

Pharmacy Services Administrative Organization (PSAO) Coalition
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Director of Regulatory Affairs
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD. 21202

Submitted via: InsuranceRegReview.mia@maryland.gov

Re: Comments on proposed Pharmacy Services Administrative Organization (PSAO) regulations

The purpose of this letter is to address key concerns with the proposed PSAO Regulation, including the following: 1) the PSAO Regulation does not appear to recognize the key differences between a PSAO and a pharmacy benefit manager (“PBM”) and/or Payer; 2) the PSAO Regulation does not address the required disclosure of contractual terms of pharmaceutical wholesalers, specifically where such disclosure is unrelated to any PSAO activities or the PSAO entity; 3) the potential impact of the PSAO Regulation on independent pharmacies, their patients, and PSAOs in Maryland.

1. The PSAO regulations appear to conflate the role of the PSAO with the role of the pharmacy benefit manager (“PBM”) and/or payer.

The relationship an independent pharmacy has with a PSAO is fundamentally different and distinct from an independent pharmacy’s relationship with PBMs and payers. As a preliminary matter, PSAOs execute contracts with payers and PBMs on behalf of the pharmacies they serve. The PSAOs stand in the shoes of a pharmacy when they execute these contracts. The PSAOs bring administrative efficiency to the table for the PBMs by allowing them to contract with thousands of pharmacies at a time.

A PSAO also bring administrative efficiency to their pharmacy members by allowing the back office contracting functions to be performed by the PSAO, thereby allowing the pharmacists more time to focus on their patients and the operation of their businesses. Additionally, PSAOs help pharmacies get into pharmacy networks that they otherwise may have difficulty getting into as an individual pharmacy location. The result is that the pharmacies have the ability to cut through the complexity of managed care contracting and focus their time providing service to their customers.

Pharmacies gain administrative efficiencies by using a PSAO; however, pharmacies are not required to use a PSAO. In fact, pharmacies may switch PSAOs if they choose, and generally, may terminate their agreements with PSAOs upon a 30-day notice. Additionally, pharmacies may choose not to use a PSAO at all and pursue direct contracts with PBMs.

It is important to also understand what PSAOs *do not* do. PSAOs do not perform the same functions as PBMs. PSAOs do not dictate reimbursement rates. It is the PBMs and/or payers who determine what drugs are on formulary drug lists and how much pharmacies will be paid for dispensing them. PSAOs do not set Maximum Allowable Costs (MACs) for generic drugs. MACs are set by the PBMs. Additionally, PSAOs do not retain *any* portion of pharmacy reimbursement for their own revenue, profit or use (including any dispensing fees or Direct Indirect Remuneration (DIR) fees); instead, the PSAOs are paid a transparent, flat fee for their services.

Different from PSAOs, PBMs are third-party administrators of prescription drug programs for commercial health, self-insured employer, Medicare Part D, and state government plans. PBMs are responsible for developing and maintaining the formulary, contracting with pharmacies, setting the reimbursement rates paid to pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. Unlike PSAOs, PBMs are responsible for determining the drug reimbursements for pharmacies, and drug coverage and out of pocket cost for patients. Additionally, independent pharmacies survival is dependent on having contracts with PBMs and/or payers.

In light of these key and significant differences between PSAOs and PBMs, and because the proposed regulations related to PBM functions are not germane to what PSAOs actually do, we respectfully request that any requirements related to reimbursement, MAC, formulary listings, patient coverage, audits, and network/plan structures be removed from the proposed PSAO Regulations including those outlined in submission requirements related to contract and amendment filing contained in Chapter 50, Section .03 and Section .04.

Additionally, we also request that any requirements related to the establishment of and inclusion in agreements of claims appeal, audits, and complaint process as outlined in Chapter 49, Section .04-.05, be removed. As stated above, PSAOs have no hand in the claims submission and claim adjudication/ audit process. Such provisions are rightfully addressed in PBM and/or payer agreements.

2. Disclosure of Contracts outside of PSAO and Pharmacy Relationship

While not addressed explicitly in the PSAO Regulation, Article §15-2001 of the Annotated Code of Maryland (“PSAO Law”) appears to extend disclosure requirements beyond the PSAO and independent pharmacy relationship. Specifically, the PSAO law seems to require a PSAO that owns or is owned by any entity that manufactures, sells, or distributes drugs, biologics, or medical devices to disclose any agreement for the purchase of prescription drugs, biologics, or medical devices even where the PSAO is not the legal entity that has entered into or negotiated the agreement with the independent pharmacy. As you may be aware, PSAOs do not enter into agreements with independent pharmacies for the purchase of prescription drugs, biologics or medical devices and are not involved in the negotiations of such agreements with independent pharmacies. Such agreements are outside of the legal control of a PSAO.

We believe the PSAO Regulations should be clear and address that any disclosures of agreements are between PSAO and the independent pharmacy only. Any agreement between the independent pharmacy and any other entity that is not a PSAO should be excluded.

3. PSAO Regulation Could Lead to Possible Exit of PSAOs from the Marketplace and May Increase Cost and Administrative Burden to Independent Pharmacies.

The draft PSAO Regulation places requirements and civil penalty liability on PSAOs that is unrelated or inapplicable to the function and role of the PSAO. Such unrelated and inapplicable regulatory requirements leave the PSAO in an unattainable position with respect to compliance with the draft PSAO Regulation and whether to continue to operate a PSAO in the Maryland market.

Additionally, we believe that the implementation of a registration process and fee for PSAOs and the increased administrative requirements could result in cost and impact to independent pharmacies. The PSAO Regulation and PSAO law may result in a change in programs, operating and IT infrastructure to accommodate new PSAO members who are unaffiliated with the parent pharmaceutical wholesalers. The additional operating cost and administrative burden may further lead to PSAOs exiting the Maryland PSAO market altogether. PSAO exit will have significant and direct impact on Maryland pharmacies and impede their ability to enter into and negotiate fair agreements with PBM and/or payers.

It is critical that the PSAO Regulations take into account the function, role, and duties of a PSAO and distinguish and exclude requirements that relate to those functions, roles and duties of PBMs and payers. The current draft PSAO regulations seek to impose the same regulatory framework on PSAOs as PBMs. This is outside of the scope of the enabling statute and is a fundamental misunderstanding of the role of PSAOs.

In closing, PSAOs function as an extension of the pharmacies that hire them. The PSAOs and pharmacies are partners. The PSAOs exist to assist the independent pharmacies and we are committed to and focused on supporting independent pharmacies so that they can have the ability to service the patients in their community. PSAOs are fundamentally different than PBMs and payers, and again do not set the formulary, MAC pricing, and reimbursement. PSAOs charge pharmacies a transparent set fee (often a monthly fee) for providing contracting and administrative services, and do not retain a portion of prescription reimbursement for their profit. As the current draft PSAO Regulation stands, there may be unintended negative consequences (fee increase, PSAO exit) on the independent pharmacies we are working to support.

We appreciate your time in reviewing and considering our comments as you refine the PSAO Regulations, and we are happy to answer any questions and to be a resource for the Administration.

Warmest regards,



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