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Via email: sara.worten@oid.ok.gov

Re: Comments on Draft Emergency Rules Implementing HB 2632 (Patient's Right to Pharmacy Choice Act)

Dear Ms. Worten:

We are writing to provide the Pharmaceutical Care Management Association (PCMA) and Oklahoma Association of Health Plans (OAHP) joint comments on the Oklahoma Insurance Department's (OID) draft emergency rule implementing HB 2632, enacted earlier this year. PCMA is the national trade association representing pharmacy benefit managers (PBMs), which manage prescription drug benefits for large employers, health insurance carriers, labor trusts, government programs, and other payers. OAHP is a non-profit trade association representing licensed Health Plans within the state of Oklahoma that promote quality and affordable health care across the state. We appreciate the willingness of the OID to solicit feedback from stakeholders on the draft emergency rules and provide our comments below. We would be happy to discuss any of these comments if needed.

ERISA Preemption

Section 29-2 in the proposed rule establishes a broad exemption from the terms of the law for ERISA plans. PCMA and OAHP support this clear exemption. The Employee Retirement Income Security Act of 1974 (ERISA)[1] established a federal regulatory framework that governs both insured and self-insured "employee welfare benefit plans"[2] and retirement plans sponsored by employers, labor unions, and certain other entities. Employer-sponsored health benefit plans are "welfare benefit plans" and thus subject to ERISA. ERISA does not cover governmental plans[3] or church plans.[4]

ERISA includes an express preemption provision, which preempts all state laws that "relate to" ERISA-governed employee benefit plans. Congress adopted this express preemption provision to establish a uniform federal regulatory scheme and protect ERISA plans from the administrative

[1] 29 U.S.C. § 1001 *et seq.*
[2] *Id.* § 1002(1).
[3] *Id.* § 1003(1).
[4] *Id.* § 1003(2).

and compliance burdens of satisfying a patchwork of different state regulations.[5] The US Supreme Court has construed ERISA's broad preemption provision to supersede any state law that has a "reference to" or "connection with" ERISA-governed plans.[6]

Under the Supreme Court's "connection with" test, ERISA preempts state laws that govern central matters of plan administration or that interfere with nationally uniform plan administration.[7] Matters of plan administration include calculating benefit levels, making disbursements, monitoring the availability of funds, and keeping records to comply with reporting requirements.[8] Where a state law impacts either the structure[9] or administration[10] of ERISA-governed plans, preemption occurs.[11] Because ERISA's express preemption provision reaches both "direct [and] indirect" state regulation of ERISA plans,[12] preemption occurs even where a state's regulation is imposed on third-party administrators (TPAs) administering ERISA-governed plans.[13]

PBMs serve as TPAs for ERISA-governed health benefit plans. In that capacity, PBMs perform the essential functions necessary to deliver prescription drug benefits to plan members. PBMs contract with health plans to establish pharmacy networks, administer pharmacy credentialing and performance requirements, and otherwise administer the prescription drug benefits provided by plans. PBMs in turn contract with pharmacies to provide access for plan members to a plan's prescription drug benefits. Such contracts necessarily include arrangements for how much PBMs will reimburse (on behalf of a plan) network pharmacies for any particular prescription drug covered by the plan.

A state regulation of the PBM-pharmacy relationship and/or the PBM-plan relationship has an impermissible "connection with" ERISA when it impermissibly dictates administrator choices pertaining to plan structure and administration. Oklahoma, by enacting a law that seeks to regulate health plan and pharmacy reimbursement requirements, setting network adequacy requirements, and establishing other restrictions in contracting, has impermissibly dictated choices in plan structure and administration. Thus, the application of most this law is preempted by ERISA.

We appreciate that the proposed rule acknowledges that the Patent's Right to Pharmacy Choice Act is preempted with respect to ERISA-governed plans, but are concerned that, as currently written, the proposed rule may create some unintended ambiguity about the scope of the exemption. We recommend the following revision to the OID's draft in order to clarify the proposed rule on this point.

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[5] *Id.* § 1144(a); s*ee, e.g.*, *Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1, 11–12 (1987).
[6] *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).
[7] *Gobeille*, 136 S. Ct. at 943.
[8] *Pharm. Care. Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 730 (8th Cir. 2017); *see also Fort Halifax*, 482 U.S. at 9.
[9] *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983).
[10] *Gobeille*, 136 S. Ct. at 943.
[11] *Minn. Chapter of Associated Builders & Contractors, Inc. v. Minn. Dep't of Pub. Safety*, 267 F.3d 807, 816 (8th Cir. 2001).
[12] *See* 29 U.S.C. § 1144(c)(2).
[13] *Pharm. Care Mgmt. Ass'n v. Rutledge*, 891 F.3d 1109, 1112–13 (8th Cir. 2018); *Gerhart*, 852 F.3d 722; *Pharm. Care Mgmt. Ass'n v. Dist. of Columbia*, 613 F.3d 179 (D.C. Cir. 2010).

