

902 KAR 55:060. Requirements for distribution of small amounts of controlled substances without manufacturer's or wholesaler's licenses.

RELATES TO: KRS 218A.010-218A.020, 218A.150-218A.200, 21 C.F.R. 1304.03, 1305.03, 1307.11

STATUTORY AUTHORITY: KRS 194.050, 218A.250

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.250 directs the Cabinet for Human Resources to adopt rules and administrative regulations for carrying out the provisions of KRS Chapter 218A relating to controlled substances. KRS 218A.170(2) provides that all sales and distributions of controlled substances shall be in accordance with the federal controlled substances laws, including the requirements governing the use of order forms. The purpose of this administrative regulation is to provide for the distribution of small amounts of controlled substances by pharmacies to practitioners or other pharmacies, without the necessity of obtaining a state license as a manufacturer or a wholesaler, in accordance with applicable federal laws and regulations.

Section 1. Distribution of Controlled Substances by Pharmacy to Practitioner or other Pharmacy. (1) A pharmacy may distribute a quantity of a controlled substance to a practitioner or another pharmacy, without being licensed as a manufacturer or wholesaler in Kentucky if it:

- (a) Is licensed in Kentucky;
- (b) Is registered with the U.S. Drug Enforcement Administration; and
- (c) Makes the distribution to a practitioner or pharmacy that is registered with the U.S. Drug Enforcement Administration.

(2) The distribution shall be recorded by the distributing pharmacy and by the receiving practitioner or pharmacy in accordance with KRS 218A.200;

(3) A readily retrievable record of the distribution shall be maintained showing:

- (a) Date of distribution;
- (b) Name, form and quantity of the substance distributed; and
- (c) Name, address and registration number of the purchaser.

(4) The total number of dosage units of all controlled substances distributed by a pharmacy pursuant to this administrative regulation during a twelve (12) month period shall not exceed five (5) percent of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the twelve (12) month period. If the five (5) percent limitation is expected to be exceeded, the pharmacy shall obtain a license to distribute controlled substances in accordance with KRS 218A.160 and 218A.170; and

(5) A prescription shall not be issued by a practitioner to obtain any controlled substance for the purpose of general dispensing, administering or office use. (7 Ky.R. 888; eff. 6-3-1981; Recodified from 901 KAR 1:070, 4-14-1982; 11 Ky.R. 1681; eff. 6-4-1985; 18 Ky.R. 1244; 1890; eff. 11-25-1991; 20 Ky.R. 1425; eff. 1-10-1994; Crt eff. 1-11-2019.)