

October 12, 2020

Director of Regulatory Affairs
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, MD 21202

Via email: InsuranceRegReview.mia@maryland.gov

Re: Pharmacy Services Administration Organizations Rulemaking Comments on Title 31.10.49-50

Dear Director:

As the General Counsel for Arete Pharmacy Network LLC (Arete), I am writing to offer Arete's comments on the Maryland Insurance Administration's (MIA) proposed rules regarding the regulation of Pharmacy Services Administration Organizations (PSAOs). We greatly appreciate the opportunity to provide the following feedback pertaining to the proposed regulations.

Arete is a PSAO that has independent pharmacies located within Maryland.

Chapter 49 – Pharmacy Services Administration Organizations

.02 Definitions

- There are no definitions for “medication.” Arete recommends adding one.
- (10) “Working days” is ill-defined by centering on the Administration's schedule, which is generally unknown to the pharmacy and the PSAO. Arete recommends the timing for submissions and disclosures be revised to reflect actual calendar days – e.g. 15 days from the execution of the contract.

.03 Disclosures to Independent Pharmacy

- The requirement of disclosure to an independent pharmacy as defined in Insurance Article §15-2001(b) makes no sense when it comes to a PSAO's obligation of disclosures. PSAOs have contractual relationships with “Contracted Pharmacies” but have no contractual relationship with “Independent Pharmacies.” As written, a PSAO would be required to disclose changes outlined in the regulation to entities with which it has no contractual relationship and therefore, has no contractual obligation to inform or disclose. Arete recommends changing “independent” to “contracted.”
- Section A states that, “A PSAO shall provide to an independent [“independent” should be changed to “newly contracted pharmacy”] pharmacy a copy of any contracts, amendments, payment schedules, or reimbursement rates within five working days after execution....” Arete recommends defining “execution” to mean the effective date. Be it that certain contracts and amendments must be filed with the Commissioner and then approved, it does not make sense to require a PSAO to disclose a copy of a

contract or amendment to a member pharmacy, only to have to later notify the pharmacy that said contract or amendment is invalid.

- In Section B the sentence concludes, “... before entering into a contract.” This language is overbroad and implies that such disclosure must be made before a PSAO enters into ANY contract. Arete suggests clarifying this language by inserting “pharmacy services administrative” such that the sentence would conclude, “before entering into a pharmacy services administrative contract.”

.04 Internal Appeal Procedures

- Section A requires that a PSAO develop written procedures to, “... investigate and resolve disputes.” Arete finds this language overly broad and suggests clarifying what types of disputes it is obligated to investigate and resolve.
- Section B does not provide much guidance as to what the Commissioner and the State of Maryland would consider an acceptable Internal Appeal Process. The appeal process should be limited to issues that the PSAO has the ability and authority to address.

.05 Complaint Process

- This regulation seems to outline an administrative process for presenting a Complaint to the Commissioner for resolution, but it seems very vague and does not explain how a resolution by the Commissioner will be determined.
- Section A sets forth the jurisdictional hurdle for the complaining Contracted Pharmacy to bring this to the Commissioner.
- Section B specifies the Complaint and supporting evidence the complaining Contracted Pharmacy must file with the Commissioner.
- Section C is missing.
- Subsection D (1) is the provision of notice from the Commissioner to the PSAO, which is analogous to Service of Process.
- Paragraph D (2)(a) appears to be the PSAO’s Answer to the Complaint and initial filing of its evidence supporting the decision made under the PSAO’s Internal Appeal Process.

- Paragraph D (2)(b) is a *non sequitur*. It is not clear if this is a list of items the Commissioner needs or might need to decide the dispute and whether the PSAO or someone else is obliged to provide to the Commissioner items (i), (ii), and (iii).
- It is not clear how, after the two sides present their evidence and authority, this dispute will be resolved. Will there be a hearing? Will there be a determination without a hearing?

Need for Safe Harbor provisions.

Disputes between Arete and Contracted Pharmacies often involve issues surrounding reimbursement rates and claw backs from an insurance company/PBM. Arete does not set the wholesale drug price, insurance plan coverage, the reimbursement rates and does not, on its own, initiate claw backs from pharmacies for improperly paid benefits by the insurance company/PBM. As a consequence, aside from checking that a reimbursement was consistent with the negotiated rate structure, these types of issues should not be subject to an appeal involving a PSAO like Arete. This regulation as drafted does not have a safe harbor to protect Arete and other PSAOs from becoming a “guarantor” for a PBM/insurance company’s errors in making a benefits payment and initiating recovery. Conceivably, when a PBM/insurance company errs in reimbursements for several thousand transactions involving a particular medication (or class of medication) and attempts to claw back overpayments, a PSAO like Arete could be inundated with appeals from aggrieved Contracted Pharmacies who are upset at having to repay an overpayment. Often a PBM/insurance company uses the “self-help” remedy of deducting the over-paid amount from the next set of payments to the Contracted Pharmacy meaning that the Contracted Pharmacy will be overpaid on one medication and underpaid on another medication to compensate for the first error. This means that an error by the PBM can result in two appeals. Without a safe harbor in the regulation to protect the PSAO such as Arete, the processing of appeals could overwhelm the PSAO’s business activities. Arete recommends that there be safe harbors created by defining limitations on the scope of what disputes should be subject to this regulation.

The entire regulation should probably be rewritten to clarify and add safe harbors protecting the PSAO.

Chapter 50 – Filing of PSAO Contracts and Amendments

.01 Applicability and Scope

- The statute and the submission requirements under chapter 50, regulation .01 do not align. Namely, chapter 50, regulation .01 asserts that the filing requirements only apply to “pharmacy services administrative contracts” or an amendment thereto, whereas the statute makes clear that they apply to “pharmacy services administration contracts/amendments” and any applicable contract or amendment between a PSAO and a PBM. For clarity, Arete suggests adding language to make clear that this

regulation also applies to contracts and certain amendments that a PSAO enters into with PBMs or Purchasers.

.03 Submission Requirements

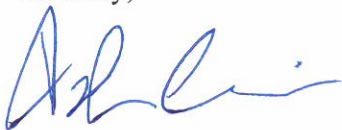
- Section B does not require the Commissioner to provide actual notice of approval of a contract or amendment that a PSAO files. Arete feels strongly that the Commissioner should always provide notice of approval or denial.
- Subsection E (1) invites confusion by placing emphasis on a PSAO's intent. For the avoidance of doubt, Arete recommends striking "intent."

.05 Noncompliant Contract or Amendment

- Arete has concerns that the language contained in this regulation will result in a disruption to patient access. Arete suggests adding language that clarifies how MIA will mitigate and prevent patient disruption in instances where a contract or amendment was initially approved, only to later be disapproved.
- Arete and other PSAOs have many pharmacies under contract in Maryland. It's not clear from the proposed regulation how these existing contracts will be treated, especially if there are no changes to the contracts. This comes into play when implementing regulation .04 "Internal and Appeal Procedures." Does the establishment of a written procedure for dispute resolution and appeal require all of these pre-existing contracts to be filed with the Commissioner or alternatively, can a document separate and apart from the already existing contracts be given to an independent pharmacy without triggering the need to redraft the already existing contract to include a written appeal procedure thereby triggering a chapter 50 filing of a contract that would appear to be grandfathered in. Arete suggests an express and definitive rule addressing the filing of existing contracts.

Thank you for allowing Arete Pharmacy Network LLC the opportunity to provide feedback pertaining to the proposed regulations.

Sincerely,



Asher Mannari, Esq.
General Counsel
Arete Pharmacy Network, LLC