

Title 31 MARYLAND INSURANCE ADMINISTRATION

Subtitle 10 HEALTH INSURANCE – GENERAL

Chapter 46 Pharmacy Benefit Managers—Maximum Allowable Cost

Authority: Insurance Article, §§ 15-1601, 15-1604, 15-1605, 15-1607, 15-1609, 15-1628, 15-628.1, 15-1630, 15-1642, Annotated Code of Maryland

.01 Scope.

This chapter applies to all maximum allowable cost pricing claims made to a pharmacy benefit 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 notice provided to a contracted pharmacy that includes a reason for the appeal denial, the national drug code of the drug, and the name of a wholesale distributor from which a drug was available on the date the claim was adjudicated at a price at or below the maximum allowable cost by a pharmacy benefits manager.

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

(3) “Compensation program” means the program, policy, and process by which or through which sources and pricing information are utilized by a pharmacy benefits manager to determine the terms of payment as stated in a participating pharmacy contract.

(4) “Contracted pharmacy” means a pharmacy that participates in the network of a pharmacy benefits manager through a contract with:

(a) The pharmacy benefits manager;

(b) A pharmacy services administration organization; or

(c) A group purchasing organization.

(5) “Maximum allowable cost” or “MAC” means:

(a) The maximum amount that a pharmacy benefits manager or a purchaser will reimburse a contracted pharmacy for the cost of a multisource generic drug, a medical product, or a device.

(b) “Maximum allowable cost” does not include dispensing fees.

(6) “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.

(7) “MAC complaint form” means the form adopted by the Commissioner in Regulation .05 of this chapter.

(8) “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.

(9) “Participating pharmacy contract” means a contract through which a contracted pharmacy and pharmacy benefits manager agree to specific terms, including but not limited to:

(a) Pharmacy benefits management services;

(b) A MAC list or lists;

(c) Payment or payments; and

(d) MAC.

(10) “Pharmacist” has the meaning stated in Health Occupations Article, § 12–101, Annotated Code of Maryland.

(11) “Pharmacy” has the meaning stated in Health Occupations Article, § 12–101, Annotated Code of Maryland.

(12) “Pharmacy benefits manager” or “PBM” means a person that performs pharmacy benefits management services.

(13) “Pharmacy benefits management services” means:

(a) The procurement of prescription drugs at a negotiated rate for dispensation within the State to beneficiaries;

(b) The administration or management of prescription drug coverage provided by a purchaser for beneficiaries; and

(c) Any of the following services provided with regard to the administration of prescription drug coverage:

(i) Mail service pharmacy;

(ii) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

(iii) Clinical formulary development and management services;

(iv) Rebate contracting and administration;

(v) Patient compliance, therapeutic intervention, and generic substitution programs; or

(vi) Disease management programs.

(d) “Pharmacy benefits management services” does not include any service provided by a nonprofit health maintenance organization that operates as a group model, provided that the service:

(i) Is provided solely to a member of the nonprofit health maintenance organization; and

(ii) Is furnished through the internal pharmacy operations of the nonprofit health maintenance organization.

(14) "Pharmacy services administrative organization" or "PSAO" means an entity that provides contracting and other administrative services to pharmacies with respect to:

- (a) Third-party payers;
- (b) Pharmacy benefits managers;
- (c) Drug wholesalers; or
- (d) Other entities.

(15) "Pricing information" means any source, information, factor, or data used in a PBM's methodology to establish any reimbursement amount for a MAC pricing claim.

(16) "Purchaser" means:

(a) The State Employee and Retiree Health and Welfare Benefits Program, an insurer, a nonprofit health service plan, or a health maintenance organization that:

- (i) Provides prescription drug coverage or benefits in the State; and
- (ii) Enters into an agreement with a PBM for the provision of pharmacy benefits management services.

(b) "Purchaser" does not include a person that provides prescription drug coverage or benefits through plans subject to The Employee Retirement Income Security Act of 1974, as amended ("ERISA") and does not provide prescription drug coverage or benefits through insurance, unless the person is a multiple employer welfare arrangement as defined in 29 U.S. C. §514(b)(6)(a)(ii).

(17) "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 shall, establish a reasonable process by which a contracted pharmacy has timely access to the current and applicable MAC lists and pricing.

B. In each participating pharmacy contract, the PBM shall disclose to the contracted pharmacy the sources used to determine any MAC pricing.

C. A PBM 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 price lists 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.

.04 Investigation of Appeals.

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

B. The procedures established by the PBM shall:

- (1) Be in writing; and
- (2) Include 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.

C. The appeal procedures established by the PBM shall be provided to the Commissioner on request.

.05 Complaint Process.

A. Prior to filing a MAC complaint with the Commissioner, a contracted pharmacy shall exhaust the internal appeals process established in the applicable contracting pharmacy contract and used by the PBM to appeal, investigate, and resolve disputes 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 Subtitle 16 of Title 15 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 only 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 applicable participating pharmacy contract; and
- (3) A contracted pharmacy provides a copy of the appeal decision.

D. A contracted pharmacy may file a complaint with the Commissioner using the assistance of a PSAO or group purchasing organization.

E. A complaint may not include more than ten MAC claims 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 generic 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 the Insurance Article, this chapter, the Compensation Program, or the applicable terms of the applicable participating pharmacy contract.*