365:25-29-2. Scope

This Subchapter shall apply to all pharmacy benefits managers which must be licensed pursuant to 59 O.S. § 358(A) and to all health insurers subject to compliance with 36 O.S. § 6958 et seq. The Patient's Right to Pharmacy Choice Act, 36 O.S. §§ 6958-6968 and ~~T~~this subchapter do~~es~~ not apply to any employee benefit plan which is subject to the Employee Retirement Income Security Act of 1974 (ERISA) including any individual or entity acting as a pharmacy benefit manager for such ERISA plan.

Medicare Preemption

In addition to the ERISA preemption language, the rule should indicate that the statute does not apply to Medicare Part D prescription drug plans. The Medicare Modernization Act (MMA) establishes a broad rule of preemption. It preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established "standards" in the area regulated by the state law; and (2) that the state law acts "with respect to those standards."[14] A standard within the meaning of the preemption provision is either a statutory provision or a duly promulgated and published regulation.[15] "Conflict between the state law and the federal standard is unnecessary."[16] If the state law in question merely acts with respect to the standard, it is preempted. Here, the Medicare program sets requirements relating to pharmacy networks, contracts with plan sponsors, audit requirements, and other items contained both in these rules and the statute that these rules implement. We suggest adding a clear exemption for Medicare plans, similar to the exemption language for ERISA plans.

Comments on Remaining Provisions

- There are multiple new audit requirements outlined in the proposed rule (29-7.1(a)(1); 29-9(b)(2); 29-9(c)). As you know, insurers regularly audit PBM performance and evaluate PBM compliance with contract terms. It has been communicated to PCMA member companies that the audits outlined in the rule do not need to be separate and apart from the audits that are currently done, so long as the underlying substantive requirements of the statute are met. Our member companies appreciate this interpretation; however, suggest that the regulatory requirements be streamlined for clarity and to prevent an excessive number of audits. We recommend that the audit requirements in the rule be consolidated into one audit requirement that should be done annually. The requirements should further state that if no change has been made from the prior year, the requirement for the PBM should be a certification only, not another audit.

  In addition, Section 29-7.1(a)(1) requires that an insurer has 30 days after Nov. 1 to conduct an audit, and 30 days after Nov. 1 to submit the required certification. We are concerned that having the same due date for both the audit and certification does not make sense. We suggest that the insurers have an additional 30 days after the finalization of the audit to submit the certification. Ideally, the rules would have one section addressing audits instead of multiple separate sections. For ease on these emergency rules, however,

[14] 42 U.S.C. § 1395w-26(b)(3).
[15] *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010).
[16] *Pharm. Care Mgment. Ass'n v. Rutledge*, 891 F.3d 1109, 1113 (8th Cir. 2018).

we suggest amendments below based on the language OID has proposed. We look forward to working with the OID on a more appropriate structure for the final rules.

PCMA and OAHP suggest the following language to clarify these items:

29-7.1(a)(1) Every insurer that utilizes the services of a pharmacy benefit manager shall within thirty (30) days of the effective date of the act, and then on an ~~semi-~~annual basis, conduct audits of its pharmacy network access to ensure compliance with the provisions of the act.

29-9(b)(2): … for conducting an ~~semi-~~annual audit of transactions and practices utilized by its contracted PBMs and members of its retail pharmacy network to ensure compliance with the act.

29-9(c): Every insurer that utilizes the services of a pharmacy benefit manager shall within thirty (30) days of the effective date of the act, and then on an ~~semi-~~annual basis, conduct audits of the PBMs, acting on its behalf, to ensure compliance with the provisions of 36 O.S. § 6962 and O.A.C. 365:25-29-9(b). The results of the audit shall be submitted to the Commissioner and accompanied by a certification attested to by an officer or director of the insurer that the contents of the audit are true and correct. The certification is to be submitted to the Commissioner within 30 days of the ~~effective date of the act~~ finalization of the audit, and then on an ~~semi-~~annual basis when the audits are completed.

