

# Title 14

## INDEPENDENT AGENCIES

### Subtitle 01 – Prescription Drug Affordability Board

#### Chapter 06 – Implementation and Monitoring of Upper Payment Limits

Authority: Health-General Article, §§ 21-2C-03(f)(1), 21-2C-08(b), 21-2C-09, 21-2C-14, 21-2C-16, Annotated Code of Maryland

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

A. These regulations establish mechanisms for implementing and monitoring upper payment limits for eligible governmental entities.

B. The terms defined in COMAR 14.01.05.01 apply to this chapter.

C. These regulations apply to prescription drug products that are:

(1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including:

(a) State or county correctional facilities;

(b) State hospitals; and

(c) Health clinics at State institutions of higher education; or

(2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan.

D. These regulations do not apply to:

(1) The Maryland State Medical Assistance Program;

(2) Eligible governmental entities that provide health benefits through a Self-Insured Employer Group Waiver Plan (EGWP);

(3) The Maryland AIDS Drug Assistance Program (MDAP);

(4) Eligible government entities that receive Medicaid prices; or

(5) Eligible government entities that purchase prescription drug products under the 340B program.

##### **.02 Contracting and Initial Reporting Requirements.**

A. An eligible governmental entity shall require that the provisions specified in §B of this regulation be included in all contracts:

(1) Through which prescription drug products are paid for or purchased by, or on behalf of, the eligible governmental entity;

(2) That are executed or amended on or after January 1, 2028, and take effect on or after January 1, 2028.

B. All contracts through which prescription drug products are paid for or purchased by, or on behalf of, an eligible governmental entity shall include the following provision in this, or substantially similar, form:

“The Contractor shall comply with all federal, State, and local laws, regulations, and ordinances applicable to its activities and obligations under this Contract, including any Maryland upper payment limits promulgated in regulation and in effect during the term of the Contract.”

C. The Board shall develop ~~forms and a Reporting Submission Manual that contains the forms, technical specifications, calculations, and required reports for submitting providing technical details to collect~~ the information and data required under §§D, E and F of this regulation.

D. Within 30 days of executing or amending a contract that contains the terms required in §B of this regulation, an eligible governmental entity shall certify, on the form provided that:

(1) The contract contains the specified terms; and

(2) The effective date and duration of the contract.

E. By December 31, 2026, an eligible governmental entity shall submit to the Board information detailing the value of and contracting cycles for contracts through which prescription drug products are paid for or purchased by, or on behalf of, the eligible governmental entity including health benefit plans.

F. On an annual basis, an eligible governmental entity shall report to the Board by April 1:

(1) Total prescription drug budget for the prior calendar year;

(2) The sum of total gross spending for all prescription drug products; and

(3) Total rebates, discounts, and price concessions received for the prescription drug contract.

##### **.03 Application of Upper Payment Limits.**

A. This chapter and COMAR 14.01.07 do not prohibit a pharmacy benefit manager, third party administrator, vendor or other entity from negotiating and applying more favorable rates.

B. An upper payment limit established under COMAR 14.01.07 shall apply to all payments for drugs dispensed, administered, or purchased on or after the effective date of the upper payment limit.

C. After an eligible governmental entity has executed or amended a contract that contains the terms required in Regulation .02B of this chapter, and that contract is in effect, the eligible governmental entity shall comply with all upper payment limits established by the Board in COMAR 14.01.07 in effect during the term of the contract.

**.04 UPL Monitoring and Data Reporting**

- A. For each prescription drug product for which a UPL has been established and is in effect, an eligible governmental entity subject to that UPL shall report the following data for the prescription drug product:
- (1) Total gross spend to the eligible governmental entity;
  - (2) Final net cost to the eligible governmental entity;
  - (3) Final net system ingredient cost;
  - (4) Formulary placement, if applicable, of the drug subject to the UPL before implementation and after implementation;
  - (5) Units paid for or purchased in the preceding 12 months; and
  - (6) For payors,
    - (a) For each enrollee, calculate and report the GovUPLs in effect during the prior calendar year; and
    - (b) Calculate and report a weighted average of all GovUPLs for prescription drug products used during the reporting period based on utilization (multiply each GovUPL by its assigned weight (the percent of usage of the GovUPL), sum those products together).
- B. The eligible governmental entity shall submit the data report to the Board:
- (1) By April 1, following the end of the first calendar year in which the eligible governmental entity is subject to the UPL; and
  - (2) By April 1, for each subsequent calendar year in which the eligible governmental entity is subject to the UPL.