

# **Title 31 MARYLAND INSURANCE ADMINISTRATION**

## **Subtitle 10 HEALTH INSURANCE – GENERAL**

### ***Chapter 49 Pharmacy Services Administrative Organizations***

*Authority: Insurance Article, §§15-2001 through 15-2019, Annotated Code of Maryland*

#### **.01 Scope.**

*This chapter applies to all contractual agreements between a pharmacy services administrative organization and an independent pharmacy in which a pharmacy services administrative organization negotiates on behalf of an independent pharmacy with purchasers or pharmacy benefit managers for prescription drug coverage or benefits, medical devices, or biologics provided to a beneficiary of a purchaser.*

#### **.02 Definitions.**

*A. In this chapter, the following terms have the meanings indicated.*

*B. Terms Defined.*

*(1) “Appeal decision” means a written or electronic notice in response to an appeal under this chapter provided to a contracted pharmacy that includes a reason for the appeal denial.*

*(2) “Contracted pharmacy” means an independent pharmacy in a pharmacy services administrative contract.*

*(3) “Independent pharmacy” has the meaning in Insurance Article, § 15-2001(b), Annotated Code of Maryland.*

*(4) “Material change” means a change in control or business operations of a pharmacy services administrative organization after a purchase, merger, or acquisition of a parent company, subsidiary, or other organization.*

*(5) “Medical device”*

*(a) “Medical device” means a device used in the diagnosis, treatment, or prevention of disease.*

*(b) “Medical device” does not include:*

*(i) Any surgical or dental instrument;*

*(ii) Physical therapy equipment;*

*(iii) Any x-ray apparatus; or*

*(iii) Any component or accessory of any of these items.*

*(6) “Pharmacy benefits manager” or “PBM” has the meaning in Insurance Article, § 15-1601, Annotated Code of Maryland.*

*(7) “Pharmacy services administrative contract” has the meaning in Insurance Article, § 15-2001(d), Annotated Code of Maryland.*

*(8) “Pharmacy services administrative organization” or “PSAO” has the meaning in Insurance Article, § 15-2001(e), Annotated Code of Maryland.*

*(9) “Purchaser” has the meaning stated in Insurance Article, §15-2001(f), Annotated Code of Maryland.*

*(10) “Working days” means any day that the Maryland Insurance Administration is open for business.*

#### **.03 Disclosures to an Independent Pharmacy.**

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

*B. A PSAO organization shall disclose to an independent pharmacy written notice of any ownership interest or control by a parent company, subsidiary, or other organization before entering into a contract.*

*C. A PSAO shall disclose to a contracted pharmacy in writing within 5 working days of any material change of ownership or control or a parent company, subsidiary, or other organization.*

*D. The written disclosures required in §§ B and C of this regulation shall identify the extent of any ownership interest or control, to include the percent of shares owned, by a parent company, subsidiary, or other organization that:*

*(1) Provides pharmacy services, prescription drug or device services; or*

*(2) Manufactures, sells, or distributes prescription drugs, biologics, or medical devices.*

#### **.04 Internal Appeal Procedures.**

*A. Each PSAO subject to this chapter shall establish written procedures to investigate and resolve disputes filed by a contracted pharmacy.*

*B. The internal appeal procedures shall:*

*(1) Be in writing; and*

*(2) Contain administrative processes and safeguards designed to ensure and verify that payments and reimbursements were determined in accordance with the PSAO contract and Maryland law, and that the contract provisions have not been applied in an arbitrary or capricious manner.*

*C. The procedures established by the PSAO may not require:*

*(1) More than one appeal before filing a complaint with the Commissioner; or*

(2) The payment of a fee to file an appeal.

D. The internal appeal procedures established by the PSAO shall be provided to the Commissioner on request.

**.05 Complaint Process.**

A. Prior to filing a complaint with the Commissioner, a contracted pharmacy or its designee shall exhaust the internal appeal process established by the PSAO.

B. A complaint is properly completed and may be filed if a contracted pharmacy or designee for the pharmacy:

(1) Completes all applicable portions of the Commissioner's complaint form; and

(2) Provides a copy of the relevant contract or the provisions that are related to the internal dispute, including but not limited to any applicable remittance and copy of any appeal decision.

