657—22.3(126) Prepackaging.

22.3(1) *Control record.* Pharmacies may prepackage and label drugs in convenient quantities for subsequent labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall be responsible for the preparation and maintenance of a packaging control record containing the following information:

a. Date.
b. Identification of drug.
(1) Name of drug.
(2) Dosage form.
(3) Manufacturer.
(4) Manufacturer's lot number.
(5) Strength.
(6) Expiration date.
c. Container specification.
d. Copy of a sample label.
e. Initials or unique identification of the packager.
f. Initials or unique identification of the supervising pharmacist.
g. Quantity per container.
h. Internal control number or date.

22.3(2) *Label information.* Each prepackaged container shall bear a label containing the following information:

a. Name of drug.
b. Strength.
c. Internal control number or date.
d. Expiration date consistent with USP standards.
e. Auxiliary labels, as needed.

22.3(3) *Labeling for delivery.* Prior to the delivery of a prepackaged drug to a patient, an appropriate label shall be affixed to the drug container pursuant to the labeling requirements of the appropriate pharmacy practice rules.

This rule is intended to implement Iowa Code sections 126.10 and 126.11.