

WAC 246-945-246 Wholesaler. (1) Every wholesaler who engages in wholesale distribution into, out of, or within Washington state must be licensed by the commission before engaging in wholesale distribution of drugs. Entities required to be licensed as a wholesaler includes:

- (a) In-state and out-of-state pharmaceutical wholesalers;
- (b) Out-of-state manufacturer that distribute or sell drugs into Washington;
- (c) Virtual wholesalers;
- (d) Out-of-state virtual manufacturers that distribute or sell drugs into Washington;
- (e) Outsourcing facilities required to be registered with the FDA as an outsourcing facility as defined in 21 U.S.C. Sec. 353b(d)(4)(A) that are located in Washington, or distribute or sell drugs into Washington; and
- (f) Reverse distributors.

(2) The commission may issue a wholesaler license to an applicant that is in compliance with the requirements in WAC 246-945-230 and this section.

(3) In addition to the requirements in subsection (2) of this section if the applicant is located outside of Washington, the applicant must provide:

- (a) A copy of a site inspection conducted by the regulatory authority in the resident U.S. jurisdiction or third-party inspection program recognized by the commission within the last two years and every two years with the distributor's renewal;
- (b) A copy of the resident state license; and
- (c) A list of licenses, registrations, permits or certificates held in other U.S. jurisdictions.

(4) In addition to the requirements in subsection (2) of this section if the applicant plans to export noncontrolled drugs to persons in a foreign jurisdiction, the applicant must provide letters from the consulate of the country to which the drugs are exported and should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the commission upon its request. The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

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

- (a) 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;
- (b) Any felony convictions of the applicant under federal, state, or local laws;
- (c) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- (d) Any false or fraudulent material furnished by the applicant on any application made in connection with drug manufacturing or distribution;
- (e) 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;

(f) Compliance with licensing requirements under any previously granted licenses;

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

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

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

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-246, filed 6/1/20, effective 7/1/20.]