

Missouri Board of Pharmacy  
Drug Distributor Newsletter  
September, 2001

**REGULATION CHANGES**

The following highlights recent changes in regulations affecting drug distributors. The complete regulations can be found at <http://mosl.sos.state.mo.us/csr/4csr/4c220-5.pdf> Statutes relating to drug distributors (chapters 338.330 to 338.370) can be found at <http://www.moga.state.mo.us/STATUTES/C338.HTM>

**4 CSR 220-5.020 Drug Distributor Licensing Requirements (Effective 9/30/00)**

- (1) As defined in section 338.315, RSMo, pharmacies and all individuals employed by pharmacies shall purchase or receive legend drugs only from a licensed or registered drug distributor or licensed pharmacy. For purposes of this rule, the term drug distributor is used to define anyone engaged in an activity as defined in section 338.330, RSMo. **Drug distributors as defined in 338.330, RSMo, shall only purchase or receive legend drugs and drug related devices from a licensed or registered drug distributor or licensed pharmacy.**

**4 CSR 220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors (Effective 9/30/00)**

- (2) (B) A person must also have appropriate education, experience, or both, before assuming the duties of a manager in charge. **Appropriate education for purposes of this section is defined as education in the areas of work environment, standards of operation and knowledge of laws concerning drug distributor compliance requirements.**
1. Minimum requirements for education/experience may be attained separately or in combination total **two (2) years.**
- (2) (C) Any individual that is considered a manager or supervisor within a facility but is not the manager in charge of the facility must meet the minimum education/experience requirements as set forth in this rule for a total of **one (1) year.**

(2) (E) **Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge.** When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(9) As used in section 338.330(3), RSMo, the term “drug related device” shall be defined as an article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360(j)(e)

(10) **Brokers, their agents and employees, who act only in the capacity of an agent who arranges or negotiates agreements or contracts for the transfer of drugs or drug related devices and do not take actual possession of the drugs or drug related devices are exempt from maintaining any equipment or physical location requirements involved in the actual storage and distribution of drugs. Brokers shall be responsible for all recordkeeping requirements as outlined in subsections (I), (J), (K) and (L).**

#### **4 CSR 220-5.050 Out of State Distributor License Registration Requirement (Effective 9/30/00).**

Where the word “state” appears in this rule, amendments were made to add the term **“or foreign jurisdiction”**,

#### **4 CSR 220-5.070 Standards of Operation for Medical Gas Distributors (New rule effective 9/30/00)**

- (1) Medical gases are defined as compressed gases and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law.
- (2) Medical gas distributor is defined as an entity which is licensed by the board as a drug distributor and is involved in the distribution of medical gases and related medical devices pursuant to a medical gas order to medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute medical gases.
- (3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: 4 CSR 220-5.030(3)(B); (3)(C)4., 9., 11., 12., 13.; (3)(E); (3)(H) and (3)(M)4. Medical gas distributors that store, transfer or transfill

nitrous oxide are exempt from 4 CSR 220-5.030(3)(B); (3)(C)4., 9., 11.; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

- (4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.

#### **4 CSR 220-5.020 Drug Distributor Licensing Requirements (Effective 6/30/01)**

- (1) (B) Revises the language to establish a 5% threshold for sale of drugs from a pharmacy to other entity, before licensure as a drug distributor is required.

#### **4 CSR 220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors (Effective 6/30/01)**

- (3) (J) Increases the length of time a drug distributor must maintain certain records to **three (3) years**, to comply with federal law.

### **COMPLIANCE ISSUES**

- Regulation CSR 220.5.020 now requires that licensed drug distributors only purchase/receive legend drugs and drug related devices from licensed or registered drug distributors or licensed pharmacies. Receipt of legend drugs/devices from out-of-state unlicensed distributors continues to be a major compliance issue. Missouri drug distributors should ensure they are receiving product from other licensed distributors. Some ways this can be accomplished included:
  - Ask vendors to provide copies of their Missouri licenses.
  - Download a listing of licensed distributors from the web:  
<http://www.ecodev.state.mo.us/pr/>
  - Perform a search for a particular distributor on the web:  
<http://riversrun.ded.state.mo.us/cgi-bin/professionalregistration.pl>

There is no exemption from licensure for multi-site firms. Each distribution site must have its own license.

- Product storage concerns include the storing of drug products in facilities which have no temperature regulation. Distributors must be aware of the labeled temperature requirements of the products they handle and must store the products within these requirements. A major concern is the storage of drug products in non-air-conditioned facilities in the summer. Drug distributors are required to keep daily temperature and humidity recordings on their warehouses and refrigeration/freezer units.
- Other common deficiencies noted during inspections include:

#### Facility

- No alarm system on facility.
- Insufficient outside lighting.
- No separate/labeled area for distressed/outdated product.
- No separate area for flammable product.
- All products not kept off floor or on pallets.
- Veterinary products stored separately from human products.

#### Records

- No written current authorized personnel list.
- No written job description of Manager-In-Charge or any other supervisors of distribution or control.
- No or incomplete written policy and procedures including topics of:
  - a. Drug disposition and control
  - b. Drug security
  - c. Drug storage
  - d. Monitoring/reporting losses or thefts
  - e. Inventory inaccuracies
  - f. Stock rotation
  - g. Drug recalls
  - h. Emergency and crisis management.
- Disposition and recordkeeping for outdated drugs.

#### Miscellaneous:

- Distributing to customers not appropriately licensed to receive legend drugs/devices.

## **COUNTERFEIT DRUGS**

Recently there have been reports of counterfeit biotech drugs being distributed throughout the United States. Distributors should be suspect of drugs coming through unusual channels.

## **CHANGES IN MANAGER-IN-CHARGE**

Regulation requires any change in the manager-in-charge to be reported to the Board office immediately. You may contact the Board office (573-751-9056) to request the required form.

## **CHARITABLE DONATIONS**

Charitable entities must be appropriately licensed in order to receive legend drugs. Also, federal law prohibits the distribution of outdated drugs (even for charitable purposes).

## **DISCIPLINARY ACTIONS**

**KV Pharmaceutical Company**, #900173, St. Louis, MO--April 10, 2001. Probation for three (3) years, until 4/9/04. Pled guilty to two counts of violating 21 U.S.C. 331(e) and 355(k)(1) concerning failure to investigate or report an antibiotic drug below the required potency levels of the label claim; and two counts of violating 21 U.S.C. 331(a) and 352(a) concerning interstate distribution of misbranded drugs.

**Helget Gas Products**, #901086, Kansas City, MO—November 16, 1999. Suspension for two (2) weeks, until November 29, 1999, followed by probation for five (5) years, November 30, 1999 to November 29, 2004. Manufacturing of oxygen with malfunctioning equipment causing deviations from Federal Current Good Manufacturing Practices and trans-filled medical gases to be adulterated; recordkeeping violation; failure to establish a quality control unit and complaint handling system; failure to conduct product recall as requested; and failure to notify Board of manager-in-charge change. Section 338.055.2(1), (5), (13), and (15), RSMO 1994.

**C.R. Bard, Inc.**, #901039, Murray Hill, NJ—March 31, 1999, Probation for five (5) years, until March 30, 2004. Guilty plea entered in Federal District Court, District of Massachusetts, in October 1993 on 391 counts of violating federal laws. Sections 338.353.1 and 338.055.2(2), (5) and (13), RSMo 1994.

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