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 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).

(62) "System net cost" means the sum of the net cost as defined above and the per unit patient out-of-pocket cost.

[(61)] *(63)* "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)] *(64)* "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)] *(65)* "Therapeutic equivalent" has the meaning stated in 21 CFR §314.3.

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

[(65)] *(67)* "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)] *(68)* "Trade secret" has the meaning stated in Commercial Law Article, §11-1201, Annotated Code of Maryland.

[(67)] *(69)* "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)] *(70)* "Wholesale distributor" has the meaning stated in Health Occupations Article, §12-6C-01, Annotated Code of Maryland.

(71) "Utilization" means information about the use of a drug including the number of units, the number of patients and number of prescriptions or claims.