

**Title 31
MARYLAND INSURANCE
ADMINISTRATION**

**Subtitle 09 LIFE INSURANCE AND
ANNUITIES**

31.09.07 Charitable Gift Annuities

Authority: Insurance Article, §§2-109 and 16-114, Annotated Code of Maryland

Notice of Proposed Action

[20-002-P]

The Insurance Commissioner proposes to amend Regulations .02 and .03 under COMAR 31.09.07 Charitable Gift Annuities.

Statement of Purpose

The purpose of this action is to amend Regulations .02 and .03 under COMAR 31.09.07 Charitable Gift Annuities. Specifically, the regulations will be amended regarding the annual requirement that charitable organizations provide evidence of sufficient reserves covering outstanding gift annuities by clarifying that supplemental reserve schedules to the audited financial statement can be verified by an independent certified public accountant or a qualified actuary.

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, Regulations Manager, Maryland Insurance Administration, 200 St. Paul Place, Suite 2700, Baltimore, MD 21202, or call 410-468-2007, or email to insuranceregreview.mia@maryland.gov, or fax to 410-468-2020. Comments will be accepted through February 3, 2020. A public hearing has not been scheduled.

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)---(2) (text unchanged)

(3) "Qualified actuary" means an individual who is a member in good standing of the American Academy of Actuaries and is qualified to sign statements of actuarial opinion in accordance with the American Academy of Actuaries' standards.

.03 Required Reserves.

A.—C. (text unchanged)

D. As part of the organization's annual *audit* report, the organization shall submit a statement by a certified public accountant or *qualified actuary* verifying the existence of adequate reserves among the organization's assets.

E. (text unchanged)

ALFRED W. REDMER, JR.
Insurance Commissioner

**Subtitle 10 HEALTH INSURANCE —
GENERAL**

Notice of Proposed Action

[20-008-P]

The Insurance Commissioner proposes to adopt:

(1) New Regulations .01—.05 under a new chapter, COMAR 31.10.46 Pharmacy Benefits Managers—Maximum Allowable Cost;

(2) New Regulations .01—.05 under a new chapter, COMAR 31.10.47 Cost Pricing and Reimbursement Other than MAC; and

(3) New Regulations .01—.05 under a new chapter, COMAR 31.10.48 Filing of Contracts and Amendments.

Statement of Purpose

The purpose of this action is to adopt new regulations to comply with Ch. 400, Acts of 2019, which amended Insurance Article, §§15-102.3, 15-1601, 15-1628, 15-1628.1, 15-1628.3, 15-1631, and 15-1642, Annotated Code of Maryland. These changes require the Maryland Insurance Administration to promulgate regulations regarding pharmacy benefits managers (PBM), their contracts with pharmacies, and the appeal process for pharmacies to use when there is a dispute over cost pricing between them and the PBMs. These regulations implement these legislative changes.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact. To the extent that pharmacy benefits managers (PBMs) will be required to submit additional paperwork to the Maryland Insurance Administration (MIA) in the MIA's review of complaints, the PBMs may incur minimal administrative costs.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	NONE	
Administrative cost	(-)	Minimal
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D. Assuming pharmacy benefits managers (PBMs) will have to submit additional paperwork to the Maryland Insurance Administration in the MIA's review of grievances, the PBMs may incur minimal administrative costs

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, Regulations Manager, Maryland Insurance Administration, 200 Saint Paul Place, Suite 2700, Baltimore, MD 21202, or call 410-468-2007, or email to insuranceregreview.mia@maryland.gov, or fax to 410-468-2020. Comments will be accepted through February 3, 2020. A public hearing has not been scheduled.

**31.10.46 Pharmacy Benefits Managers—
Maximum Allowable Cost**

Authority: Insurance Article, §§15-1601, 15-1604, 15-1605, 15-1607, 15-1609, 15-1628, 15-1628.1, and 15-1642, Annotated Code of Maryland

.01 Scope.

