C)(4)(A)(II)(C); 17-92-507(C)(4)(C)(I)(C); 17-92-507(C)(4)(C)(II)-(III); 17-92-507(E))

67. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 66 as if fully set forth herein.

68. The dormant Commerce Clause of the United States Constitution limits the extent to which States can regulate interstate commerce. U.S. Const. art I, § 8, cl. 3.

69. Act 900 violates the dormant Commerce Clause by imposing an undue burden on interstate commerce. The PBM and prescription drug market is an interstate market. For example, PCMA's member PBMs are all incorporated in and have headquarters outside of Arkansas, but all provide pharmacy benefit management services to plan beneficiaries within Arkansas. Many of the health plans that contract with PBMs to provide services to Arkansas

beneficiaries are located outside of Arkansas, and many of those plans serve beneficiaries both inside and outside of Arkansas within the same plan. The prescription drugs that are sold in pharmacies located inside Arkansas are primarily manufactured outside of the state and shipped into the state by out-of-state wholesalers. Many of the pharmacies that are purportedly protected by Act 900 are part of national or international chains with outlets and headquarters outside of Arkansas. Even some of the independent pharmacies engage out-of-state and/or national pharmacy services administrative organizations ("PSAOs") to contract with managed care organizations and PBMs on behalf of their members.

70. Act 900 will harm this national prescription drug market The act's requirements that collectively operate to force PBMs to set MAC pricing to match pharmacy acquisition cost, as defined by the statute, will reduce competition among pharmaceutical wholesalers and pharmacies, which will result in increased prescription drug prices for health plans and their members, including some members that work outside of Arkansas but fill prescriptions in Arkansas.

71. PBMs do not have the ability to avoid doing business in Arkansas due to the national nature of the PBM business and member mobility.

72. The local benefits of Act 900 will be minimal, if there are any at all. In fact, Act 900 ultimately will harm Arkansas consumers by driving up prescription drug costs.

73. Defendants' imminent enforcement of Act 900 is under color of state law and violates the rights, privileges and immunities of Plaintiff under the dormant Commerce Clause, and therefore is actionable under 42 U.S.C. § 1983.

74. Plaintiffs' members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT FOUR

(FEDERAL CONTRACTS CLAUSE, §§ 17-92-507(C)(4)(A)(I)(B); 17-92-507(C)(4)(A)(II)(C); 17-92-507(C)(4)(C)(I)(C); 17-92-507(C)(4)(C)(II)-(III); 17-92-507(E))

75. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 74 as if fully set forth herein.

76. The Contracts Clause prohibits states from passing any law impairing the obligations of contracts. U.S. Const. art. 1, §10, cl. 1 ("No state shall… pass any… law impairing the obligation of contracts).

77. Act 900 significantly impairs both Pharmacy Contracts and Customer Contracts, including the terms relating to pricing, guaranteed dispensing, and reimbursement appeals.

78. Act 900 does not serve a significant and legitimate public purpose. The law was drafted with the sole purpose of changing contract rights between PBMs and pharmacies in order to benefit pharmacies. Further, Act 900 is harmful to the societal interest of maintaining affordable prescription drug prices and increasing access to prescription drugs.

79. The purposes of Act 900 do not warrant contractual adjustments.

80. Plaintiffs' members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT FIVE

(CONTRACTS CLAUSE, ARKANSAS CONSTITUTION)

81. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 80 as if fully set forth herein.

82. The Arkansas Constitution prohibits the impairment of contracts. Ark. Const., art. II, §17 ("No… law impairing the obligation of contracts shall ever be passed").

83. Act 900 significantly impairs both Pharmacy Contracts and Customer Contracts, including the terms relating to pricing, guaranteed dispensing, and reimbursement appeals.

84. Act 900 does not serve a significant and legitimate public purpose. The law was drafted with the sole purpose of changing contract rights between PBMs and pharmacies in order to benefit pharmacies. Further, Act 900 is harmful to the societal interest of maintaining affordable prescription drug prices and increasing access to prescription drugs.

