

657—10.35 (124,155A) Physical count and record of inventory. Responsibility for ensuring that a required inventory is timely completed shall rest with the registrant or, in the case of a registered business, shall rest with the owner of the business. A registrant or owner of a registered business may delegate the actual taking of any inventory. The person or persons responsible for taking the inventory shall sign the completed inventory record.

10.35(1) Record and procedure. Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(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. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant.

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; and
- (3) The quantity of the substance.

g. For all substances listed in Schedule I or II, and for all solid oral and injectable hydrocodone-containing products, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, except for hydrocodone-containing products identified in paragraph “g” herein, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Liquid oral hydrocodone-containing products packaged in incremented containers shall be measured to the nearest increment; products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.35(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, 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.

10.35(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 one year or seven days after the date of the previous annual inventory.

10.35(4) Change of ownership. Both the current owner and the prospective owner shall be responsible for ensuring that an inventory of all controlled substances is timely completed whenever there is a change of ownership of any pharmacy or drug wholesaler licensed pursuant to Iowa Code section 155A.13 or 155A.17, respectively. The inventory shall be taken following the close of business the last day under terminating ownership and prior to opening for business the first day under the new ownership. The inventory shall serve as the ending inventory for the terminating owner as well as a record of beginning inventory for the new owner.

10.35(5) *Change of pharmacist in charge (PIC).* An inventory of all controlled substances shall be completed whenever there is a change of PIC. The inventory shall be taken following the close of business the last day of the terminating PIC's employment and prior to opening for business the first day of the new PIC's employment. A single inventory shall be sufficient if there is no lapse between employment of the terminating PIC and the new PIC.

10.35(6) *Change of registered location.* A registrant shall take an inventory of all controlled substances whenever there is a change of registered location. The inventory shall be taken following the close of business the last day at the location being vacated. This inventory shall serve as the ending inventory for the location being vacated as well as a record of beginning inventory for the new location.

10.35(7) *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 whom the substances are transferred.

10.35(8) *Newly controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances, any registrant who possesses the newly controlled substance shall take an inventory of all stocks of the substance on hand. That initial inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the newly controlled substance shall be included in each inventory made by the registrant.

[ARC 1575C, IAB 8/20/14, effective 9/24/14]