Chapter Phar 13

DISTRIBUTOR REQUIREMENTS

Phar 13.01 Authority. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 450.07 (4), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Phar 13.02 Definitions. In this chapter:

(1) "Controlled substance" has the meaning set forth in s. 161.01 (4), Stats.

(2) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(3) "Distribute" has the meaning set forth in s. 450.01 (8), Stats.

(4) "Distributor" means a person licensed by the board under this chapter.

(5) "Establishment" means a place of business under one management at one general physical location.

(6) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Phar 13.03 License; application. (1) No person may sell or distribute at wholesale any prescription drug or device unless a license is granted to the person by the board under this chapter.

(2) To obtain a license a person shall:

(a) Submit an application on a form provided by the board;

(b) Pay the fee specified in s. 440.05 (8), Stats.;

(c) Meet the inspection requirement under s. Phar 13.04;

(d) If applicable, register with the drug enforcement administration and comply with all appropriate requirements in 21 C.F.R. ss. 1301, 1304, 1305 and 1307 (1985); and,

(e) Comply with all applicable requirements of 21 C.F.R. ss. 211.142 (b), 211.150 (a) and 211.196 (1985).

Note: An application form may be obtained from the board office, 1400 East Washington Avenue, Madison, Wisconsin 53702. Copies of federal applications, laws and regulations may be obtained from the Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

(3) A distributor license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

(4) If the license is denied, the applicant may request a hearing before the board on the denial.

(5) The board shall act on the license within 60 business days after receiving the completed application.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87; correction in (2) (e) made under s. 13.93 (2m) (b) 7, Stats., Register, March, 1989, No. 399.

Phar 13.04 Inspection. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets standards specified in 21 U.S.C. ss. 351 and 352 (1984) and 21 C.F.R. ss. 211.142 (b) (1985).

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Phar 13.05 Distribution requirements. Any controlled substance or any prescription drug or device may be offered for sale, sold or distributed by distributors only to a person or firm which is required to be registered or exempt under 21 C.F.R. s. 1301 (1985), and s. 450.07 (3), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.

Phar 13.06 Compliance. Failure to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9-1-87.