This chapter applies to all maximum allowable cost pricing claims made to a pharmacy benefits manager for a multisource generic prescription drug, medical product, or device, 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 issued by a PBM in response to an appeal filed by a contracted pharmacy of the maximum allowable cost used to adjudicate a claim.

(2) "Beneficiary" means an individual who receives prescription drug coverage or benefits from a purchaser.

(3) "Carrier" means:

- (a) An insurer;*
- (b) A nonprofit health service plan; or*
- (c) A health maintenance organization.*

(4) "Compensation program" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.

(5) "Contracted pharmacy" has the meaning stated in Insurance Article, §15-1628.1, Annotated Code of Maryland.

(6) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any downward adjustment of an adjudicated claim and includes, but is not limited to, using the application of the following:

- (a) Refill rates of generic, brand name, or preferred drugs;*
- (b) Comparison of dispensing rates of a pharmacy or pharmacist to another pharmacy or pharmacist; or*
- (c) Combined aggregate overall percentage discounts applied to all adjudicated claims.*

(7) "MAC complaint" means a communication by a contracted pharmacy that disputes the appeal decision, and is submitted on a MAC complaint form to the Commissioner, after the pharmacy benefits manager's internal appeal process has been exhausted as required by Insurance Article, §15-1628.1(f), Annotated Code of Maryland.

(8) "MAC complaint form" means the form adopted by the Commissioner under Regulation .05 of this chapter.

(9) "MAC list" means a list of multisource generic drugs, medical products, and devices for which a MAC has been established by a pharmacy benefits manager or a purchaser.

(10) "Maximum allowable cost" or "MAC" has the meaning stated in Insurance Article, §15-1628.1, Annotated Code of Maryland.

(11) "Multisource generic drug" means a generic drug as defined in Health-General Article, §21-2C-01(f), Annotated Code of Maryland, for which there is at least one other drug and does not include a brand name drug as that term is defined in Health Occupations, §12-504, Annotated Code of Maryland.

(12) "Participating pharmacy contract" means a contract filed with the Commissioner that is:

(a) Between a pharmacy and a:

- (i) Pharmacy benefits manager;*
- (ii) Pharmacy services administrative organization; or*
- (iii) Group purchasing organization;*

(b) Filed at least 30 days before the contract or an amendment to the contract is to become effective;

(c) Filed as required by the Commissioner;

(d) Not disapproved by the Commissioner; and

(e) In compliance with the requirements stated in this chapter.

(13) "Pharmacist" has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.

(14) "Pharmacy" has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.

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

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

(17) "Pharmacy services administration organization" or "PSAO" means an entity that provides a contracted pharmacy with contracting administrative services relating to prescription drug benefits.

(18) "Pricing information" means anything used in the mathematical calculation to determine the payment to a contracted pharmacy.

(19) "Purchaser" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.

(20) "Source" means the publisher or publishers stated in the participating pharmacy contract, used by the PBM, in any manner, to establish the basis of the PBM's MAC reimbursement amount to a contracted pharmacy, under a participating pharmacy contract compensation program.

(21) "Working day" means any day that the Maryland Insurance Administration is open for business.

.03 Disclosures to a Contracted Pharmacy.

A. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose to a contracted pharmacy at the time of entering into a contract with a pharmacy and at least 30 working days before any contract change for a contracted pharmacy:

(1) The applicable terms, conditions, and reimbursement rates, including:

- (a) The sources; and*
- (b) The terms of the compensation program;*

(2) The process and procedures for verifying pharmacy benefits and beneficiary eligibility;

(3) The dispute resolution, internal appeal process under Regulation .04 of this chapter, and audit appeals process; and

(4) The process and procedures for verifying the prescription drugs included on the formularies used by the PBM.

B. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall:

- (1) Update its pricing information at least every 7 days;
- (2) Establish a reasonable process by which a contracted pharmacy has access to the current and applicable MAC lists and price list in an electronic format as updated in accordance with the requirements of this section; and
- (3) Immediately after a pricing information update occurs pursuant to this regulation, use the updated pricing information in calculating the payments made to all contracted pharmacies.

