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 the OKLAHOMA INSURANCE DEPARTMENT, Defendants.	)	Civil Action No. CIV-19-977-J

BRIEF OF *AMICI CURIAE*
THE STATE CHAMBER OF OKLAHOMA
AND HOBBY LOBBY STORES, INC.

Amicus Curiae, the State Chamber of Oklahoma (the "State Chamber"), and Hobby Lobby Stores, Inc. ("Hobby Lobby"), submit their *amici curiae* brief in support of the Plaintiff's position. Movants acknowledge that there are no rules in either the Federal Rules of Civil Procedure or the Local Rules for the Western District of Oklahoma governing *amicus curiae* briefs, so Movants are following the procedure set forth in Fed. R. App. P. 29 regarding the submission of this brief.

Statement of Counsel

Counsel for *amici* states that: (i) no party's counsel authored this brief in whole or in part; (ii) no party or a party's counsel contributed money that was intended to fund preparing or submitting this brief; and (iii) no person – other than the *amici curiae*, their

members, or their counsel – contributed money that was intended to fund preparing or submitting this brief.[1]

The State Chamber's Interest

The State Chamber of Oklahoma "is the leading statewide advocate for business in Oklahoma." *About*, STATE CHAMBER OF OKLAHOMA, https://www.okstatechamber.com/about (last visited May 14, 2020). It "work[s] on behalf of its members, the Oklahoma business community, to affect legislative change and create a pro-growth climate statewide." *Id.* As a "private, membership-based advocacy organization, the State Chamber speaks for more than 1,500 Oklahoma companies and 350,000 employees." *Id.*

The State Chamber has employer-members in the private sector that maintain both fully-insured and self-funded employee benefit plans that are regulated by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001-1461, as amended ("ERISA"). Many if not most of these benefit plans utilize Pharmacy Benefits Managers ("PBMs") to deliver significant cost savings not only to the plans themselves, but to the employee-members and their dependents.

The State Chamber is concerned about the impact the Oklahoma Patient's Right to Pharmacy Choice Act, 36 Okla. Stat. §§ 6958-6968 ("PRPCA" or the "Act") will have on

[1] Counsel for *amici* authored and submitted in *Rutledge* on April 1, 2020, a brief for *amicus curiae*, J.B. Hunt Transportation Services, Inc., https://www.supremecourt.gov/DocketPDF/18/18-540/139670/20200402083353215_18-540%20JB%20Hunt%20Amicus%20Brief%20-%20Revised.pdf. Some of the text from that brief has been copied verbatim in this brief.

Oklahoma's employers, employee benefit plans, employees, dependents, and Oklahoma's general business environment.

Hobby Lobby's Interest

With more than 900 stores, Hobby Lobby is the largest privately owned arts-and-crafts retailer in the world with over 43,000 employees and operating in forty-seven states. Hobby Lobby is primarily an arts-and-crafts store but also includes hobbies, picture framing, jewelry making, fabrics, floral and wedding supplies, cards and party ware, baskets, wearable art, home accents and holiday merchandise. Mardel Christian and Education Supply, an affiliate company, offers books, Bibles, gifts, church and education supplies, as well as homeschooling curriculum. Hobby Lobby also maintains offices in Hong Kong, Shenzhen, and Yiwu, China. *See* https://www.hobbylobby.com/about-us/our-story.

Hobby Lobby sponsors a self-funded employee welfare benefit plan (the "Plan") which provides, among other things, medical, surgical, and hospital benefits, and benefits in the event of sickness. The Plan has a third party administrator ("TPA") that initially processes claims for benefits in accordance with ERISA, 29 U.S.C. § 1133(1). Denied claims can be appealed to Hobby Lobby in accordance with ERISA, 29 U.S.C. § 1133(2). The TPA utilizes a network of medical providers. Under this arrangement providers in Oklahoma contract with the network so that network members (including the members of the Plan) can obtain treatment at discounted rates rather than at the providers' normal full rates.

The Plan also provides prescription drug benefits. Hobby Lobby has retained a PBM, CerpassRx, to assist in the administration of prescription drug benefits under the Plan.

Hobby Lobby has carefully vetted its PBM and is keenly aware of its ability to deliver massive cost savings to the Plan and its members.

The Reason why an Amicus Brief is Desirable and why the Matters Asserted are Relevant to the Disposition of the Case

The ERISA preemption issues presented in this case, and in *Rutledge*, are critically important to the State Chamber, Hobby Lobby, and many other employers. *Amici* are united in their commitment to the strong ERISA preemption principles long recognized by the Supreme Court's jurisprudence. It is absolutely critical for employers, especially employers like Hobby Lobby that operate in multiple states, to have the protection of uniform administration.

