

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michael Carnahan, Clerk, Maryland State Board of Contract Appeals, 6 St. Paul Street, Suite 601, Baltimore, MD 21202, or call 410-767-8227, or email to michael.carnahan@maryland.gov. Comments will be accepted through January 18, 2022. A public hearing has not been scheduled.

Editor's Note: The text of this document will not be printed here because it appeared as a Notice of Emergency Action in 48:21 Md. R. 883—888 (October 8, 2021), referenced as [21-146-E].

BETHAMY N. BEAM, ESQ.
Chairman

Title 31

**MARYLAND INSURANCE
ADMINISTRATION**

**Subtitle 10 HEALTH INSURANCE —
GENERAL**

Notice of Proposed Action

[21-200-P]

The Insurance Commissioner proposes to adopt:

- (1) New Regulations .01—.05 under a new chapter, **COMAR 31.10.49 Pharmacy Services Administrative Organizations**; and
- (2) New Regulations .01—.05 under a new chapter, **COMAR 31.10.50 Filing of PSAO Contracts and Amendments**.

Statement of Purpose

The purpose of this action is to adopt new Regulations .01—.05 under a new chapter, COMAR 31.10.49 Pharmacy Services Administrative Organizations and new Regulations .01—.05 under a new chapter, COMAR 31.10.50 Filing of PSAO Contracts and Amendments. Specifically, these regulations are being implemented pursuant to Insurance Article, Title 15, Subtitle 20, Annotated Code of Maryland, which was enacted during the 2020 legislative session. The statute includes requirements for disclosure and contract filing requirements for pharmacy services administrative organizations. These regulations implement these statutory requirements.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Lisa Larson, Director of Regulations, Maryland Insurance Administration, 200 St. Paul Place, Suite 2700 Baltimore, MD 21202, or call 410-468-2007, or email to insuranceregview.mia@maryland.gov, or fax to 410-468-2020. Comments will be accepted through January 18, 2022. A public hearing has not been scheduled.

31.10.49 Pharmacy Services Administrative Organizations

Authority: Insurance Article, §§15-2001—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) "Delivered by electronic means" includes:

(a) Delivery to an electronic mail address at which an independent pharmacy or contracted pharmacy has consented to receive notice; and

(b) Posting on an electronic network, together with separate notice to an independent pharmacy or contracted pharmacy directed to the electronic mail address at which the independent pharmacy or contracted pharmacy has consented to receive notice of the posting.

(4) "Independent pharmacy" has the meaning stated in Insurance Article, §15-2001(b), Annotated Code of Maryland.

(5) "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.

(6) 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

(iv) Any component or accessory of any of these items.

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

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

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

(10) "Purchaser" has the meaning stated in Insurance Article, §15-2001(f), Annotated Code of Maryland.

(11) "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 a contracted 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 contracted pharmacy by the PSAO.

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

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.

E. The copies, notices, and disclosures required in §§A—C of this regulation may be delivered by electronic means provided:

(1) The independent pharmacy or contracted pharmacy has affirmatively consented to that method of delivery and has not withdrawn the consent;

(2) The independent pharmacy or contracted pharmacy, before giving consent, is provided with a clear and conspicuous statement informing the pharmacy of:

(a) Any right or option of the pharmacy to have the notice provided or made available in paper or another nonelectronic form;

(b) The right of the pharmacy to withdraw consent to have notice delivered by electronic means and any fees, conditions, or consequences imposed in the event consent is withdrawn;

(c) Whether the consent applies:

(i) Only to notices or communications related to a particular transaction; or

(ii) To identified categories of notices that may be delivered by electronic means during the course of the parties' relationship; and

(d) The procedures the pharmacy must use to withdraw consent to have notice delivered by electronic means and to update information needed to contact the party electronically;

(3) The independent pharmacy or contracted pharmacy, before giving consent, is provided with a statement of the hardware and software requirements for access to and retention of a notice delivered by electronic means; and

(4) The process used to obtain consent of the independent pharmacy or contracted pharmacy to have notice delivered by electronic means meets the requirements of Commercial Law Article, Title 21, Subtitle 1, Annotated Code of Maryland.

.04 Internal Appeal Procedures.

A. Each PSAO subject to this chapter shall establish written procedures to investigate and resolve disputes filed against the PSAO 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 a PSAO remits payment to a contracted pharmacy in accordance with the pharmacy services administrative 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.

C. 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 with:

(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.

31.10.50 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 contract or amendment required to be filed under Insurance Article, Title 15, Subtitle 20, Annotated Code of Maryland, including a pharmacy services administrative contract and a contract between a PSAO, on behalf of an independent pharmacy, and a PBM or a group purchasing organization.

.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) "Independent pharmacy" has the meaning stated in Insurance Article, §15-2001(b), Annotated Code of Maryland.

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

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

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

(7) "Pharmacy services administrative organization" or "PSAO" has the meaning stated 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 contract forms and amendments to pharmacy services administrative contract forms; and

(2) All contract forms or amendments to contract forms 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 form or amendment to a contract form 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 form or amendment to a contract form may be used in Maryland.

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

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

E. Amendments to Contracts.

(1) A PSAO that amends any of the following provisions of a previously filed contract, shall file the amendment form with the Commissioner:

(a) Any provision dealing with prohibitions on certain communications between a pharmacy or pharmacist and a beneficiary, as described in Insurance Article, §15-1611, Annotated Code of Maryland;

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

(c) 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;

(d) 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;

(e) 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;

(f) 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 a reconciliation process, as described in Insurance Article, §15-1628.3, Annotated Code of Maryland;

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

(h) 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;

(i) 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;

(j) 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;

(k) 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;

(l) 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;

(m) 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;

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

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

(2) An amendment to a previously filed contract form that does not amend a provision described in §E(1) of this regulation is not required to be filed with the Commissioner.

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

(1) A list of the contract forms and amendment forms included in the submission; and

(2) A brief description of the purpose of each contract form and amendment form 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 contract forms and amendment forms comply with applicable statutes and regulations.

I. Effective July 1, 2021, a PSAO may not file a contract form or amendment form 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 form in accordance with Insurance Article, §15-2006—15-2019, Annotated Code of Maryland.

.04 Noncompliant Contract Terms.

A. A PSAO may have a contract form or amendment to a contract form 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, §§15-1611, 15-1628, 15-1628.1, 15-1628.2, 15-1628.3, 15-1629, 15-1631, 15-1633, 15-1634—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 COMAR 31.46, 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.

KATHLEEN A. BIRrane
Insurance Commissioner