

Title 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 10 HEALTH INSURANCE – GENERAL

Chapter 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, 15-1630, 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, a 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) "Compensation program" has the meaning stated in Insurance Article, § 15-1601, Annotated Code of Maryland.

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

(5) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any 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.

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

(7) "MAC complaint" means a communication by a contracted pharmacy, that disputes the appeal decision, and which 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 in 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) "Multisource generic drug" means interchangeable biological product as defined in Health Occupations Article, § 12-101, Annotated Code of Maryland and does not include a brand name drug as that term is defined in Health Occupations, § 12-504, Annotated Code of Maryland.

(11) "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) A 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) Complies with the requirements stated in this chapter.

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

(13) "Pharmacy" has the meaning stated in Health Occupations Article, § 12-101, 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 benefits management services" has the meaning stated in Insurance Article, § 15-1601, Annotated Code of Maryland.

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

(17) "Pricing information" means the modifiers or factors applied in the mathematical calculation to determine the payment to a contracted pharmacy.

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

(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 MAC reimbursement amount to a contracted pharmacy, under a participating pharmacy contract compensation program.

.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 program, policy, or process;
- (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 seven days;
- (2) Establish a reasonable process by which a contracted pharmacy has access to the current and applicable MAC lists and pricing 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. 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 disclosing:

- (1) The specific dollar amount of a fee that may apply to the claim during claim processing; or
- (2) The specific percentage of the potential adjustment relating to reimbursement of a claim on the initial remittance advice.

D. Except as provided in §E of this regulation, a contracted pharmacy shall not be 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.

E. A purchaser or PBM may charge a fee or performance-based reimbursement on an adjudicated claim or incentive program if:

- (1) Itemized during claims processing by specifically identifying the actual alternate reimbursement amount that will be reimbursed; or
- (2) Described in detail on the initial remittance advice by specifically identifying the amount provided at claims processing and the actual reimbursement amount of an adjudicated claim.

F. A claim paid to a contracted pharmacy under a participating pharmacy contract is subject to the requirements of the 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 been applied consistently with respect to similarly situated pharmacies.

C. The procedures established by the PBM shall not:

- (1) Require more than one appeal before filing a complaint with the Commissioner; or
- (2) Require 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 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 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 Title 15, Subtitle 16, of the Insurance Article, 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:

- (1) A contracted pharmacy completes all applicable portions of the Commissioner's MAC complaint form;
- (2) A contracted pharmacy 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) A contracted pharmacy provides a copy of the appeal decision.
- D. A contracted pharmacy or its designee may file a MAC complaint with the Commissioner.
- E. A MAC complaint shall not include more than ten appeal decisions using a single MAC complaint form.
- F. 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 three business days of receiving the Commissioner's notice, the PBM shall provide the Commissioner:
 - (a) A complete, unredacted copy of the applicable participating pharmacy contract or any other contract under which MAC pricing 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) The Insurance Article, Annotated Code of Maryland;
 - (ii) This chapter;
 - (iii) The compensation program; or
 - (iv) The applicable terms of the applicable participating pharmacy contract.

Title 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 10 HEALTH INSURANCE – GENERAL

Chapter 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, 15-1642, Annotated Code of Maryland

.01 Scope.

This chapter applies to all cost pricing and reimbursement disputes made to a pharmacy benefit manager by a pharmacist or pharmacy for a prescription drug, a 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) "Compensation program" has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.
 - (4) "Contracted pharmacy" has the meaning stated in Insurance Article, § 15-1628.1, Annotated Code of Maryland.
 - (5) "Complaint" means a communication by a contracted pharmacy, that disputes the appeal decision, and which 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 in Regulation .05 of this chapter.
 - (7) "Fee or performance-based reimbursement related to an adjudicated claim or incentive program" means any 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.
 - (8) "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) A 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) Complies with the requirements stated in this chapter.