In *Rutledge v. Pharmaceutical Care Mgm't. Ass'n*, No. 18-540, the Supreme Court will soon define the contours of ERISA preemption with respect to an Arkansas PBM law similar to the PRPCA. By orders dated April 3 and 13, 2020, oral argument has been postponed and rescheduled for October 2020. A decision could be expected in 2020 or 2021.

All *amicus* are concerned that, in the interim, if an injunction is not granted, and Oklahoma begins regulating PBMs, significant changes will need to be made in the structure, administration, and finances of employee benefit plans, and the administration and costs of prescription drug benefits will be adversely affected. If the Supreme Court subsequently

holds that ERISA preempts state PBM laws, the damage will have been irreparable, and significant changes will need to be made to restore the current status quo.[2]

ARGUMENT

As noted in the Respondent's Brief (page 9) in *Rutledge*, 40 States "and counting" have enacted legislation regulating PBM reimbursement practices. To *amicis*' knowledge, Oklahoma is the only state that is moving forward despite *Rutledge* – everyone else is on hold. Soon, this Court, Oklahoma, and everyone else will learn from *Rutledge* whether ERISA preempts state laws like the Oklahoma PRPCA. There is no point in permitting Oklahoma to begin enforcing the PRPCA because it could very well be preempted by ERISA. In the meantime, Oklahoma employers would have to implement massive changes to comply with the PRPCA, only to then have to undo those changes depending on the outcome of *Rutledge*.[3]

Oklahoma has made a decision to restrict how PBMs, employers, and ERISA plans do business. In doing so it has impaired core functions of federally-regulated benefit plans like the Hobby Lobby Plan and their members. Oklahoma has codified this policy choice in 36 Okla. Stat. §§ 6958-6968. Oklahoma is thus directly regulating the Hobby Lobby Plan

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[2] Because Oklahoma apparently intends to proceed full-bore in attempting to regulate PBMs, this brief will address, in addition to the PRPCA, other Oklahoma laws that target PBMs including the Oklahoma Pharmacy Audit Integrity Act, 59 Okla. Stat. §§ 356-356.5; and the Oklahoma Pharmacy Benefit Plans Statutes, 59 Okla. Stat. §§ 357-360.

[3] The following courts have ruled on the issue of whether ERISA preempts state PBM laws: *Pharmaceutical Care Mgm't Ass'n v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018) (on certiorari to the Supreme Court); *Pharmaceutical Care Mgm't Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017); *Pharmaceutical Care Mgm't Ass'n v. D.C.*, 613 F.3d 179 (D.C. Cir 2010); *Pharmaceutical Care Mgm't Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005); *Pharmaceutical Care Mgm't Ass'n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018) (on appeal to the Eighth Circuit).

and other plans, and such state regulation is preempted by ERISA. Such efforts by Oklahoma to control PBMs have a negative financial impact on the Plan and its Members.

The Structure of Benefit Plans

If an employer wants to offer health care benefits to its employees, including prescription drug benefits, it can provide the benefits directly or it can purchase them from a third party such as an insurance company. Most health care benefits are provided through either fully-insured or self-funded plans. The difference between a self-funded plan and a fully-insured plan is explained in *FMC Corp. v. Holliday*, 498 U.S. 52, 54 (1990) ("The Plan is self-funded; it does not purchase an insurance policy from any insurance company in order to satisfy its obligations to its participants"); *accord Soc'y of Professional Eng'g Emp. in Aerospace, v. Spirit Aerosystems, Inc.*, 681 Fed. App'x 717, 719 n.2 (10th Cir. Mar. 15, 2017) ("A 'self-funded' health insurance plan differs from fully insured health insurance plans in that the employer assumes responsibility for payment of claims rather than the insurance company"). The Hobby Lobby Plan is self-funded; Hobby Lobby makes contributions to the Plan and the employees make contributions through payroll deductions. The State Chamber represents employers that maintain both self-funded and fully-insured plans.

An important point is that many health plans, like the Hobby Lobby Plan, offer prescription drug benefits as a component of their group health plans. In other words, there can conceivably be stand-alone prescription drug benefit plans, but most plans feature prescription drug benefits in addition to other health care benefits (*e.g.,* doctor visits, medical procedures, hospitalization, diagnostic testing, medical supplies, etc.). Hobby Lobby does not have a "PBM plan" or a "prescription drug plan"; it has a health care benefit plan that

offers a variety of health care benefits including prescription drug benefits. Hobby Lobby has retained a third party vendor, a PBM, CerpassRx to administer the prescription drug component of the Plan. For the Hobby Lobby Plan, a PBM is a critical component of the ongoing operation of the Plan.