For the audits referenced in 365:25-29-7.1(a)(1), 365:25-29-9(b)(2), and 365:25-29-9(c), it is not required that insurers perform these audits at separate times or at a different time than other audits being performed, so long as the underlying statutory requirements ensuring compliance are met. If no changes have been made since the previous audit on any of the required items, an insurer may demonstrate compliance with a certification from a PBM that indicates that no changes have occurred.

- Section 29-7.1(a)(2) refers to the statutory definition of a member of a "retail pharmacy network" saying that the "pharmacy primarily fills… medications." In the rule, "primarily" is defined as "70% of gross retail pharmacy sales" in its "retail, storefront location." It is unclear why the term "primarily" needs to be defined in rule. PBMs do not have insight into the business practices of pharmacies and do not know specifically how much of a pharmacy's business is made up of pharmacy sales. Furthermore, the term "retail pharmacy network" is already defined in statute and is clear on its face. No further clarification is needed.

- Section 29-7.1(a)(4) references the applicability of the statute with regard to specialty drugs. This language is not in the statute, it is unnecessary, and it should be eliminated.

- Section 29-7.1(a)(6) uses the term "preferred participation status" that appears inconsistent with the definition of "preferred participating pharmacy" established in section 29-4(4). In addition, section 29-7.1(a)(6) states that "preferred participation status" means that *a pharmacy accepts a lower reimbursement in exchange for a guaranteed amount of prescription business*. This is not necessarily the way preferred status is defined or used by insurers or PBMs. We suggest that a definition of "preferred participation status" is

unnecessary because it is a matter of contract between the insurer, PBM, and pharmacy. If the Department opts to define it, the definition should refer back to the contract between the pharmacy and insurer or PBM, and the use should be consistent within the rule (Sections 29-4(4) and 29.71(a)(6)).

PCMA and OAHP suggest: For purposes of the act, "preferred participation status" in any retail pharmacy network means a plan design whereby ~~acceptance by~~ a participating pharmacy accepts the terms of a preferred network pharmacy contract ~~of a reduced amount of reimbursement in exchange for a guaranteed amount of prescription business~~.

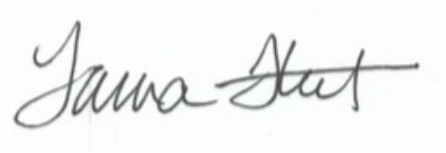
- Section 29-9(b) refers to the insurer-PBM relationship being a "principal-agent relationship." The relationship between PBM and insurer is an arms-length contract that sets out the rights and responsibilities of the parties, as well as compensation terms. We suggest that the OID strike this sentence, or in the alternative, indicate that the relationship be described instead as a "contractual relationship."

- Section 29-9(b)(1) requires insurers to approve "all" contractual documents used by PBMs and members of the retail pharmacy network. While Section 6 of the Act requires a health insurer to *monitor* all activities carried out on its behalf under the Act, the Act does not require health insurers to proactively *approve* PBM-pharmacy contracts. Thus, this requirement in the regulations exceeds the Commissioner's regulatory authority under the statute and should be stricken.

- Section 29-12 establishes the guidelines for the advisory committee created by HB 2632. We appreciate that in 29-12(c), there is an acknowledgement that since committee members will be dealing with confidential materials, there is a need for an NAIC background check. We support this requirement. However, because committee members will be dealing with potentially sensitive information of pharmacies, PBMs, and insurers, there needs to be a mechanism in place to protect confidential, proprietary, or competitively sensitive information from being viewed or used inappropriately.

  To that end, PCMA and OAHP suggest that committee members be required to avoid conflicts of interest and recuse themselves from being involved in any actions where they may have insight into a competitor's or a contracting partner's pricing or proprietary information. Committee members should be required to sign conflict of interest forms that disclose potential conflicts *before* serving on the committee, and affirmatively recuse themselves when a potential conflict arises. A conflict arises when a committee member (1) has a financial stake in an outcome of a complaint or issue before the committee, or (2) has an existing contract with a PBM, pharmacy, or insurer that is the subject of the committee's review. In addition, committee members should be required to sign confidentiality commitments that bar any public disclosure of confidential information that is discussed in the committee meetings. We encourage the OID to develop language establishing these protections and would like an opportunity to discuss the process before the emergency rules are finalized.

Thank you for the opportunity to provide our initial feedback on the issues above. We look forward to working with you as you further develop these rules. If you have any questions, please contact us at the information below, or April Alexander, Vice President of Legislative and Regulatory Affairs, PCMA, at aalexander@pcmanet.org. Thank you.



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