

907 KAR 23:001. Definitions for 907 KAR Chapter 23.

RELATES TO: KRS 205.560, 205.561, 205.5631, 205.5632, 205.5634, 205.5636, 205.5638, 205.5639, 205.6316(4), 217.015, 42 C.F.R. 440.120, 447.500 - 447.520, 42 U.S.C. 256b, 1396a - 1396d, 1396r-8

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.560, 205.561(2), 205.6316(4), 42 U.S.C. 1396a(a)(30), 42 U.S.C. 1396r-8

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with a requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the definitions for 907 KAR Chapter 23.

Section 1. Definitions. (1) "340B ceiling price" means the maximum statutory price established under Section 340B of the Public Health Service Act (340B Program), 42 U.S.C. 256b, and as calculated according to 42 C.F.R. 10.10.

(2) "Actual 340B acquisition cost" means the actual price paid for a drug purchased through the 340B program.

(3) "Average sales price" or "ASP" means the average sales price reported quarterly by the drug manufacturer to the Centers for Medicare and Medicaid Services (CMS).

(4) "Brand name drug" means the registered trade name of a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(5) "Commissioner" is defined by KRS 205.5631(1).

(6) "Covered drug" means a drug for which the Department for Medicaid Services provides reimbursement if medically necessary, not otherwise excluded, and provided in accordance with 907 KAR 23:010.

(7) "Covered outpatient drug" is defined by 42 U.S.C. 1396r-8(k)(2), unless excluded by 907 KAR 23:010 or 907 KAR 23:020.

(8) "Department" means the Department for Medicaid Services or its designated agent.

(9) "Department's pharmacy webpage" means the site maintained by the Department for Medicaid Services and accessible at <http://www.chfs.ky.gov/dms/Pharmacy>.

(10) "Department's pharmacy web portal" means the portal that:

(a) Provides online access to prescription and Kentucky specific plan information as well as supporting documentation; and

(b) Is accessible through the department's pharmacy webpage.

(11) "Dosage form" means the type of physical formulation used to deliver a drug to the intended site of action and includes a tablet, an extended release tablet, a capsule, an elixir, a solution, a powder, a spray, a cream, an ointment, or any other distinct physical formulation recognized as a dosage form by the Food and Drug Administration.

(12) "Drug Management Review Advisory Board" or "DMRAB" means the advisory board established pursuant to KRS 205.5636.

(13) "Effective" or "effectiveness" means a finding that a pharmaceutical agent does or does not have a significant, clinically-meaningful therapeutic advantage in terms of safety, usefulness, or clinical outcome over the other pharmaceutical agents based on pertinent information from a variety of sources determined by the department to be relevant and reliable.

(14) "Emergency supply" means a seventy-two (72) hour supply.

(15) "Enrollee" means a recipient who is enrolled with a managed care organization.

(16) "Federal financial participation" is defined by 42 C.F.R. 400.203.

(17) "Federal upper limit" or "FUL" means the upper payment limit for multiple source drugs for which a limit has been established by CMS as defined by 42 C.F.R. 447.512, 447.514, and 447.516.

(18) "Food and Drug Administration" or "FDA" means the Food and Drug Administration of the United States Department of Health and Human Services.

(19) "Generic drug" or "generic form" means a drug that contains identical amounts of the same active drug ingredients in the same dosage form and that meets official compendia or other applicable standards of strength, quality, purity, and identity in comparison with the brand name drug.

(20) "Kentucky Medicaid Fee-for-Service Outpatient Drug List" or "Outpatient Drug List" means each list available through the department's pharmacy webpage that:

(a) Specifies drugs, drug categories, and related covered items;

(b) Indicates prior authorization requirements or special prescribing or dispensing restrictions;

(c) Identifies excluded medical uses; and

(d) Includes other drug related information, such as:

1. Formulary status, drug coverage, and other plan limitations (prior authorization, quantity limits, step therapy, and diagnosis) associated with a drug;

2. The selected drugs available to fee-for-service recipients that have been included based on proven clinical and cost effectiveness and that prescribers are encouraged to prescribe if medically appropriate;

3. Physician administered drugs that may be billed to the fee-for-service medical benefit using appropriate Healthcare Common Procedure Coding System codes, National Drug Codes, and appropriate units;

4. Over-the-counter drugs that, if prescribed, are eligible for fee-for-service coverage and reimbursement through the pharmacy benefit;

5. Legend cold and cough drugs and legend vitamin products that, if prescribed and FDA indicated for the intended use, are eligible for fee-for-service coverage and reimbursement through the pharmacy benefit;

6. Over-the-counter drugs that, if provided to a Medicaid nursing facility service recipient, are included in the nursing facility's standard price or daily per diem rate and are not otherwise reimbursed by the department;

7. Covered drugs that have a quantity limit consistent with the maximum dosage that the FDA has approved to be both safe and effective; and

8. Covered drugs that require a diagnosis code or a prerequisite to therapy, or both.

(21) "Legend drug" means a drug so defined by the FDA and required to bear the statement: "Caution: Federal law prohibits dispensing without prescription".