ERISA Regulation and Preemption

One of ERISA's primary goals is to protect the financial soundness of employee benefit plans, as evidenced by the Congressional finding:

> that despite the enormous growth in [benefit] plans many employees with long years of employment are losing anticipated retirement benefits owing to the lack of vesting provisions in such plans; that owing to the inadequacy of current minimum standards, ***the soundness and stability of plans with respect to adequate funds to pay promised benefits may be endangered***; that owing to the termination of plans ***before requisite funds have been accumulated***, employees and their beneficiaries ***have been deprived of anticipated benefits***; and that it is therefore desirable in the interests of employees and their beneficiaries, for the protection of the revenue of the United States, and to provide for the free flow of commerce, that minimum standards be provided assuring the equitable character of such plans ***and their financial soundness***.

29 U.S.C. § 1001(a) (emphasis added). Another goal of ERISA is to establish uniform standards of conduct, responsibilities, and liabilities for plan fiduciaries:

> It is hereby declared to be the policy of this chapter to protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto, ***by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies, sanctions***, and ready access to the Federal courts.

Id. at § 1001(b) (emphasis added).

Congress capped off ERISA with a preemption provision, 29 U.S.C. § 1144(a), that has been described as "sweeping." *Metro. Life Ins. Co. v. Mass.*, 471 U.S. 724, 746 (1985).

Under federal preemption principles, "A [state] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983); *accord N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 656 (1995). ERISA preempts state laws even if they are **consistent** with ERISA's federal standards. *See, e.g., D.C. v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 130 (1992) (ERISA preempts state laws that are consistent with its provisions); *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 139 (1990) ("'[p]re-emption is also not precluded simply because a state law is consistent with ERISA's substantive requirements,'" quoting *Metro. Life Ins. Co. v. Mass.,* 471 U.S. 724, 739 (1985)). ERISA does not just preempt state statutory laws, but **any** state action having the force or effect of law: "The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State." 29 U.S.C. § 1144(c)(1).

Certain laws are saved from ERISA preemption, including laws that regulate insurance. 29 U.S.C. § 1144(b)(2)(A). To be saved from preemption a state law must: 1) be specifically directed toward entities engaged in insurance; and 2) substantially affect the risk pooling arrangement between the insurer and the insured. *KY Ass'n. of Health Plans, Inc. v. Miller,* 538 U.S. 329, 342 (2003). However, a benefit plan itself, whether fully insured or self-funded, cannot be deemed to be in the business of insurance. 29 U.S.C. § 1144(b)(2)(B). Consequently, <u>all</u> Oklahoma law is preempted to the extent it "relates" to the Hobby Lobby Plan. 29 U.S.C. § 1144(a). This does not mean the Oklahoma laws are nullified or invalid; it simply means they <u>cannot be enforced against</u> the Plan, or against the other ERISA plans in Oklahoma.

ERISA establishes a comprehensive federal system for regulating and protecting benefit plans like the ones in question. Under ERISA, Hobby Lobby (and other employers who sponsor benefit plans) is an employer, 29 U.S.C. § 1002(5), directly engaged in commerce, 29 U.S.C. § 1002(11), and in industries and activities that affect commerce, 29 U.S.C. § 1002(12). It is a private sector employer. It is the sponsor, 29 U.S.C. § 1002(16)(B), administrator, 29 U.S.C. § 1002(16)(A), and a fiduciary, 29 U.S.C. § 1002(21)(A), of the Plan. Other persons or entities that manage the Plan are fiduciaries, 29 U.S.C. § 1002(21)(A), of the Plan. ERISA articulates duties, 29 U.S.C. § 1104(a), standards of conduct, 29 U.S.C. § 1104(a)(1)(B), and liabilities, 29 U.S.C. § 1105, 1109(a), for the Plan's fiduciaries, and civil actions that can be brought against the Plan's fiduciaries, 29 U.S.C. § 1132(a)(2), § 1132(a)(3), or for other things like the recovery of benefits, including pharmacy or drug benefits, 29 U.S.C. § 1132(a)(1)(B), or for equitable and injunctive relief involving the terms of ERISA and the benefit plans, 29 U.S.C. § 1132(a)(3).

The Plan is an "employee welfare benefit plan" and an "employee benefit plan," 29 U.S.C. § 1002(1), under ERISA. The Plan's funds are assets of the Plan and are deemed to be held in trust. 29 U.S.C. § 1103(a). The funds can only be used to provide benefits to Plan members and to defray reasonable expenses in administering the Plan. 29 U.S.C. § 1103(c), § 1104(a)(1)(A). Fiduciaries of the Plan can be liable for causing losses to the Plan. 29 U.S.C. § 1109(a), § 1132(a)(2).