D. Notification of the complaint to the PSAO.

(1) Upon receipt of a completed complaint form, the Commissioner shall provide a copy to the PSAO.

(2) Within 15 working days of receiving the Commissioner's notice, the PSAO shall provide the Commissioner:

(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; and

(b) Any other information the Commissioner may require for the purposes of determining a PSAO's compliance with:

(i) The Insurance Article, Annotated Code of Maryland;

(ii) This chapter; or

(iii) The applicable terms of the applicable pharmacy services administrative contract, PBM contract, or applicable purchaser's contract.

## **Chapter 50 Filing of PSAO Contracts and Amendments**

Authority: Insurance Article, §§2-109, 15-2010, 15-2011, 15-2013, 15-2015, and 15-2016 Annotated Code of Maryland

**.01 Applicability and Scope.**

This chapter applies to the submission of any pharmacy services administrative contract or amendment required to be filed under Insurance Article, Title 15, Subtitle 20, Annotated Code of Maryland.

**.02 Definitions.**

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Commissioner" means the Maryland Insurance Commissioner.

(2) "Contracted pharmacy" means an independent pharmacy in a contract with a pharmacy services administrative organization;

(3) "Noncompliant" means a contract or amendment that is not in compliance with Maryland statutes and regulations.

(4) "Pharmacy benefits manager" or "PBM" has the meaning in Insurance Article, § 15-1601, Annotated Code of Maryland.

(5) "Pharmacy services administrative contract" has the meaning stated in Insurance Article, §15-2001(D), Annotated Code of Maryland.

(6) "Pharmacy services administrative organization" or "PSAO" has the meaning in Insurance Article, § 15-2001(E), Annotated Code of Maryland.

**.03 Submission Requirements.**

A. Pursuant to the requirements of Insurance Article, §15-2010, Annotated Code of Maryland, and except as provided in §E of this regulation, a PSAO shall submit to the Commissioner:

(1) All pharmacy services administrative contracts and amendments to pharmacy services administrative contracts; and

(2) All contracts or amendments to contracts a PSAO enters into on behalf of a contracted pharmacy between:

(a) A PSAO and a pharmacy benefits manager; or

(b) A PSAO and a group purchasing organization.

B. Unless it is disapproved by the Commissioner, and except as provided in §E of this regulation, a PSAO may not use a contract or amendment to a contract unless it has been filed with the Commissioner and:

(1) 60 days have passed since the filing was acknowledged by the Commissioner in writing as having been received; or

(2) Subject to the filing corrections under §C of this regulation, a PSAO receives written notice from the Commissioner that the contract or amendment to a contract may be used in Maryland.

C. A PSAO that receives written notice from the Commissioner that its contract or amendment to a contract contains defects and is disapproved, may re-submit the filing indicating the corrections made.

D. Except for the circumstances in §C of this regulation, a PSAO may not file a contract or amendment that has been previously disapproved by the Commissioner.

E. Amendments to contracts.

(1) A PSAO that intends to amend any of the following provisions of a previously filed contract, shall be filed with the Commissioner:

(a) Any provision dealing with the responsibility of a PBM to disclosure specified information to a pharmacy, as described in Insurance Article, § 15-1628, Annotated Code of Maryland;

(b) Any provision dealing with fees for credentialing a pharmacy or pharmacist to participate in the network of a PBM or purchaser or the frequency of credentialing renewals, as described in Insurance Article, § 15-1628, Annotated Code of Maryland;

(c) Any provision describing the sources used to determine maximum allowable cost pricing, the process for updating pricing information, or the process to appeal, investigate, and resolve disputes regarding maximum allowable cost pricing, as described in Insurance Article, § 15-1628.1, Annotated Code of Maryland;

(d) Any provision describing the process to appeal, investigate, and resolve disputes regarding cost pricing and reimbursement, as described in Insurance Article, § 15-1628.2, Annotated Code of Maryland;

(e) Any provision dealing with a pharmacy being charged or held responsible for a fee or performance-based reimbursement related to the adjudication of a claim or an incentive program or being subject to a reduction in payment due to reconciliation process, as described in Insurance Article, § 15-1628.3, Annotated Code of Maryland;

(f) Any provision describing the process to audit pharmacies, as described in Insurance Article, § 15-1629, Annotated Code of Maryland;

