Title 14 Independent Agencies

Subtitle .01 Prescription Drug Affordability Board

Chapter .01 General Provisions

.01 Definitions.

A. In this subtitle, the following terms have the meanings indicated.

[B.] (proposed for repeal) ALL NEW

B. Terms Defined.

(1) "Abbreviated new drug application (ANDA)" means a submission to the FDA for the review and potential approval for marketing of a generic drug product, including bioequivalence data, as defined in 21 CFR §314.3 and described under 21 CFR §314.50.

(2) "Accelerated approval" means the FDA drug approval process defined in 21 U.S.C. §356(c)(1)(A).

(3) "Active ingredient" means a component of a drug that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body, as defined in 21 CFR §314.3.

(4) "Active moiety" means the molecule or ion responsible for the physiological or pharmacological action of the drug substance, excluding those appended portions of the molecule that cause the drug to be an ester, salt, or other noncovalent derivative of the molecule, as defined in 21 CFR §314.3.

(5) "Average cost share" means the sum of the cost share of a prescription drug product for each patient divided by the number of patients.

(6) "Average payor cost per patient" means the sum of the total dollars paid by all payors over the most recent calendar year divided by the number of patients.

(7) "Average sales price (ASP)" has the meaning stated in 42 U.S.C § 1395w-3a(c)(1).

(8) "Average total out-of-pocket cost" means the sum of all patient total out-of-pocket costs divided by the number of patients.

(9) “Average wholesale price (AWP)” means the average suggested price paid by a retailer to buy a drug from a wholesaler, excluding price concessions, discounts, and rebates.

(10) “Biologic” means a biological product, as defined in 42 U.S.C. §262(i)(1).

(11) “Biologics license application (BLA)” means a request to the FDA to introduce, or deliver for introduction, a biological product, as defined in 21 CFR §600.3(h), into interstate commerce, as regulated under 21 CFR §600-680.

(12) “Biosimilar” means a biological product, as defined in 42 U.S.C. §262(i)(2), that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. §262(k)(3).

(13) “Board” has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.

(14) “Board staff” means an employee of the Board or a qualified independent third party that has contracted with the Board and is subject to a nondisclosure or confidentiality agreement.

(15) “Brand name drug” has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.

(16) “Carrier” has the meaning stated in Health-General Article, §19-132, Annotated Code of Maryland.

(17) “Chair” means the chair of the Board, as provided in Health-General Article, §21-2C-03, Annotated Code of Maryland.

(18) “Coinsurance” means the percentage of costs paid by the patient after meeting the deductible.

(19) “Consumer Price Index for All Urban Consumers (CPI-U)” means the measure of the average change over time in the prices paid by urban consumers for a defined market basket of consumer goods and services.

(20) “Copayment” means the set dollar amount that a patient pays for prescriptions or services covered by the patient’s health insurance, separate from the deductible.

(21) “Cost share” means the patient total out-of-pocket costs divided by gross spending.

(22) “Deductible” means the set amount a patient pays for health and medical services and products each calendar year before a health insurance plan begins to provide coverage, usually expressed in dollars.

(23) “Discount” means a monetary adjustment that reduces the price paid or dollar amount received by an entity engaging in a prescription drug transaction that occurs during the prescription drug transaction as reflected on the invoice.

(24) “Disease burden” means the impact of a health condition measured by financial cost, mortality, morbidity, severity, and epidemiological indicators.

(25) “Drug class” means the grouping of medications based on a common active ingredient (or ingredients) or by pharmacologic or therapeutic class.

(26) “Drug-specific patient access program” means a program designed to provide a patient with assistance in affording a prescription drug or paying for a prescription drug, including but not limited to the provision of a drug to a patient, coupons supplied by the manufacturer, donations to a nonprofit or foundation associated with the manufacturer, and donations to an independent nonprofit that are earmarked expressly for the manufacturer’s drugs.

(27) “Fund” means the Prescription Drug Affordability Fund, as provided for in Health-General Article, §21-2C-11, Annotated Code of Maryland.

(28) “Federal Supply Schedule (FSS)” means the drug pricing program under the collection of multiple award contracts used by federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors.