(22) "Managed care organization" means an entity for which the department has contracted to serve as a managed care organization as defined by 42 C.F.R. 438.2.

(23) "Manufacturer" is defined by 42 U.S.C. 1396r-8(k)(5).

(24) "Maximum allowable cost" or "MAC" means a Kentucky-specific maximum amount that:

(a) May be established for any drug for which there are two (2) or more A-rated therapeutically equivalent, multiple-source, non-innovator drugs, as established in 907 KAR 23:020, Section 5; and

(b) Is an acquisition cost based model that includes all types of medications, including specialty and hemophilia products.

(25) "Medically necessary" or "medical necessity" means that a covered benefit is deter-

mined to be needed in accordance with 907 KAR 3:130.

(26) "National Average Drug Acquisition Cost" or "NADAC" means the average acquisition cost for drug ingredients for prescribed and covered outpatient drugs determined by a survey of retail community pharmacy providers as published by CMS.

(27) "Official compendia" or "compendia" is defined by 42 U.S.C. 1396r-8(g)(1)(B)(i).

(28) "Over-the-counter" or "OTC" means a drug approved by the FDA to be sold without bearing the statement "Caution: Federal law prohibits dispensing without prescription".

(29) "Pharmacy and Therapeutics Advisory Committee" or "P&T Committee" means the pharmacy advisory committee established by KRS 205.564 and in compliance with 45 C.F.R. 156.122.

(30) "Pharmacy provider" means a pharmacy that is:

(a) Within the scope of practice under Kentucky licensing laws and has the legal authority to operate as a pharmacy;

(b) Enrolled in the Medicaid Program pursuant to 907 KAR 1:672; and

(c) Currently participating in the Medicaid Program pursuant to 907 KAR 1:671.

(31) "Physician administered drug" or "PAD" means any rebateable covered outpatient drug that is:

(a) Provided or administered to a Medicaid recipient;

(b) Billed by a provider other than a pharmacy provider through the medical benefit, including providers who are physician offices or another outpatient clinical setting; and

(c) An injectable or non-injectable drug furnished incident to provider services that are billed separately to Medicaid.

(32) "Prescribed drug" is defined by 42 U.S.C. 1396r-8(k)(4).

(33) "Prescriber" means a health care professional who:

(a) Within the scope of practice under Kentucky licensing laws, has the legal authority to write or order a prescription for the drug that is ordered;

(b) Is enrolled in the Medicaid Program pursuant to 907 KAR 1:672; and

(c) Is currently participating in the Medicaid Program pursuant to 907 KAR 1:671.

(34) "Prior authorization request form" means a form that is:

(a) Used to request prior authorization for a prescription as established by 907 KAR 23:010; and

(b) Called either the:

1. Kentucky Medicaid Substance Use Treatment Pharmacy Prior Authorization Form for Buprenorphine Products; or

2. Kentucky Medicaid Pharmacy Prior Authorization Form.

(35) "Professional dispensing fee" means the fee paid to reimburse a pharmacy provider for professional costs associated with dispensing as defined by 42 C.F.R. 447.502.

(36) "Rebateable drug" means a drug for which the drug manufacturer has entered into and has in effect a rebate agreement in accordance with 42 U.S.C. 1396r-8(a).

(37) "Recipient" is defined by KRS 205.8451(9).

(38) "Supplemental rebate" means a cash rebate that offsets a Kentucky Medicaid expenditure and that supplements the Centers for Medicare and Medicaid Services National Rebate Program.

(39) "Therapeutically equivalent" means determined to be therapeutically equivalent by the FDA.

(40) "Usual and customary price" means the provider's usual and customary charge to the public, as identified by the claim charge.

(41) "Wholesale acquisition cost" or "WAC" means the list price paid by a wholesaler, dis-

tributor, or other direct accounts for drugs purchased from the wholesaler's supplier as listed in a nationally recognized comprehensive drug data file for which the department has contracted. (43 Ky.R. 2088; eff. 10-6-2017.)