The fiduciaries of the Plan, including Hobby Lobby, are charged with the responsibility of ensuring that prescription drug benefits are provided prudently to the Plan and its Members. Hobby Lobby could have structured its Plan in a way that gave parity to

the smaller pharmacies the Oklahoma law desires to protect. Exercising its discretion and responsibilities under ERISA, Hobby Lobby instead opted to utilize a different Plan design that uses a PBM to deliver low-cost prescription drug benefits to the Plan and its Members. That choice must be respected, and cannot be regulated or overridden, by the State of Oklahoma or any other state.

I. THE PRPCA IS PREEMPTED BY ERISA BECAUSE IT PURPORTS TO DIRECTLY REGULATE THE HOBBY LOBBY PLAN AND SIMILAR PRIVATE SECTOR BENEFIT PLANS.

A. The PRPCA Purports to Capture ERISA Plans By Requiring a License.

Oklahoma has attempted to regulate PBMs since at least 2008. Oklahoma's definition of a "pharmacy benefits manager," although vague and overbroad, arguably captures employers who sponsor benefit plans. 59 Okla. Stat. § 356.1(A); 36 Okla. Stat. § 6960(3). By capturing the employers through licensing requirements Oklahoma would gain control over the ERISA plans they sponsor. Oklahoma could do this, for example, by conditioning a license on how the employers structure their ERISA plans, how they and others conduct themselves in managing the ERISA plans, which vendors they choose to manage their ERISA plans, etc.

In Oklahoma, "a pharmacy benefits manager or PBM means a person that performs pharmacy benefits management and any other person acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management for a managed-care company, nonprofit hospital, medical service organization, insurance company, third-party payor or a health program administered by a department of this state." 59 Okla. Stat. § 356.1(A); 36 Okla. Stat. § 6960(3) (emphasis added).

Employers who sponsor benefit plans arguably fit this definition. Employers "manage" their plans, for example, by enrolling their employees and dependents, changing and updating their plans, hiring vendors, managing plan funds, etc. In fact, ERISA mandates that employers (who are typically "sponsors, "administrators," and "fiduciaries" of their plans under 29 U.S.C. § 1002(16), (21)(A)), perform various "management" activities for their plans. *See, e.g.,* 29 U.S.C. §§ 1021, 1024, 1025, 1102, 1103, 1104, 1132(c), 1161(a), 1166.

Moreover, PBMs like CerpassRx act "for such persons" like Hobby Lobby under a contractual or employment relationship in the performance of pharmacy benefits management. The PRPCA thus appears to have intentionally targeted both employer-sponsors of benefit plans and the PBMs with whom they contract to manage the prescription drug benefit component of their plans. Because of this, from this point forward this brief will refer to the more traditional pharmacy benefits managers as "PBMs," and those entities falling within Oklahoma's broader definition (including self-funded employers) as "OPBMs."[4]

If an employer falls within Oklahoma's definition of an OPBM then "In order to provide pharmacy benefits management or any of the services included under the definition of pharmacy benefits management in this state," the employer must first obtain a license from the Oklahoma Insurance Department ("OID"). 59 Okla. Stat. § 358(A). The

[4] To be certain, the recent enactment of the PRPCA, coupled with Oklahoma's efforts to enforce it, raise concerns for employers. These concerns implicate Oklahoma statutes other than the PRPCA itself. Regardless of the current intentions of Oklahoma authorities the Oklahoma statutes in question purport to give them authority to regulate ERISA plans and the private sector employers who establish and maintain them.

employer must comply with OID regulations, pay fees, and be subject to subpoenas and even prosecutions. 59 Okla. Stat. § 358(B), (C). Most important:

> The [OID] may suspend, revoke or refuse to issue or renew a license for noncompliance with any of the provisions hereby established or with the rules promulgated by the [OID]; for conduct likely to mislead, deceive or defraud the public or the [OID]; for unfair or deceptive business practices or for nonpayment of a renewal fee or fine. The [OID] may also levy administrative fines for each count of which a licensee has been convicted in [an OID] hearing.

59 Okla. Stat. § 358(D). Thus, if the employer-sponsor of a federally-regulated health benefit plan chooses to offer its employees prescription drug benefits at the deeply discounted costs that a PBM can deliver, the employer must, according to Oklahoma, first pay a fee and obtain a license from the OID. The OID can subpoena witnesses and information from the federally-regulated plan and its sponsor. The OID can fine, discipline, and even prosecute the employer.

But even more fundamentally, Oklahoma can deny or revoke the license of an OPBM. For example, if Hobby Lobby is an OPBM, Oklahoma says it can deny or revoke a license to the company. If that occurred it would appear that Hobby Lobby would have to cease providing PBM-driven prescription drug benefits to its employees under its federally-regulated ERISA plan. By capturing employers through licensing mandates,

Oklahoma captures their ERISA plans, and can thus claim authority to regulate the prescription drug benefits provided by the plans.[5]

But Oklahoma law captures more than just employers who establish and maintain health plans. The Act is obviously directed at PBMs like CerpassRx. But third-party administrators for self-funded plans, insurers of fully-insured plans, and other vendors or managers arguably "perform" pharmacy benefits management, in whole or in part, under 59 Okla. Stat. § 356.1(A); 36 Okla. Stat. § 6960(3). By purporting to have the power to regulate these entities, Oklahoma thus purports to have the additional power to regulate prescription drug benefits offered by ERISA plans.

