

COMAR 14.01.01.01**.01 Definitions.**

A. (unchanged)

B. Terms Defined.

(1)-(43) (unchanged)

(44) “Net cost” means the per-unit cost paid by payors *and purchasers* of a drug after accounting for all price concessions, discounts, and rebates.

(45)-(55) (unchanged)

(56) “Purchaser” means an entity that purchases prescription drug products that is not a payor or a patient.

[(56)] (57) “Rebate” means a monetary adjustment that reduces the price paid or dollar amount received by an entity engaging in a prescription drug transaction that occurs after the prescription drug transaction.

[(57)] (58) “Regulatory exclusivity” means any exclusive marketing rights or data exclusivity rights conferred by the FDA with respect to a pharmaceutical product other than patents, including but not limited to 180-day exclusivity, orphan drug exclusivity, new chemical entity exclusivity, data exclusivity, and pediatric exclusivity.

[(58)] (59) “Stakeholder Council” means the Prescription Drug Affordability Stakeholder Council, as provided for in Health-General Article, §21-2C-04, Annotated Code of Maryland.

[(59)] (60) “Standard medical practice” means the customary treatment by medical professionals:

(a) Based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community;

(b) Consistent with physician specialty society recommendations; or

(c) Consistent with the views of physicians practicing in the relevant clinical areas.

[(60)] (61) “State actual acquisition cost (SAAC)” has the meaning stated in COMAR 10.09.03.01B(42).

[(61)] (62) “Therapeutic alternative” means a drug product that has *one or more of* the same or similar indications for use as a particular drug but is not a therapeutic equivalent to that drug.

[(62)] (63) “Therapeutic class” means a group of drugs containing active moieties that share scientifically documented properties and are defined on the basis of any combination of three attributes: mechanism of action, physiologic effect, and chemical structure.

[(63)] (64) “Therapeutic equivalent” has the meaning stated in 21 CFR §314.3.

[(64)] (65) “Total gross spending” means the sum of all monies paid for a prescription drug product in a calendar year.

[(65)] (66) “Total patient out-of-pocket cost” means the sum of all patient out-of-pocket costs in a calendar year, including items such as copayments, coinsurance, and deductibles.

[(66)] (67) “Trade secret” has the meaning stated in Commercial Law Article, §11-1201, Annotated Code of Maryland.

[(67)] (68) “Wholesale acquisition cost (WAC)” means the manufacturer’s list price for a prescription drug product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, as reported in a wholesale price guide or other publication of prescription drug product pricing data.

[(68)] (69) “Wholesale distributor” has the meaning stated in Health Occupations Article, §12-6C-01, Annotated Code of Maryland.

(70) “*Utilization*” means *information about the use of a drug including the number of units, the number of patients and number of prescriptions or claims.*