

WAC 246-887-020 Uniform Controlled Substances Act. (1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306. Although those regulations are automatically applicable to registrants in this state, the (~~board~~) pharmacy quality assurance commission (commission) is nevertheless adopting as its own regulations the existing regulations of the federal government published in the Code of Federal Regulations revised as of April 1, 1991, and all references made therein to the director or the secretary shall have reference to the (~~board of pharmacy~~) commission, and the following sections are not applicable: Section 1301.11-.13, section 1301.31, section 1301.43-.57, section 1303, section 1308.41-.48, and section 1316.31-.67. The following specific rules shall take precedence over the federal rules adopted herein by reference, and therefore any inconsistencies shall be resolved in favor of the following specific rules.

(2) A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the (~~pharmacy board~~) commission, and all information called for thereon must be supplied unless the information is not applicable, in which case it must be indicated. An applicant for registration must hold the appropriate wholesaler, manufacturer or pharmacy license provided for in chapter 18.64 RCW.

(3) Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include:

(a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;

(b) Distribution records; i.e., invoices, etc. from wholesalers and manufacturers and prescriptions records for dispensers;

(c) In the event of a loss by theft or destruction, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the (~~board~~) commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to and from whom. Said record must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to section 1307.11 (federal rules).

(4) The records must be maintained separately for Schedule II drugs. The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant. Prescription records will be deemed readily retrievable if the prescription has been stamped in red ink in the lower right hand corner with the letter "C" no less than one inch high, and said prescriptions are filed in a consecutively

numbered prescription file which includes prescription and noncontrolled substances.

(5) A federal order form is required for each distribution of a Schedule I or II controlled substance, and said forms along with other records required to be kept must be made readily available to authorized employees of the ~~((board))~~ commission.

(6) Schedule II drugs require that a dispenser have a signed prescription in his possession prior to dispensing said drugs. An exception is permitted in an "emergency." An emergency exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the physician to provide a written prescription for the drug at that time. If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within 72 hours, and further he must note on the prescription that it was filled on an emergency basis.

(7) A prescription for a substance included in Schedule II may not be refilled.

(8) A prescription for a substance included in Schedule II may not be filled more than six months after the date the prescription was issued.

(9) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written, oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription for a substance included in Schedule III, IV, or V may not be filled or refilled more than six months after the date issued by the practitioner or be refilled more than five times, unless the practitioner issues a new prescription.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-887-030 Dispensing Schedule V controlled substances.