## 205.5631 Definitions for KRS 205.5631 to 205.5639.

- (1) As used in KRS 205.5631 to 205.5639, "commissioner" means the commissioner of the Department for Medicaid Services.
- (2) As used in KRS 205.5632, "new drug" means a drug that is approved for marketing by the Federal Food and Drug Administration under a product licensing application, new drug application, or a supplement to a new drug application, and that is a new chemical or molecular entity, but shall not mean the following:
  - (a) Drugs, classes of drugs, or medical uses identified in 42 U.S.C. sec. 1396r-8(d)(2), as amended;
  - (b) Drugs that are considered to be less than effective by the Federal Food and Drug Administration or drugs that are considered to be identical, related, or similar to the less than effective drugs; and
  - (c) Drugs that are excluded from coverage by the Kentucky Medicaid program due to lack of compliance by the drug manufacturer with federal drug rebate requirements.

**Effective:** February 21, 2002

**History:** Amended 2002 Ky. Acts ch. 7, sec. 2, effective February 21, 2002. -- Created 1998 Ky. Acts ch. 561, sec. 1, effective July 15, 1998.