CHAPTER 490

An Act to amend and reenact §§ 54.1-3415, 54.1-3422, 54.1-3423, and 54.1-3424 of the Code of Virginia, relating to requirements for controlled substances registration.

[H 1300]

Approved April 14, 1998

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3415, 54.1-3422, 54.1-3423, and 54.1-3424 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3415. Distribution of drugs in Schedules II through VI by manufacturers and wholesalers.

A. A permitted manufacturer or wholesaler may distribute Schedule II drugs to any of the following persons, but only on official written orders:

1. To a manufacturer or wholesaler who has been issued permits pursuant to this chapter;

2. To a *licensed* pharmacist, *permitted pharmacy or a licensed practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine*;

3. To a person who has been issued a controlled substance registration certificate pursuant to § 54.1-3422, if the certificate of such person authorizes such purchase;

4. On a special written order accompanied by a certificate of exemption, as required by the federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal, or insular government, purchasing, receiving or possessing drugs by reason of his official duties;

5. To a master of a ship or a person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft when not in port. However, such drugs shall be sold to a master of such ship or person in charge of such aircraft pursuant to a special order form approved by a commissioned medical officer or acting assistant surgeon of the United States Public Health Service; and

6. To a person in a foreign country in compliance with the provisions of the relevant federal laws.

B. A permitted manufacturer or wholesaler may distribute drugs classified in Schedule III through Schedule VI and devices to all persons listed in subsection A of this section without an official written order. However, this section shall not be construed to prohibit the distribution of a Schedule VI drug or device to any person who is otherwise authorized by law to administer, prescribe or dispense such drug or device.

§ 54.1-3422. Controlled substances registration certificate required in addition to other requirements; exemptions.

A. Every person who manufactures, distributes or dispenses any substance which is controlled in Schedules I through V or who proposes to engage in the manufacture, distribution or dispensing of any such controlled substance except permitted pharmacies, those persons who are licensed pharmacists, and those persons who are licensed practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine shall obtain annually a controlled substances registration certificate issued by the Board. This registration shall be in addition to other licensing or permitting requirements enumerated in this chapter or otherwise required by law.

B. Registration under this section and under all other applicable registration requirements shall entitle the registrant to possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by this registration and in conformity with the other provisions of this chapter.

C. The following persons need not register and may possess controlled substances ~~in~~ *listed on* Schedules I through ~~V~~ *VI*:

1. An agent or employee of any holder of a controlled substance registration certificate *or of any practitioner listed in subsection A of this section as exempt from the requirement for registration,* if ~~he~~ *such agent or employee* is acting in the usual course of his business or employment;

2. A common or contract carrier or warehouseman, or his employee, whose possession is in the usual course of business or employment; or

3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a prescriber or in lawful possession of a Schedule V substance.

D. A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent

with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research with controlled substances in Schedules II through ~~V~~ *VI*. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping. The first such regulations shall be promulgated within 280 days of the enactment of this provision.

~~D.~~ *E.* Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

F. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within fourteen days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

§ 54.1-3424. Suspension or revocation of registration, license or permit; limitation to particular controlled substance; controlled substances placed under seal; sale of perishables and forfeiture; notification to DEA.

A. A registration to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Board upon a finding that the registrant:

1. Has furnished false or fraudulent material information in an application filed under this chapter;

2. Has been convicted of a felony under any state or federal law relating to any controlled substance;

3. Has had his federal registration to manufacture, distribute or dispense controlled substances suspended or revoked;

4. Has violated or cooperated with others in violating any provision of this chapter or regulations of the Board relating to the manufacture, distribution or dispensing of controlled substances.

B. The Board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

C. If the Board suspends or revokes a registration, or if the license or permit of a person possessing ~~Schedule I through V~~ controlled substances under an exemption in § 54.1-3422 A is suspended or revoked by the issuing board, all controlled substances owned or possessed by the registrant, licensee or permittee at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances shall be forfeited to the Commonwealth.

D. The Board shall promptly notify the DEA of all orders suspending or revoking registration and all forfeitures of controlled substances.