C. Except as provided in §§D and E of this regulation, a contracted pharmacy may not be charged a fee or held responsible by a purchaser or PBM for:

- (1) A fee or performance-based reimbursement related to an adjudicated claim; or
- (2) An incentive program.

D. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

- (1) The specific dollar amount of a fee or alternative reimbursement; or
- (2) The specific percentage of the potential adjustment relating to reimbursement of a claim.

E. The disclosure described in §D shall be:

- (1) Provided during claims processing; or
- (2) Described in detail on the initial remittance advice.

F. A claim paid on behalf of a carrier to a contracted pharmacy under a participating pharmacy contract is subject to the requirements of Insurance Article, §§15-1005, 15-1008, 15-1009, and 15-1631, Annotated Code of Maryland.

.04 Internal Appeal Procedures.

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

B. The internal appeal procedures established by the PBM shall:

- (1) Be in writing; and
- (2) Contain administrative processes and safeguards designed to ensure and verify that the MAC pricing was determined in accordance with the participating pharmacy 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 PBM 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 PBM shall be provided to the Commissioner on request.

.05 MAC Complaint Process.

A. Prior to filing a MAC complaint with the Commissioner, a contracted pharmacy or its designee shall exhaust the internal appeal process established in the participating pharmacy contract and used by the PBM to appeal, investigate, and resolve a dispute regarding the MAC claim amount.

B. A contracted pharmacy or its designee may file a MAC complaint with the Commissioner to dispute a PBM's appeal decision for the following reasons:

- (1) The PBM's MAC pricing did not meet the requirements of Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland, related to MAC pricing; or
- (2) The PBM's MAC pricing did not meet the applicable terms of the applicable participating pharmacy contract.

C. A MAC complaint is properly completed and may be filed if a contracted pharmacy or designee:

- (1) Completes all applicable portions of the Commissioner's MAC complaint form;
- (2) Provides a copy of the relevant contract or the provisions that are related to the MAC appeal, including but not limited to:
 - (a) MAC;
 - (b) MAC pricing;
 - (c) Sources;
 - (d) Pricing information; and
 - (e) The compensation program of the applicable participating pharmacy contract; and
- (3) Provides a copy of the appeal decision.

D. A MAC complaint may not include more than ten appeal decisions using a single MAC complaint form.

E. Notification of the MAC Complaint to the PBM.

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

(2) Within 5 working days of receiving the Commissioner's notice, the PBM shall provide the Commissioner:

- (a) A complete, unredacted copy of the applicable portion of the participating pharmacy contract relating to the compensation program and the complaint filed with the Commissioner, including any other contract under which the pricing information is determined;
- (b) A copy of the applicable source and pricing information used to calculate the MAC;
- (c) The MAC calculated on a per unit basis based on the same generic product identifier or national drug code number;
- (d) A mathematical calculation that demonstrates how the reimbursement amount was determined;
- (e) All information required to complete the response portion of the MAC complaint form; and
- (f) Any other information the Commissioner may require for the purposes of determining a PBM's compliance with:
 - (i) Insurance Article, Annotated Code of Maryland;
 - (ii) This chapter;
 - (iii) The compensation program; or
 - (iv) The applicable terms of the applicable participating pharmacy contract.

31.10.47 Cost Pricing and Reimbursement Other than MAC

Authority: Insurance Article, §§15-1601, 15-1604, 15-1605, 15-1607, 15-1609, 15-1628, 15-1628.2, 15-1630, and 15-1642, Annotated Code of Maryland

.01 Scope.

This chapter applies to all cost pricing and reimbursement disputes or a request to review the failure to pay the contractual reimbursement amount of a submitted claim made to a pharmacy benefits manager by a pharmacist or pharmacy for a prescription drug, medical product, or device, 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) "Beneficiary" means an individual who receives prescription drug coverage or benefits from a purchaser.

