

657—42.10(155A) Requirements.

42.10(1) *Physical requirements.* A distributor's location shall:

- a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- c. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated products and for any suspect products;
- d. Be maintained in a clean and orderly condition;
- e. Be free from infestation by insects, rodents, birds, or vermin of any kind.

42.10(2) *Operation requirements.* Distributors shall operate in compliance with all applicable federal, state, and local laws, rules, and regulations.

a. *Purchasing.* Distributors shall purchase products from a legitimate source that is properly licensed in the state in which it is located and that is properly licensed in the distributor's home state, if such licensure is required. Distributors shall exercise due diligence in determining the legitimacy of a product's source and maintain documentation of the distributor's verification of the legitimate source.

b. *Examination of materials.* Distributors shall ensure, upon receipt and prior to distribution, that a product is suitable for distribution.

c. *Verification.* Qualified personnel shall verify, prior to distribution, that the product matches the order for which the product is being distributed.

d. *Instructions for use.* Qualified personnel shall provide to the patient or the patient's caregiver adequate instructions for use when a product is distributed pursuant to a prescription order.

[ARC 4191C, IAB 12/19/18, effective 1/23/19]