Thus, for example, Oklahoma could deny, revoke, non-renew, or condition a PBM license to CerpassRx. Hobby Lobby might then have to make significant adjustments to its Health Plan, including changing PBMs to one that is licensed in Oklahoma, and might not be able to deliver the same benefits as those delivered through CerpassRx.

The PRCPA broadens the definition of an OPBM including arguably an employer to offer the same comprehensive benefits at the same reduced cost levels through another PBM. If this happened in 2020 while we are awaiting a decision in *Rutledge*, Hobby Lobby might have to go to the unnecessary time and expense of changing PBMs, only to incur additional time and expense to change back to CerpassRx depending on the outcome of

[5] To argue that regulating employers is not the same as regulating their benefit plans is like arguing that a statute that prohibits trustees from distributing more than 5% of their trust corpus annually is not regulating the trusts themselves. One can regulate a trust by regulating its trustees. The trust analogy is appropriate because "ERISA abounds with the language and terminology of trust law." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 110 (1989).

Rutledge. This is another reason to preserve the status quo while *Rutledge* is under consideration.

B. Oklahoma Purports to Directly Regulate Significant Aspects of ERISA-Regulated Plans.

A few examples of this are as follows. The PRPCA requires OPBMs to include certain things in their contracts with providers.[6] This includes disclosures regarding the sourcing, pricing, and placement of drugs on maximum allowable cost ("MAC") lists, 59 Okla. Stat. § 360(A)(1)-(3), (B), and providing for dispute resolution procedures, *id.* at § 360(A)(4)-(5). ERISA establishes federal procedures for processing and adjudicating claims for benefits by members and their pharmacies,[7] 29 U.S.C. § 1133; 29 C.F.R. § 2560.503-1, as well as civil actions for pursuing claims for benefits from plans, 29 U.S.C. § 1132(a)(1)(B), which Congress intended to be "exclusive," *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 62-63 (1987). Oklahoma's dispute resolution provisions are preempted, and the sourcing, pricing, and placement requirements are plainly a form of restriction on the very benefits that ERISA plans provide.

The PRPCA purports to force benefit plans, like the Hobby Lobby Plan, to include certain providers in its network. 36 Okla. Stat. §§ 6961, 6962(4). It mandates that OPBMs "shall not in any manner on any material, including but not limited to mail and ID cards, include the name of any pharmacy, hospital or other providers unless it specifically lists all

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[6] These arguably include not only contracts between PBMs like CerpassRx and pharmacies, but also employer-OPBMs and their "chains" of contracts with PBMs and pharmacies, *i.e.,* employer-PBM-pharmacy.

[7] Pharmacies typically have to follow ERISA's claims procedures either as in-network providers who have contracted to do so, or as assignees of the members' rights to benefits.

pharmacies, hospitals and providers participating in the preferred and nonpreferred pharmacy and health networks." 36 Okla. Stat. §§ 6961(D). This purports to prohibit all OPBMs from including the name of an in-network pharmacy, such as CVS, Walgreens or another pharmacy or PBM, on member ID cards. And this ostensibly applies not only to employers and PBMs that are headquartered in Oklahoma, but also to employers and PBMs whose members reside, work, or fill their prescriptions in Oklahoma – and ostensibly elsewhere.

The PRPCA contains mandates and restrictions on the relationship between pharmacies and the benefit plans, through their OPBMs. 36 Okla. Stat. §§ 6962(B), (C). The PRPCA purports to prohibit OPBMs from charging fees to contracting providers, 36 Okla. Stat. §§ 6962(B), from failing to pay claims in certain circumstances, id. at § 6962(B)(4)-(7), and it forces OPBMs to establish and maintain electronic claim inquiry processing systems, *id.* at § 6962(C)(3). These mandates and restrictions are preempted by ERISA.

The PRPCA purports to force the insurers of fully-insured ERISA plans to monitor certain activities. 36 Okla. Stat. § 6963. This type of mandate is not saved from preemption under ERISA, 29 U.S.C. § 1144(b)(2)(A); *KY Ass'n. of Health Plans, Inc. v. Miller*, 538 U.S. 329, 342 (2003).

The PRPCA purports to force plans, like the Hobby Lobby Plan, to accept any willing pharmacy into the network, 36 Okla. Stat. § 6961(A)-(C), and then purports to require patients to have unfettered access to their choice of in-network providers including those "forced" into the network, 36 Okla. Stat. § 6963(D). This fundamentally alters the way

ERISA plan networks are structured. This type of state restructuring of ERISA plans is preempted. 29 U.S.C. § 1144(a).

