

WAC 246-879-070 Application for full line wholesaler license and over-the-counter only wholesaler license. (1) All applications for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in chapter 246-907 WAC.

(2) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (6) of this section.

(3) A change of ownership or location requires a new license.

(4) The license is issued to a person or firm and is nontransferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(5) The license fee cannot be prorated.

(6) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs.

(a) Minimum required information for licensure. The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.

(i) The name, full business address, and telephone number of the licensee;

(ii) All trade or business names used by the licensee;

(iii) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(iv) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(v) The name(s) of the owner and/or operator of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(vi) When operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the board.

(vii) Change in any information required by this section shall be submitted to the board within thirty days after such change.

(b) Minimum qualifications. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:

(i) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;

(ii) Any felony convictions of the applicant under federal, state, or local laws;

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(iv) Any false or fraudulent material furnished by the applicant in any application made in connection with drug manufacturing or distribution;

(v) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(vi) Compliance with licensing requirements under previously granted licenses, if any;

(vii) Compliance with requirements to maintain and/or make available to the board, federal, state, or local enforcement officials those records required to be maintained by wholesale drug distributors; and

(viii) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

(c) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based on factors and qualifications that are directly related to the protection of the public health and safety.

(d) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

[Statutory Authority: RCW 43.70.280. WSR 98-05-060, § 246-879-070, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. WSR 92-15-069 (Order 289B), § 246-879-070, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. WSR 91-18-057 (Order 191B), recodified as § 246-879-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. WSR 82-06-042 (Order 165), § 360-21-070, filed 3/2/82.]