304.17A-535 Drug utilization waiver program -- Limitations on generic substitution -- Application to drug formulary.

(1) A managed care plan shall include a drug utilization review program, the primary emphasis of which shall be to enhance quality of care for enrollees by assuring appropriate drug therapy within the health care provider's legally authorized scope of practice, that includes the following:

(a) Retrospective review of prescription drugs furnished to enrollees;

(b) Education of health care providers and enrollees regarding the appropriate use of prescription drugs; and

(c) Ongoing periodic examination of data on outpatient prescription drugs to ensure quality therapeutic outcomes for enrollees.

(2) The drug utilization review program shall utilize the following to effectuate the purposes of subsection (1) of this section:

(a) Relevant clinical criteria and standards for drug therapy;

(b) Nonproprietary criteria and standards developed and revised through input from participating health care providers;

(c) Intervention that focuses on improving therapeutic outcomes; and

(d) Measures to ensure the confidentiality of the relationship between an enrollee and a health care provider.

(3) When, in the professional opinion of a provider with prescriptive authority, the provider determines that generic substitution of a pharmaceutical product is medically inappropriate, the provider shall prescribe the pharmaceutical product the provider determines medically appropriate with the indication "Do Not Substitute," and no substitution shall be made without the provider's approval.

(4) A managed care plan that restricts pharmacy benefits to a drug formulary shall have an exceptions policy through which the managed care plan may cover a prescription drug not included on the formulary.

Effective: July 14, 2000

History: Amended 2000 Ky. Acts ch. 500, sec. 9, effective July 14, 2000. -- Created 1998 Ky. Acts ch. 496, sec. 32, effective April 10, 1998.