The PRPCA purports to regulate the composition and activities of pharmacy and therapeutics committees of the insurers of fully-insured ERISA plans. 36 Okla. Stat. § 6964. This is not saved from preemption. 29 U.S.C. § 1144(b)(2)(A); *Miller*, 538 U.S. at 342.

In the area of disputes, The PRPCA authorizes the OID and an "advisory committee" to hear and adjudicate complaints involving an OPBM. 36 Okla. Stat. § 6966(B). This includes the authority:

> to review complaints, hold hearings, subpoena witnesses and records, initiate prosecution, reprimand, place on probation, suspend, revoke and/or levy fines not to exceed Ten Thousand Dollars ($10,000.00) for each count for which any pharmacy benefits manager (PBM) has violated a provision of this act. The Advisory Committee may impose as part of any disciplinary action the payment of costs expended by the Insurance Department for any legal fees and costs including, but not limited to, staff time, salary and travel expense, witness fees and attorney fees. The Advisory Committee may take such actions singly or in combination, as the nature of the violation requires.

Id. Congress established civil and criminal liabilities regarding ERISA-regulated plans, *see* 29 U.S.C. § 1131, § 1132, and it gave the Secretary of Labor the exclusive authority to investigate and take action involving violations of law with respect to ERISA-regulated plans. *See* 29 U.S.C. § 1132(a)(2),(4),(5),(6),(8); § 1132(b); § 1132(c)(2),(4)-(12); § 1134; § 1136. As noted, ERISA preemption is so powerful that it displaces state laws that are consistent with its provisions, *D.C. v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 129 (1992), so it plainly preempts state laws that contravene ERISA by purporting to give state agencies and advisory committees the authority to investigate and prosecute matters involving ERISA-regulated plans and OPBMs.

Similarly, Oklahoma law purports to establish dispute resolution procedures for disputes between OPBMs and providers who fill prescriptions for plan members. 59 Okla. Stat. § 360(A)(4), (5). As noted, ERISA establishes federal methods for processing and adjudicating claims for benefits by members and their pharmacies, 29 U.S.C. § 1133; 29 C.F.R. § 2560.503-1, as well as civil actions for pursuing claims for benefits, 29 U.S.C. § 1132(a)(1)(B), which Congress intended to be "exclusive," *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 62-63 (1987). Again, state law is preempted.

II. THE PRPCA IS PREEMPTED BY ERISA BECAUSE IT DIRECTLY AFFECTS THE HOBBY LOBBY PLAN AND SIMILAR PRIVATE SECTOR BENEFIT PLANS.

The aforementioned examples illustrate how Oklahoma law has a direct and impermissible effect on ERISA plans. This is true in three respects.

First, the Oklahoma law purports to regulate how benefit plans must be structured. If Oklahoma law is not preempted, ERISA plans would have to be restructured to comply with Oklahoma mandates.

Second, the Oklahoma law purports to regulate how benefit plans, including the provision of benefits and the processing of claims, must be administered. If Oklahoma law is not preempted, ERISA plan sponsors, administrators, fiduciaries, and service providers would have to alter the way they manage their plans.

Third, the Oklahoma law affects the finances of benefit plans. Many of the aforementioned laws undercut the cost savings that PBMs deliver to benefit plans. In the self-funded context, this would mean that more plan dollars must be spent to reimburse pharmacies, and this undercuts ERISA's goal of protecting plan assets. *See e.g.,* 29 U.S.C.

§§ 1001(a), 1103(a), (c)(1), 1104(a). In the fully-insured context insurers would have to charge higher premiums to employers and plan members. In both cases the federally-protected benefits become more expensive. Additionally, Oklahoma law has the effect of increasing the costs of administering ERISA plans. Finally, it does not matter whether Oklahoma law bestows a benefit upon or a detriment to ERISA plans. 29 U.S.C. § 1144(a), (c). State law, positive or negative, is preempted if it relates to ERISA plans. *Id.*

III. PERMITTING THIS TYPE OF STATE REGULATION THROWS ERISA PLANS AND THEIR MANAGERS INTO A REGULATORY MORASS.

"One of the principal goals of ERISA [was] to enable employers 'to establish a uniform administrative scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits.'" *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001) (quoting *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 9 (1987)). The Supreme Court has recognized that "[r]equiring ERISA administrators to master the relevant laws of 50 states ... would undermine the congressional goal of 'minimiz[ing] the administrative and financial burden[s]' on plan administrators—burdens ultimately borne by the beneficiaries." *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 944 (2016) (quoting *Egelhoff*, 532 U.S. at 149-50; *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142 (1990)). ERISA preemption protects benefit plans "'by eliminating the threat of conflicting and inconsistent State and local regulation.'" *Shaw*, 463 U.S. at 99 (1983). A state law is thus preempted if it "'governs ... a central matter of plan administration' or 'interferes with nationally uniform plan administration.'" *Gobeille*, 136 S.Ct. at 943.

