**PROPOSED COMMENTS TO COMAR 31.10.49 AND 31.10.50**
**BY PHARMACY PROVIDERS OF OKLAHOMA, INC.**

## Request for a waiver process

In January 2013, the United States Government Accountability Office ("GAO") issued a report to the Committee of Energy and Commerce of the House of Representatives regarding the number, role, and ownership of pharmacy services administrative organizations ("PSAOs"). The GAO report found that the majority of PSAOs in 2011 and 2012 were owned by wholesalers. Others were owned by independent pharmacy cooperatives, group purchasing organizations, or standalone private entities. Since 2012 when this data was collected, there has been substantial consolidation in the PSAO industry. However, there remains a significant distinction between those PSAOs owned by wholesalers or group purchasing organizations and those that are independent pharmacy cooperatives or owned by private entities. Namely, the latter own no competing businesses so do not have any conflicts that influence their contracting responsibilities on behalf of retail pharmacies.

Pharmacy Providers of Oklahoma, Inc. ("PPOk") is owned by UnifyRx, Inc., a Delaware not for profit, non-stock corporation and is mission driven. The mission of PPOk is to advocate for and protect independent pharmacies. It is PPOk's impression that some of the regulations being proposed and the intent of the law is to protect entities aligned with PSAOs that also own or are affiliated with wholesalers or group purchasing organizations. Thus, PPOk requests that the Commissioner consider a waiver process for those PSAOs whose sole purpose is to provide administrative services to pharmacies.

A distinction between the types of PSAOs is necessary to understand the economic impact on independent, not for profit or pharmacy cooperative PSAOs ("Independent PSAOs") such as PPOk versus those part of wholesaler or group purchasing organizations. Independent PSAOs operate on a very small margin. This is because the pharmacies, many of which are in rural areas and form a large portion of the Independent PSAO network, have very small profit margins that preclude paying large amounts to the PSAO who is contracting on behalf of the independent pharmacy. (The National Community Pharmacy Association reports average pharmacy margins at 2% or less.) PPOk currently charges each independent pharmacy in its network a flat fee per month. Due to PPOk's not for profit status and mission, PPOk is not intending to make a profit from its services, and it does not.

The financial resources required of Independent PSAOs to meet the requirements of the proposed regulations, such as registering, producing documents and making documents available at the PSAO's expense cannot be covered by the PSAO's current margins. Hence, any costs to be incurred for compliance with the regulation will be passed on to the independent pharmacies in Maryland with whom Independent PSAOs contract or will necessitate that an Independent PSAO cease doing business with pharmacies in Maryland. This leaves Maryland pharmacies with fewer PSAO choices and will eliminate those that are not-for-profit or pharmacy cooperative operating on minimal margins.

PPOK proposes that the regulations be modified to provide an opportunity for a PSAO to seek a waiver from the regulations based on the PSAO's mission and whether or not it, or a parent or affiliated company, has additional business lines that may interfere with the fiduciary duties of the PSAO to the independent pharmacies with whom it contracts. A waiver process whereby the Commissioner investigates each PSAO seeking a waiver to determine its mission, business practices, and whether particular regulations should be applicable, allows the Commissioner to assure that Independent PSAOs continue to provide services to pharmacies in Maryland, and that those PSAOs for whom there is a concern about business practices are the ones that the Commissioner is actively auditing and reviewing. Notwithstanding this general request, PPOk is making some specific comments to the proposed regulations.

COMAR 31.10.49.03

*A. A PSAO shall provide to an independent pharmacy a copy of any contracts, amendments, payment schedules, or reimbursement rates within 5 working days after the execution of a contract, or an amendment to a contract, signed on behalf of the independent pharmacy by the PSAO.*

**COMMENTS:** Contracts between PSAOs and payors or PBMs, that are signed on behalf of an independent pharmacy by the PSAO, are frequently amended by the payor or PBM through changes to the payor's or PBM's policies and procedure manual. In other words, existing contracts allow amendments to be effective upon changes to a policy and procedure manual, and frequently the amendments are effective and only known to a PSAO upon review of a policy and procedure manual. Consequently, a PSAO may not have 5 working days prior to the effective date of the amendment to notify the Independent Pharmacy and may have to do a daily check of payor's or PBM's policy and procedure amendments. Renegotiating existing contracts between PSAOs and payors or PBMs to accommodate this regulation necessitates the cooperation of the payor or PBM, which may not be given in light of the fact that the regulation only pertains to pharmacies in Maryland and this regulation does not include any enforcement power over the payors or PBMs by the Commissioner.

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**COMMENTS:** See above on the impossibility of PSAOs knowing of contract amendments. In addition, this provision violates most payor or PBM contractual confidentiality provisions. First, some contracts between PSAOs and payors or PBMs state that they are "Confidential and Proprietary – FOIA Exempt – Cannot Be Disclosed". Another typical confidentiality provision reads: "PSAO, cannot copy, reproduce, distribute or otherwise share the information contained in the agreement or the provider manual". Breach of these provisions authorize the payor or PBM to obtain specific performance including restraining orders, injunctions, and judgment for damages when provisions of the contract are released. This proposed regulation puts the PSAO in a position of breaching its agreements with payors and/or PBMs.

COMAR 31.10.49.05

*D(2)(a) A complete, unredacted copy of the applicable portion of the pharmacy services administrative contract relating to the complaint filed with the Commissioner, including any other contract applicable to the complaint;*

**COMMENTS**: This once again puts the PSAO in the position of violating its contractual commitments to payors and PBMs. In those circumstances when an exception to confidentiality is authorized due to requirements of law or the order of any court or governmental authority, the PSAO must frequently notify the payor or PBM prior to the release to provide the payor or PBM the opportunity to object to the release. At a minimum, PPOk recommends that redaction be allowed and/or that this rule and the others discussed above be revised to allow the PSAO to put forth reasons why it cannot release this information until consent has been provided by a payor or PBM.

COMAR 31.10.50.03

*Submission Requirements*

**COMMENTS**: The comments discussed above apply to this regulation.

COMAR 31.10.50.04

*A.(4) Except for instances of error or fraud, allows a PBM or PSAO to re-classify, re-categorize, or re-characterize an adjudicated claim;*

**COMMENTS:** There is no definition for a re-classified, re-categorized or re-characterized claim. PSAO's have no control over PBMs and should not be held responsible for this section. This provision is ambiguous and overreaching. Compliance is impossible given the nature of the PSAO's responsibilities to the payor or PBM.

COMAR 31.10.50.05

*A. If a PSAO uses a contract or amendment that becomes effective and the contract or amendment is subsequently found by the Commissioner to be noncompliant, the Commissioner may [make the contract or amendment ineffective and impose a civil penalty].*

**COMMENTS:** This regulation allows the Commission to accept a contract and then retroactively find that it is noncompliant. Not only is the PSAO subject to a penalty in such situation, the operations prior to the date of finding noncompliance, can be determined to be retroactively invalid. This risks the PSAO having contractual commitments to the payor or PBM and to its pharmacies that are retroactively determined to be invalid by the Commissioner and necessitate certain clawbacks of monies already paid or received. The practical problems of an intermediary, such as a PSAO, trying to reverse the flow of funds is burdensome and overreaching. At a minimum, PPOk recommends that this provision be revised to assure that any determination by the Commissioner that a contract or amendment is noncompliant be effective prospectively rather than retroactively.