- (3) "Carrier" means:
 - (a) An insurer;
 - (b) A nonprofit health service plan; or
 - (c) A health maintenance organization.
- (4) "Compensation program" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.
- (5) "Complaint" means a communication by a contracted pharmacy that disputes the appeal decision, and is submitted on a complaint form to the Commissioner, after the pharmacy benefits manager's internal appeal process has been exhausted as required by Insurance Article, §15-1628.2, Annotated Code of Maryland.
- (6) "Complaint form" means the form developed by the Commissioner under Regulation .05 of this chapter.
- (7) "Contracted pharmacy" has the meaning stated in Insurance Article, §15-1628.1, Annotated Code of Maryland.
- (8) "Direct or indirect remuneration fee" means an adjustment in total compensation received directly or indirectly by a contracted pharmacy from a PBM that is determined after the sale of the product or service, including an adjustment of an adjudicated claim based on the use of a generic effective rate or fee or performance-based reimbursement.
- (9) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any downward adjustment of an adjudicated claim and includes, but is not limited to, using the application of the following:
 - (a) Refill rates of generic, brand name, or preferred drugs;
 - (b) Comparison of dispensing rates of a pharmacy or pharmacist to another pharmacy or pharmacist; or
 - (c) Combined aggregate overall percentage discounts applied to all adjudicated claims.
- (10) "Participating pharmacy contract" means a contract filed with the Commissioner that is:
 - (a) Between a pharmacy and a:
 - (i) Pharmacy benefits manager;
 - (ii) Pharmacy services administrative organization; or
 - (iii) Group purchasing organization;
 - (b) Filed at least 30 days before the contract or an amendment to the contract is to become effective;
 - (c) Filed as required by the Commissioner;
 - (d) Not disapproved by the Commissioner; and
 - (e) In compliance with the requirements stated in this chapter.
- (11) "Pharmacist" has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.
- (12) "Pharmacy" has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.
- (13) "Pharmacy benefits management services" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.
- (14) "Pharmacy benefits manager" or "PBM" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.
- (15) "Pharmacy services administration organization" or "PSAO" means an entity that provides a contracted pharmacy with contracting administrative services relating to prescription drug benefits.
- (16) "Pricing information" means anything used in the mathematical calculation to determine the payment to a contracted pharmacy.
- (17) "Purchaser" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.
- (18) Review Decision.
 - (a) "Review decision" means a written or electronic notice in response to a request from a contracted pharmacy for a review of

a failure to pay the contractual reimbursement amount of a submitted claim.

(b) "Review decision" does not include an appeal decision.

(19) "Source" means the publisher or publishers stated in the participating pharmacy contract, used by the PBM, in any manner, to establish the basis of the PBM's pricing or the reimbursement amount to a contracted pharmacy, under a participating pharmacy contract's stated compensation program.

(20) "Working day" means any day that the Maryland Insurance Administration is open for business.

.03 Disclosures to a Contracted Pharmacy.

A. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose to a contracted pharmacy at the time of entering into a contract with a pharmacy and at least 30 working days before any contract change for a contracted pharmacy:

(1) The applicable terms, conditions, and reimbursement rates, including:

(a) The sources; and

(b) The terms of the compensation program;

(2) The process and procedures for verifying pharmacy benefits and beneficiary eligibility;

(3) The dispute resolution, internal appeal process under Regulation .04 of this chapter, and audit appeals process; and

(4) The process and procedures for verifying the prescription drugs included on the formularies used by the PBM.

B. Except as provided in §§C and D of this regulation, a contracted pharmacy may not be charged a fee or held responsible by a purchaser or PBM for:

(1) A fee or performance-based reimbursement related to an adjudicated claim; or

(2) An incentive program.

C. A PBM, whether its contract is directly with a pharmacy or indirectly with a pharmacy through a PSAO or group purchasing organization, shall disclose any fee or performance-based reimbursement that relates to the adjudication of a claim or incentive program by stating:

(1) The specific dollar amount of a fee or alternative reimbursement; or

(2) The specific percentage of the potential adjustment relating to reimbursement of a claim.

