IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, *Plaintiff,* v. GLEN MULREADY, in his official capacity as Insurance Commissioner of Oklahoma, and OKLAHOMA INSURANCE DEPARTMENT, *Defendants.*	No. CIV-19-977-J

DEFENDANT'S MOTION TO LIFT STAY AND ABEYANCE AND NOTICE OF INTENT TO ENFORCE THE PATIENT'S RIGHT TO PHARMACY CHOICE ACT

The Attorney General moves this Court to lift the stay ordered on October 31, 2019, provides notice herein of its intent to enforce the Patient's Right to Pharmacy Choice Act, and states as follows:

1. In 2019, the Oklahoma Legislature enacted the Patient's Right to Pharmacy Choice Act, Okla. Stat. tit. 36, §§ 6958 *et seq*. ("PRPCA"), to increase pharmaceutical transaction transparency, protect access to affordable prescription drugs, and in particular to reign in anticompetitive business practices of pharmacy benefit managers ("PBMs"). Plaintiff—a PBM trade association—sued to have the Act enjoined, claiming that Employee Retirement Income Security Act, 29 U.S.C. §§ 1001 *et seq*. ("ERISA") and Medicare Part D expressly preempt it. Doc. 1. Given the conditions at the time, the State agreed to stay enforcement of the Act until a final order in this case. In return, Plaintiff agreed not to seek a preliminary injunction. Doc. 19.

2. Shortly thereafter, the U.S. Supreme Court granted certiorari in *Rutledge v. PCMA*, No. 18-540, which concerns Arkansas's regulation of PBMs. Particularly, *Rutledge* will address whether the Arkansas regulation is preempted by ERISA. At the time, the parties expected adjudication by the

Supreme Court pursuant to its regular calendar, with argument in April and a decision by June at the latest. Under those conditions, it would have been an inefficient use of party and judicial resources to pursue this case before being guided by an imminent decision in *Rutledge*. Thus, parties jointly moved to hold the case in abeyance. Doc. 25. And that motion was granted by the Court. Doc. 26.

3. But conditions have changed. Although a temporary pause in enforcement and adjudication made sense when a decision in *Rutledge* was expected in the near future, that is no longer the case. Because of the COVID-19 pandemic, on April 3, 2020, the Supreme Court postponed its April calendar, which includes *Rutledge*. The Supreme Court is now "consider[ing] rescheduling some cases from the March and April sessions before the end of the Term, if circumstances permit" and "will consider a range of scheduling options and other alternatives" for arguments.[1] Thus, we no longer have certainty that a Supreme Court decision in *Rutledge* will issue by June, risking an indefinite abeyance of this action.

4. The need to begin enforcing the statute has changed as well. To start, the State has received preliminary reports from constituents that certain PBMs have been abusing their market power while the PRPCA is still not yet in force. The State needs to be able to investigate these allegations; and, if need be, to enforce the PRPCA against abusive business practices. This must include the authority to investigate and impose sanctions under Okla. Stat. tit. 36, § 6965 and § 6966, to collect data for such investigations, § 6963(A-B), and to provide for the enforcement of the provisions designed to improve (1) ***transparency***—§ 6961(D), § 6962(C)(3), and § 6964(A); (2) ***access***—§ 6961(A), § 6962(B)(4-5), and § 6963(D-E), and (3) ***affordability***—§ 6961(C) and § 6962(B)(2-3, 6-7). *Cf.* Stipulation, Doc. 19.

[1] Press Release, U.S. Supreme Court (Apr. 03, 2020), https://www.supremecourt.gov/publicinfo/press/pressreleases/pr_04-03-20

5. The need is particularly acute in rural and elderly communities. According to health economists and other experts, abusive business practices have threatened the health system's ability to provide critical pharmaceutical care to vulnerable populations. PBMs have used their market power to pay pharmacies unsustainably low reimbursement rates; to diminish access to less-profitable drugs; to restrict pharmacies from informing patients about lower-cost generic options; and to steer patients away from independent pharmacies and toward pharmacies owned by PBMs.[2] Reports show that due to self-dealing, conflicts of interest, and anticompetitive business practices by PBMs, many communities have experienced rising prescription costs and the closure of independent pharmacies—particularly in rural areas—and less access to necessary treatments.[3]

