

WAC 246-945-560 Wholesaler—Facility standards. (1) Facilities used for wholesale drug distribution must:

(a) Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations;

(b) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security;

(c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition;

(e) Be free from infestation of any kind;

(f) Be a commercial location and not a personal dwelling or residence;

(g) Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of information; and

(h) Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of drugs.

(2) Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows:

(a) Access from outside the premises must be kept to a minimum and well controlled;

(b) The outside perimeter of the premises must be well lit;

(c) Entry into areas where drugs are held must be limited to authorized personnel;

(d) Facilities must be equipped with an alarm system to detect entry after hours; and

(e) Facilities must be equipped with security systems sufficient to protect against theft, diversion, or record tampering.

[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, § 246-945-560, filed 6/1/20, effective 7/1/20.]