D. The disclosure described in §C shall be:

(1) Provided during claims processing; or

(2) Described in detail on the initial remittance advice.

E. A claim paid on behalf of a carrier to a contracted pharmacy under a participating pharmacy contract is subject to the requirements of Insurance Article, §§15-1005, 15-1008, 15-1009, and 15-1631, Annotated Code of Maryland.

.04 Internal Appeal Procedures.

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

B. The internal appeal procedures established by the PBM shall:

(1) Be in writing; and

(2) Contain administrative processes and safeguards designed to ensure and verify that the pricing was determined in accordance with the participating pharmacy 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 PBM 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 PBM shall be provided to the Commissioner on request.

E. The internal procedures established by the PBM shall:

(1) Provide written notice of the PBM's decision no later than 90 days after receipt of the appeal or review;

(2) Pay any money due within 30 days after the internal review is complete; and

(3) Provide a contracted pharmacy:

(a) 21 days to file an appeal after the contracted pharmacy is charged a direct or indirect remuneration fee; or

(b) A minimum of 180 days to request review of the reimbursement amount of a submitted claim.

.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 in the participating pharmacy contract.

B. A contracted pharmacy or its designee may file a complaint with the Commissioner to dispute a PBM's appeal decision for the following reasons:

(1) The PBM's cost pricing did not comply with Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland; or

(2) The PBM's cost pricing or reimbursement amount determination did not meet the terms of the applicable participating pharmacy contract.

C. A complaint is properly completed and may be filed if a contracted pharmacy or its designee:

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

(2) Provides a copy of the relevant contract or the provisions that are related to the appeal, including but not limited to establishing a drug pricing or pharmacy reimbursement amount, sources, pricing information, and the compensation program of the applicable participating pharmacy contract; and

(3) Provides a copy of the appeal decision.

D. A complaint may not include more than ten appeal decisions using a single complaint form.

E. Notification of the Complaint to the PBM.

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

(2) Within 5 working days of receiving the Commissioner's notice, the PBM shall provide the Commissioner:

(a) A complete, unredacted copy of the applicable portion of the participating pharmacy contract relating to the compensation program and the complaint filed with the Commissioner, including any other contract under which the pricing or reimbursement amount is determined;

(b) A copy of the applicable source and pricing information used to calculate the pharmacy reimbursement amount;

(c) A mathematical calculation that demonstrates how the reimbursement amount was determined;

(d) All information required to complete the response portion of the complaint form; and

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

(i) Insurance Article, Annotated Code of Maryland;

(ii) This chapter;

(iii) The compensation program; or

(iv) The applicable terms of the participating pharmacy contract.

31.10.48 Filing of Contracts and Amendments

Authority: Insurance Article, §§2-109, 12-203(d)(2), 15-1628, and 15-1642, Annotated Code of Maryland

.01 Applicability and Scope.

This chapter applies to the submission of any participating pharmacy contract or amendment required to be filed under Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland.

.02 Definitions.

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

B. Terms Defined.

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

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

(3) "Filing entity" means a pharmacy benefits manager or PBM, pharmacy services administration organization or PSAO, or group purchasing organization or GPO required to file a contract or amendment to a contract under this chapter.

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

(5) "Participating pharmacy contract" has the meaning stated in Insurance Article, §15-1601(h)(1), Annotated Code of Maryland.

(6) "Working day" means any day that the Maryland Insurance Administration is open for business.

.03 Submission Requirements.

A. Pursuant to the requirements of Insurance Article, §15-1628(b), Annotated Code of Maryland, a filing entity shall submit to the Commissioner all participating pharmacy contracts and amendments to contracts.

B. Unless it is disapproved by the Commissioner, a filing entity may not use a contract or amendment to a contract unless:

(1) It has been filed with the Commissioner and 30 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 filing entity receives written notice that the contract or amendment to a contract may be used in Maryland and at least 30 days have passed since the initial filing was acknowledged by the Commissioner in writing as having been received.

C. A filing entity that receives written notice from the Commissioner that its contract or amendment to a contract contains defects and is disapproved may resubmit the filing indicating the corrections made.