(g) Any provision dealing with retroactive denials or modifications of reimbursement to a pharmacy or pharmacist, as described in Insurance Article, § 15-1631, Annotated Code of Maryland;

(h) Any provision dealing with therapeutic interchanges, as described in Insurance Article, §§ 15-1633, 15-1634, 15-1635, 15-1636, and 15-1637, Annotated Code of Maryland;

(i) Any provision dealing with the PSAO providing copies of contracts, amendments, payment schedules, or reimbursement rates to a pharmacy, as described in Insurance Article, § 15-2011, Annotated Code of Maryland;

(j) Any provision dealing with notification to a pharmacy, purchaser, or PBM of a material change in ownership or control of certain organizations affiliated with the PSAO, as described in Insurance Article, §§ 15-2013 and 15-2014, Annotated Code of Maryland;

(k) Any provision dealing with the PSAO passing claims remittances from a PBM or purchaser to a pharmacy, as described in Insurance Article, § 15-2015, Annotated Code of Maryland;

(l) Any provision describing an arrangement for a pharmacy to purchase drugs, biologics, or medical devices from an entity under common ownership with the PSAO, as described in Insurance Article, § 15-2016, Annotated Code of Maryland;

(m) Any provision dealing with the applicability of Maryland law; or

(n) Any provision of the contract that is revised to comply with Maryland law.

F. A filing made under this chapter shall include a cover letter which includes the following:

(1) A list of the contracts and amendments included in the submission; and

(2) A brief description of the purpose of each contract and amendment included in the submission

G. Each page of a contract or amendment shall be identified by a form number which is unique to that form. This number shall be printed in the lower left-hand corner of each page, and no other number shall appear in close proximity to the form number.

H. A filing made under this chapter shall include a signed certification from a responsible officer of the PSAO that, to the best of the officer's knowledge and belief, the contracts and amendments comply with applicable statutes and regulations.

I. Effective July 1, 2021, a PSAO may not file a contract or amendment before the PSAO has successfully registered as a PSAO with the Commissioner.

J. Effective October 1, 2020, a PSAO shall file an amendment to a contract in accordance with Insurance Article, §§ 15-2006 – 2019, Annotated Code of Maryland.

#### **.04 Noncompliant Contract Terms**

A. A PSAO may have a contract or amendment to a contract disapproved if the contract or amendment, or underlying contract with a pharmacy benefits manager, contains or uses any language that:

(1) Violates Title 15, Subtitle 16 or Subtitle 20 of the Insurance Article, Annotated Code of Maryland or any applicable statutory provisions, including but not limited to Insurance Article §§ 15-1628, 15-1628.1, 15-1628.2, 15-1628.3, 15-1629, 15-1631, 15-1633, 15-1634, 15-1635, 15-1636, 15-1637, 15-1638, 15-1639, 15-2011, 15-2013(c), 15-2014(c), 15-2015, and 15-2016, Annotated Code of Maryland;

(2) Includes a definition of “multisource generic drug” that is inconsistent with chapter 46 of this Title, or “generic” or “brand name drug” that is inconsistent with Health Occupations Article, §12-504, Annotated Code of Maryland;

(3) Allows the PBM to reimburse a covered drug in an amount that differs, including zero, based on the identity of the wholesale distributor used by a contracting pharmacy for acquisition of the covered drug;

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

(5) In any way prohibits or restricts a pharmacist or pharmacy from filing a complaint with the Commissioner; and

(6) Fails to include the internal appeal provisions in the contract.

B. No provisions in the Insurance Article, Annotated Code of Maryland or this chapter may be waived or modified by contract.

#### **.05 Use of Noncompliant Contract or Amendment.**

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:

(1) Issue an order that:

- (a) Gives notice of the disapproval;*
  - (b) States a reason for the disapproval; and*
  - (c) States the effective date of the disapproval in the notice; and*
  - (2) Impose a civil penalty as provided under Insurance Article, §15-2019, Annotated Code of Maryland.*
- B. An order under this regulation is subject to a hearing under Insurance Article, §2-210, Annotated Code of Maryland.*
- C. A request for a hearing under this regulation does not stay that portion of the order that requires a PSAO to cease and desist from the conduct identified in the order.*