As noted above, 40+ states have enacted or are in the process of enacting similar laws. The following are examples of some of the complex and often conflicting state laws that confront benefit plans, their sponsors, administrators, fiduciaries, vendors, and service providers including PBMs. For the sake of brevity, the examples cited are statutes that expressly mention or are expressly directed at ERISA-regulated plans.

Disclosure/Transparency: This includes requirements like reporting of rebates, reimbursement amounts, fees received, etc. For example, some states regulate specific required disclosures that a PBM must make to an ERISA plan sponsor. *See, e.g.,* La. Stat. Ann. §§ 22:1657, 22:1657.1, 22:976; Minn. Stat. Ann. § 62W.06. Other states only provide for differing disclosure requirements to be made by the PBM to the state itself. *See, e.g.,* Vt. Stat. Ann. tit. 18, §§ 9471, 9472.

MAC Lists: These include state requirements relating to MAC lists. There is a fair amount of variability among the states, including the frequency for which the MAC list must be updated, timelines for pharmacy appeal and PBM adjudication, the ratings of the drugs that may be included, etc. *See, e.g.,* Ga. Code Ann. § 33-64-9; Kan. Stat. Ann. § 40-3830; Mont. Code Ann. § 33-22-172; Ohio Rev. Code Ann. § 3959.111. For example, the Arkansas law at issue in *Rutledge* requires that a benefit plan's PBM must:

> [u]pdate its [MAC] 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 [MAC] List is based or in the value of a variable involved in the methodology;
>
> ... [p]rovide a process for each pharmacy subject to the [MAC] List to receive prompt notification of an update to the [MAC] List; and

> ... [p]rovide 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 ....

Ark. Code Ann. § 17-92-507(c)(2)-(4). Having to update, disclose, and revise (per individual pharmacy appeals), MAC lists in accordance with the requirements of 40+ states makes it virtually impossible to administer the Plan, let alone on a national uniform basis.

Mail-Order: These state laws are all restrictions on the use of a PBM's – and its ERISA-regulated plans' – mail order business. There are a number of such laws that are plainly directed at benefit plans. *See, e.g.,* Ga. Code Ann. §§ 33-30-4.3, 33-64-10, 33-64-11; Miss. Code. Ann. § 83-9-6; N.C. Gen. Stat. Ann. § 58-51-37(c)(6); N.D. Cent. Code Ann. § 19-02.1-16.4; N.H. Rev. Stat. Ann. § 420-J:7-b(VIII). For example, in North Dakota, if a prescription is provided through delivery or mail order, specific refill requirements must be met, while other states do not impose such requirements. N.D. Cent. Code Ann. § 19-02.1-16.4. This directly affects the way plan members purchase and receive their prescription drugs, often in bulk and at volume discounts, on a mail order basis.

Prompt Pay: These include state laws that are broadly applicable, not just on pharmacy claims. *See, e.g.,* Iowa Admin. Code r. 191-59.3(510B); Miss. Code. Ann. § 73-21-155. The number of days provided by statute in which claims must be paid varies among states, and, to add to the legal patchwork, some states have different deadlines based on whether the claim was made electronically or by other means. For example, Georgia provides a 15-day deadline for electronic claims and a 30-day deadline for paper claims. Ga. Code Ann. § 33-24-59.14. Iowa provides for a 20-day deadline for electronic claims and a 30-day deadline for other claims. Iowa Admin. Code r. 191-59.3(510B). These laws directly

conflict with the way ERISA *uniformly* mandates that claims must be processed, adjudicated, and paid or denied. *See* 29 U.S.C. § 1133; 29 C.F.R. § 2560.503-1 (articulating timeframes for deciding claims and appeals).

Specialty: These include state laws which apply to specialty pharmacy or specialty drugs. Some of these expressly apply to benefit plans. *See, e.g.,* Del. Code Ann. tit. 18, § 3580.

Penalties: These include state laws that create state penalties for violations of the state acts, some of which are broad enough to apply to ERISA-regulated plans, their sponsors, administrators, fiduciaries, etc. Minn. Stat. Ann. § 62W.06(Subd. 3); Vt. Stat. Ann. tit. 18, § 9474(e); Mo. Rev. Stat. § 376.387(6); Ga. Code Ann. § 33-64-9(h); N.D. Cent. Code Ann. § 26.1-36-12.2(5).