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

E. Nothing in this regulation shortens the time period for notice under Insurance Article, §15-1628(a), Annotated Code of Maryland, which requires a PBM to provide at least 30 working days' notice before any contract change.

F. The filing 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 the first 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 filing entity that, to the best of the officer's knowledge and belief, the contracts and amendments comply with applicable statutes and regulations.

I. A PBM may not file a contract or amendment before the PBM has successfully registered as a PBM with the Commissioner.

.04 Noncompliant Contract Terms

A. A filing entity may have a contract or amendment to a contract disapproved if the contract or amendment contains or uses any language that:

(1) Violates Insurance Article, Title 15, Subtitle 16, Annotated Code of Maryland, or any applicable statutory provisions, including but not limited to Insurance Article, §§15-112, 15-112.2(a)–(e), 15-123(d), 15-1004, 15-1005, 15-1008(c), 15-1009, 15-1628–15-1628.3, 15-1629, 15-1631, and 15-1633–15-1639, and Health-General Article, §§19-710(s) and (t) and 19-712.2, Annotated Code of Maryland;

(2) Does not disclose the components of the compensation program through which a reimbursement rate is set;

(3) Includes a definition of “multisource generic drug” that is inconsistent with COMAR 31.10.46, or “generic” or “brand name drug” that is inconsistent with Health Occupations Article, §12-504, Annotated Code of Maryland;

(4) 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;

(5) Except for instances of error or fraud, allows the PBM to reclassify, recategorize, or recharacterize an adjudicated claim;

(6) Other than a provider fee allowed under Insurance Article, §15-112, Annotated Code of Maryland, requires a pharmacy or pharmacist to pay a licensing fee or other fee to participate in the provider panel;

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

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

B. No provisions in 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 PBM uses a contract or amendment which 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 penalty as provided under Insurance Article, §15-1642, 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 PBM to cease and desist from the conduct identified in the order.

ALFRED W. REDMER, JR.
Insurance Commissioner

**Title 36
MARYLAND STATE
LOTTERY AND GAMING
CONTROL AGENCY**

Subtitle 02 LOTTERY PROVISIONS

36.02.03 Retailer Requirements

Authority: *Criminal Law Article, §12-301.1*; State Government Article, §§9-110–9-113[.]; Annotated Code of Maryland; *Ch. 603, §6, Acts of 2012*

Notice of Proposed Action

[20-006-P]

The Maryland State Lottery and Gaming Control Agency proposes to amend Regulation .12 under COMAR 36.02.03 **Retailer Requirements**. This action was considered at the Maryland Lottery and Gaming Control Commission open meeting held on November 21, 2019, notice of which was given pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to clarify that a retailer may not have an illegal gaming device or a slot machine on its premises and thus a retailer cannot offer any gaming activity except Lottery play. This proposed action also brings the structure of this regulation into compliance with the Style Manual for Maryland Regulations.

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 James B. Butler, Managing Director, Organizational Compliance, Maryland Lottery and Gaming Control Agency, 1800 Washington Blvd., Suite 330, Baltimore, MD 21230, or call 410-230-8781, or email to jbutler@maryland.gov, or fax to 410-230-8727. Comments will be accepted through February 3, 2020. A public hearing has not been scheduled.

.12 Prohibited Acts

A.—B. (text unchanged)

C. A retailer shall require all lottery tickets to be paid for by the purchaser at the time of [buying and before the time of the drawing] purchase.

D. A retailer may not:

(1) (text unchanged)

(2) Sell to or cash a lottery ticket for a person younger than 18 years old; [or]

(3) Allow an employee younger than 18 years old to sell or cash a lottery ticket or operate lottery equipment[.];

(4) Extend credit in any manner for the sale of lottery tickets;

(5) Offer customers alcoholic beverages to induce them to purchase or redeem a lottery ticket; or

(6) Except as provided in *Criminal Law Article, §§12-301.1, 12-304, and 12-308, Annotated Code of Maryland, have on its*