- (9) "Pharmacist" has the meaning stated in Health Occupations Article, § 12-101, Annotated Code of Maryland.
 - (10) "Pharmacy" has the meaning stated in Health Occupations Article, § 12-101, Annotated Code of Maryland.
 - (11) "Pharmacy benefits manager" or "PBM" has the meaning stated in Insurance Article, § 15-1601, Annotated Code of Maryland.
- (12) "Pharmacy benefits management services" has the meaning stated in Insurance Article, § 15-1601, Annotated Code of Maryland.
- (13) "Pharmacy services administration organization" or "PSAO" means an entity that provides a contracted pharmacy with contracting administrative services relating to prescription drug benefits.
- (14) "Pricing information" means the modifiers or factors applied in the mathematical calculation to determine the payment to a contracted pharmacy.
- (15) "Purchaser" has the meaning stated in Insurance Article, § 15-1601, Annotated Code of Maryland.
- (16) "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.

.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 program, policy, or process;
- (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 seven days;
- (2) Establish a reasonable process by which a contracted pharmacy has access to the current and applicable pricing 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 section, use the updated pricing information in calculating the payments made to all contracted pharmacies.

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 disclosing:

- (1) The specific dollar amount of a fee that may apply to the claim during claim processing; or
- (2) The specific percentage of the potential adjustment relating to reimbursement of a claim on the initial remittance advice.

D. Except as provided in §E of this regulation, a contracted pharmacy shall not be 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.

E. A purchaser or PBM may charge a fee or performance-based reimbursement on an adjudicated claim or incentive program if:

- (1) Itemized during claims processing by specifically identifying the actual alternate reimbursement amount that will be reimbursed; or
- (2) Described in detail on the initial remittance advice by specifically identifying the amount provided at claims processing and the actual reimbursement amount of an adjudicated claim.

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

.04 Investigation of Appeals.

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 been applied consistently with respect to similarly situated pharmacies.

C. The procedures established by the PBM shall not:

- (1) Require more than one appeal before filing a complaint with the Commissioner; or
- (2) Require 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 Complaint Process.

A. Prior to filing a complaint with the Commissioner, a contracted pharmacy shall exhaust the internal appeal process established in the participating pharmacy contract.

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

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

- (1) A contracted pharmacy completes all applicable portions of the Commissioner's complaint form;*
- (2) A contracted pharmacy 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) A contracted pharmacy provides a copy of the appeal decision.

D. A contracted pharmacy or its designee may file a complaint with the Commissioner.

E. A complaint shall not include more than ten appeal decisions using a single complaint form.

F. 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 three business days of receiving the Commissioner's notice, the PBM shall provide the Commissioner:

- (a) A complete, unredacted copy of the applicable participating pharmacy contract or any other contract under which a 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) The Insurance Article, Annotated Code of Maryland;*
 - (ii) This chapter;*
 - (iii) The compensation program; or*
 - (iv) The applicable terms of the participating pharmacy contract.*

Title 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 10 HEALTH INSURANCE -- GENERAL

Chapter 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 benefit 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.

.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 shall 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 re-submit the filing indicating the corrections made.

D. Except for the circumstances in §C of this regulation, a filing entity shall 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 shall 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 Title 15, Subtitle 16 of the Insurance Article, 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, 15-1628.1, 15-1628.2, 15-1628.3, 51-1629, 15-1631, 15-1633, 15-1634, 15-1635, 15-1636, 15-1637, 15-1638, 15-1639; and Health General Article §§19-710(s), 19-710(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 chapter 46 of this Title, or "generic" or "brand name drug" that is inconsistent with Health Occupations Article, § 12-504, Annotated Code of Maryland;

(4) Except when dispensing covered drugs under paragraph (a) of this section, requires a pharmacy to have any type of certification or accreditation standard other than the licensing requirements of the Maryland Board of Pharmacy or Insurance Article, §15-112, Annotated Code of Maryland.

(a) A PBM may require additional certification or accreditation standards to dispense a covered drug to beneficiaries of Medicare or Medicaid, or as required by law to dispense specialty or compounding drug.

(b) A PBM that has a direct or indirect ownership interest in a credentialing or accreditation organization shall provide written notice to a contracted pharmacy of the ownership interest;

(5) 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;

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

(7) 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;

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

(9) 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 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.

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