(29) “Food and Drug Administration (FDA)” means the federal agency of the U.S. Department of Health and Human Services tasked with protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, medical devices, and certain other consumer products.

(30) “Formulary” has the meaning stated in Insurance Article, §15-1601, Annotated Code of Maryland.

(31) “Generic drug” has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.

(32) “Gross spending” means the sum of all monies paid for a prescription drug product for an individual patient in a calendar year.

(33) “Health economics and outcomes research” means the form of economic analysis that compares the relative costs and outcomes of different treatments, such as cost effectiveness analysis, comparative effectiveness research, health economic information analysis, and health technology assessments.

(34) “Health maintenance organization (HMO)” has the meaning stated in Health-General Article, §19-701, Annotated Code of Maryland.

(35) “Insurance benefit design” means the rules that determine the services covered by the plan and any other cost-sharing measures.

(36) “Indication” means labeling that discusses the disease or condition the drug product is intended to diagnose, treat, prevent, cure, or mitigate, including a description of the patient population.

(37) “Manufacturer” has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.

(38) “Maryland Medical Care Database (MCDB)” means the database established and maintained by the Maryland Health Care Commission pursuant to Health-General Article, §19-133, Annotated Code of Maryland.

(39) “Managed care organization (MCO)” has the meaning stated in Health-General Article, §15-102.4, Annotated Code of Maryland.

(40) **“**Medicaid” means the public health program jointly administered by the federal government and states that primarily serves low-income people (children, parents, and, in certain states, other adults) and some medically needy patients.

(41) **“**Medicare” means the health insurance program administered by the federal government for people over the age of 65 or with certain disabilities.

(42) “National average drug acquisition cost (NADAC)” means the pricing benchmark calculated from the Centers for Medicare & Medicaid Services’ (CMS) monthly surveys of retail pharmacies that reflects the average price pharmacies pay to acquire a drug from a wholesaler or manufacturer, excluding subsequent discounts or rebates from manufacturers to wholesalers or pharmacies.

(43) “National Drug Code (NDC)” means the unique three-segment number used for identification and reporting as set forth in 21 CFR. §207.33.

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

(45) “Net price” means the per-unit amount received by manufacturers of a drug after accounting for price concessions, discounts, and rebates.

(46) “New drug application (NDA)” means a submission to the FDA for the review and potential approval for marketing of a drug product, which includes chemical, pharmacological, medical, biopharmaceutical, and statistical data, as defined in 21 CFR §314.3 and described under 21 CFR §314.50.

(47) “Other cost-sharing” means a program, benefit design, or other mechanism that determines a patient’s responsibility for a prescription drug product, such as a copayment, coinsurance, deductible, formulary, or other management tool.

(48) **“**Out-of-pocket costs” means the expenses for medical care, including prescription drug therapy, that are not reimbursed by insurance and are paid by a patient, including copayments, coinsurance, and deductibles for covered services, and the costs for all non-covered services.

(49) “Payor” means the entity other than the patient that is responsible for paying for health care costs, including health insurance carriers, health plan sponsors, PBMs, Medicare, Medicaid, MCOs, and HMOs.

(50) “Patient total out-of-pocket costs” means the sum of a patient’s out-of-pocket costs, including items such as copayments, coinsurance, and deductibles, in a calendar year.

(51) “Person” includes an individual, limited liability company, partnership, corporation, association, county, and public or private organization of any character other than an agency.

(52) “Pharmacy benefit manager (PBM)” means a third-party administrator of prescription drug programs as stated in Insurance Article, §15-1601, Annotated Code of Maryland.

(53) “Prescription drug product” has the meaning stated in Health-General Article, §21-2C-01, Annotated Code of Maryland.

(54) “Price concession” means a mechanism other than a rebate or discount that reduces the price paid by a payor.

(55) “Proprietary” means something that is used, produced, or marketed under the exclusive legal right of the inventor, maker or owner.

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

(59) “State actual acquisition cost (SAAC)” has the meaning stated in COMAR 10.09.03.01.B(42).

(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.

(61) “Trade secret” has the meaning stated in Commercial Law, §11-1201, Annotated Code of Maryland.

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

(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.

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

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

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