IV. THE CONFLICTING EFFORTS BY STATES TO REGULATE ERISA PLANS RENDERS PLAN DESIGN AND MANAGEMENT VIRTUALLY IMPOSSIBLE, AND THIS DISCOURAGES THE PROLIFERATION OF EMPLOYEE BENEFITS.

The above analysis illustrates the punitive consequences a multistate plan sponsor could face if it fails to adjust its plan's terms and procedures to comply with every state's unique regime. The aforementioned examples demonstrate how PBM laws frustrate ERISA's goal of establishing a "uniform administrative scheme" for the Plan. *Egelhoff*, 532 U.S. at 148.

First, the PRPCA overrides and nullifies the way ERISA plans, including the Hobby Lobby Plan, were designed. Many of the pertinent Plan provisions are either permitted or mandated by ERISA. *See Shaw*, 463 U.S. at 97 (holding that ERISA preempts state laws that prohibit employers from structuring their plans certain ways).

Second, the PRPCA affects the design of the Plan's documents. ERISA requires that all benefit plans be "established and maintained pursuant to a written instrument." 29 U.S.C. § 1102(a). Generally, the written terms of the plan are controlling. *See, e.g.,* 29 U.S.C. §§ 1104(a)(1)(D), 1132(a)(1)(B), 1132(a)(3). Does the Plan document need to include provisions regarding pricing, appeals, penalties, etc. so that it conforms with the PRPCA? If so, then presumably the Plan's document must include provisions covering the laws of all 40+ PBM states.

ERISA also requires employers like Hobby Lobby to design, draft, and distribute summary plan descriptions ("SPDs"). 29 U.S.C. §§ 1021(a)(1), 1022(a), 1024(b). SPDs must "be written in a manner calculated to be understood by the average plan participant, and shall be sufficiently accurate and comprehensive to reasonably apprise such participants and beneficiaries of their rights and obligations under the plan." 29 U.S.C. § 1022(a). The Supreme Court has cautioned against including unnecessary legalese or overcomplicated descriptions because it diminishes the utility of SPDs. *CIGNA Corp. v. Amara*, 563 U.S. 421, 437 (2011). Things like imprecise language, representations, and omissions in SPDs have become a fertile source of litigation. *See generally* M. R. Bosau, "Defining the Parameters: When an ERISA Summary Plan Description Trumps the Corresponding Plan Document," Megan R. Bosau, *Defining the Parameters: When an ERISA Summary Plan Description Trumps the Corresponding Plan Document*, 7 DePaul Bus. & Com. L.J. 521-53 (2009). However, legalese and over-complication are inevitable consequences in designing and drafting SPDs and plan documents that must comply with the laws of 40+ states, especially when those laws conflict.

ERISA also requires employers like Hobby Lobby to draft and distribute to the Members a summary of material modification ("SMM") any time there is a material modification (favorable or unfavorable) to the Plan, but the deadline is generally shortened to 60 days for a material reduction of benefits in group health plans like this Plan. *See* 29 U.S.C. §§ 1022(a), 1024(b)(1)(B); 29 CFR § 2520.104b-3(d). Employees often have to fill their prescriptions in different states, so a benefit modification in any state could affect those employees. Again, with the rapid-fire enactment and amendment of PBM laws by various states, employers like Hobby Lobby would have to master those changes and draft and distribute SMMs at a frenzied and almost unmanageable pace.

Finally, the PRPCA has a more fundamental effect on plan design – whether to provide prescription drug benefits in the first place, and if so, how to pay for them. Considering the adverse economic effects – and the risk of potential civil and criminal liability – resulting from the PRPCA and similar laws, should employers like Hobby Lobby require the Plan Members to pay a greater share of the cost of their prescription drugs? Or should the employers simply eliminate prescription drug benefits altogether? *See Conkright v. Frommert*, 559 U.S. 506, 517 (2010) (noting that complex administrative costs could discourage employers from providing benefits). These are the very real questions that plan sponsors are currently confronting as they draft and amend their ERISA benefit plans in the wake of oppressive and conflicting state regulation.

V. THIS COURT SHOULD PROTECT THE STATUS QUO PENDING A RULING IN RUTLEDGE.

This lawsuit was filed on October 25, 2019, shortly before the PRPCA became effective November 1, 2019. In light of this Court's January 31, 2020 stay order [Doc. # 26]

Oklahoma has not had a chance to begin enforcing the PRPCA, but it is evident that Oklahoma intends to proceed.

The status quo is the way things were before this lawsuit was filed and before the PRPCA became effective. ERISA plans and those who manage them should not be required to alter the structure, administration, or finances of the plans until *Rutledge* is decided. A contrary ruling could cause irreparable injuries to the plans and those who manage them.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of May, 2020, I electronically transmitted the attached document to the Clerk of the Court using the ECF system for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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