6. The urgency of removing these barriers to pharmaceutical access is now heightened by the COVID-19 outbreak, which has plunged the world into a state of medical and economic emergency. This particular emergency hits hardest the areas the PRPCA seeks to protect. COVID-19 poses the greatest risk to older people as well as anyone with chronic conditions or weakened immune systems, who are more vulnerable to developing serious complications from COVID-19 and requiring medical care. Moreover, it has been recognized that pharmacies providing healthcare services "will be essential during the response to COVID-19," indeed, "[i]n rural and underserved communities and in areas experiencing physician shortages, pharmacists may be the only healthcare provider that is

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[2] *See, e.g.*, Ltr. From David A. Balto on Behalf of Consumer Action to Federal Trade Commission 4 (Dec. 6, 2017) https://tinyurl.com/balto-ltr ("The largest PBMs [have] engage[d] in a wide range of deceptive and anticompetitive conduct that ultimately harms consumers and denies them access to affordable medicines."); National Rural Health Association Policy Brief, Pharmacy (May 2009), https://tinyurl.com/sgt9mcq ("Rural independent pharmacies have little leverage with which to negotiate with PBMs or insurers and are usually unable to amend contract terms.").

[3] Dep't of Health & Human Servs., Office of Inspector General, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2,340, 2,341 (Feb. 6, 2019); *see also* Linette Lopez, *What CVS is Doing to Mom-and-Pop Pharmacies in the U.S. Will Make Your Blood Boil*, Business Insider (Mar. 30, 2018), https://tinyurl.com/vqph452.

immediately accessible to patients."[4] These pharmacies are vital now and will be vital in distribution once a COVID-19 treatment and/or vaccine is developed.[5]

7. The PBM market is highly concentrated with three PBMs controlling 85% of the market. These PBMs often own pharmacies themselves and are crowding out independent pharmacies. The White House Council of Economic Advisors found that this concentration and control of the PBM market "allows them to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves." *See* The White House Council of Economic Advisors, White Paper, Reforming Biopharmaceutical Pricing at Home and Aboard (February 2018). While PBM practices today do not necessarily pose an *immediate* threat to public health, the fast-developing COVID-19 emergency has convinced the State it needs all the regulatory tools at its disposal to protect Oklahomans going forward, particularly Oklahoma's vulnerable populations. The State hopes the PCPRA will be preventative—a deterrent to abusive practices. But enforcement, or threat of enforcement, of the PCPRA will enable the State to help pharmacies in underserved areas survive during and beyond these uncertain times. Those very pharmacies will be necessary in the coming months as pharmaceutical solutions to COVID-19 become available.

8. Due to all the uncertainty, the State cannot wait until small and rural pharmacies are shuttered by PBM practices to begin investigations and enforcement. Potentially ruinous effects on these communities cannot be undone and will resonate for years to come.

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[4] Pharmacy Readiness for Coronavirus 2019 (COVID-19) ASHP (March 2020) https://www.ashp.org/-/media/assets/advocacy-issues/docs/Pharmacy-Readiness-for-Coronavirus-Disease-2019-COVID-19-STATE.ashx?la=en&hash=6420DD319DEF9C0C008B161D36615C8E3229532B

[5] *See* Crystal Fuller Lewis, *Independent pharmacies should be on frontlines for COVID-19 screening access*, The Hill (March 19, 2020) https://thehill.com/opinion/healthcare/488548-independent-pharmacies-should-be-on-frontlines-for-covid-19-screening.

For the foregoing reasons, the State proposes two actions. First, the State requests this Court to lift the stay and abeyance of this case ordered on January 1, 2020. Doc. 26. Second, the State expresses its intent to withdraw from the November 5, 2019 stipulation (Doc. 19), and will begin implementing the PCPRA no sooner than 21 days after this Court lifts the stay on this action, unless Plaintiffs move for a preliminary injunction within 21 days, in which case the State agrees not to enforce the PCPRA unless and until this Court denies such a motion. Thus, Plaintiff is relieved of its obligation to restrain from filing a motion for preliminary injunction and may do so if it chooses, and the State will not enforce the PCPRA until Plaintiffs have a reasonable opportunity to file for a preliminary injunction (*i.e.*, no more than 21 days) and this Court has the opportunity to adjudicate any such motion. *See* Doc. 19, ¶ 2. Of course, the State will oppose such a motion as we are confident in ultimate success on the merits—as expressed in the joint states' *amicus* brief in *Rutledge* by 44 states, including Oklahoma—and the balance of irreparable harms now militates toward denying any requested preliminary injunction.

s/ *Randall Yates*

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