85. The purposes of Act 900 do not warrant contractual adjustments.

86. Plaintiffs' members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their state constitutional rights, privileges and immunities caused by Act 900.

COUNT SIX

(FEDERAL DUE PROCESS CLAUSE, § 17-92-507(C)(2))

87. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 86 as if fully set forth herein.

88. The Due Process Clause of the Fourteenth Amendment of the United States Constitution, provides that no state shall "deprive any person of life, liberty or property, without due process of law." U.S. Const. amend. XIV, § 1. The Due Process Clause requires laws that regulate persons or entities to give fair notice of the conduct that is forbidden or required.

89. Act 900 violates the Due Process Clause because the regulated parties (PBMs) have no way of gaining information that will allow them to know *when* it would be required to satisfy its legal obligation to update its MAC list, or *how* to satisfy its legal obligation of reimbursing pharmacies for their acquisition cost before an appeal. A PBM is not privy to information

regarding pharmacy acquisition cost, unless a pharmacy or a wholesaler chooses to share such information with the PBM.

90. The penalties for failing to comply with any provision of Act 900, including Section 17-92-507(c)(2), include liability for an unfair and deceptive trade practice, including loss of licensure to practice pharmacy in Arkansas. Therefore, if a PBM were to remain non-compliant due to its lack of notice of when its legal obligations have occurred, it could be deprived of the ability to conduct business in the state.

91. Plaintiffs' members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their federal rights, privileges and immunities caused by Act 900.

COUNT SEVEN

(ARKANSAS DUE PROCESS CLAUSE)

92. Plaintiff repeats and re-alleges each and every allegation contained in paragraphs 1 through 91 as if fully set forth herein.

93. The Due Process Clause of the Constitution of the State of Arkansas provides that "No person shall… be deprived of life, liberty, or property, without due process of law." Ark. Const., art. II, §8.

94. Plaintiffs' members have no adequate remedy at law available against Defendants for the injuries and irreparable harm they will imminently suffer as a result of the deprivations of their state constitutional rights, privileges and immunities caused by Act 900.

REQUEST FOR RELIEF

WHEREFORE, PCMA respectfully prays that this Court:

(1) declare that Act 900 is preempted by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001 *et seq.*;

(2) declare that Act 900 is preempted by the Medicare Part D statute, 42 U.S.C. §§ 1395w-12(g) and 1395w-26(b)(3);

(3) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(C)(i)(c); 17-92-507(c)(4)(C)(ii)-(iii); and 17-92-507(e) violate the Commerce Clause of the United States Constitution because they excessively burden interstate commerce

(4) declare that Arkansas Code § 17-92-507(c)(2) violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution because it fails to provide adequate notice;

(5) declare that Arkansas Code § 17-92-507(c)(2) violates the Due Process Clause of the Constitution of the State of Arkansas because it fails to provide adequate notice;

(6) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(A)(ii)(c); 17-92-507(c)(4)(C)(i)(c); 17-92-507(c)(4)(C)(ii)-(iii); 17-92-507(e) violate the Contracts Clause of the United States Constitution because they substantially impair PBMs' contracts with pharmacies and customers,

(7) declare that Arkansas Code §§ 17-92-507(c)(4)(A)(i)(b); 17-92-507(c)(4)(A)(ii)(c); 17-92-507(c)(4)(C)(i)(c); 17-92-507(c)(4)(C)(ii)-(iii); 17-92-507(e) violate the Contracts Clause of the Constitution of the State of Arkansas because they substantially impair PBMs' contracts with pharmacies and customers

(8) enter a permanent injunction enjoining Defendants and their agents from taking any action under or to enforce Act 900;

(9) enter, after hearing, a preliminary injunction, pending final resolution of this action, enjoining Defendants and their agents from taking any action under or to enforce Act 900;

(10) award Plaintiff its reasonable attorneys; fees and costs; and

(11) grant Plaintiff such additional or different relief as it deems just and proper.

Respectfully submitted,

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, INC.

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