

657—10.19(124) Physical count and record of inventory. Each registrant shall be responsible for taking a complete and accurate inventory of all stocks of controlled substances under the control of the registrant pursuant to this rule. The responsible individual may delegate the actual taking of any inventory.

10.19(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. Controlled substances on hand shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical service programs, care facility or hospice emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

- (1) The name of the substance.
- (2) The strength and dosage form of the substance.
- (3) The quantity of the substance, which shall be an exact count or measure of the substance and may not be an estimated count or measure, except for liquid products packaged in nonincremented containers, which may be estimated to the nearest one-fourth container.

(4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

(5) The signature of the person or persons responsible for taking the inventory.

(6) The date and time (opening or closing) of the inventory.

10.19(2) Initial inventory. A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, storage, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.19(3) Annual inventory. After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within 372 days after the date of the previous annual inventory.

10.19(4) Change of ownership, pharmacist in charge, or registered location.

a. When there is a change in ownership or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following the close of business on the last day under terminating ownership or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner or location being vacated, as well as a record of the beginning inventory for the new owner or location.

b. When there is a change of pharmacist in charge, including when the incoming pharmacist in charge is temporary or interim pursuant to 657—paragraph 8.35(6) “d,” an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). An inventory shall be taken following the close of business on the last day of duty of the outgoing pharmacist in charge. The inventory may serve as the beginning inventory for the incoming pharmacist in charge, unless the incoming pharmacist in

charge did not immediately assume the duties of pharmacist in charge following the outgoing pharmacist in charge. Any lapse in time between the outgoing pharmacist in charge and the incoming pharmacist in charge shall cause an inventory to be taken prior to the opening of business on the first day of duty of the incoming pharmacist in charge. An inventory count shall not be required in the case of an interim pharmacist in charge if the pharmacy maintains perpetual inventory logs for all controlled substances pursuant to rule 657—10.20(124).

10.19(5) *Discontinuing registered activity.* A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to which the substances are transferred.

10.19(6) *New or rescheduled controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances or the rescheduling of a previously controlled substance to another schedule, any registrant who possesses the newly scheduled or rescheduled controlled substance shall take an inventory of all stocks of the substance on hand. That inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the controlled substance shall be included in the appropriate schedule of each inventory made by the registrant.

[ARC 3345C, IAB 9/27/17, effective 11/1/17; ARC 6330C, IAB 6/1/22, effective 7/6/22]