IOWA ADMINISTRATIVE CODE 653—CHAPTER 13

Standards of practice—packaging, labeling and records of prescription drugs dispensed by a physician.

13.1(1) A physician shall dispense a prescription drug only in a container which meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471-1476 (2001), unless otherwise requested by the patient, and of Section 502G of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. ss. 301 et seq.(2001).

13.1(2) A label shall be affixed to a container in which a prescription drug is dispensed by a physician which shall include:

1. The name and address of the physician.
2. The name of the patient.
3. The date dispensed.
4. The directions for administering the prescription drug and any cautionary statement deemed appropriate by the physician.
5. The name and strength of the prescription drug in the container.

13.1(3) The provisions of subrules 13.1(1) and 13.1(2) shall not apply to packaged drug samples.

13.1(4) A physician shall keep a record of all prescription drugs dispensed by the physician to a patient which shall contain the information required by subrule 13.1(2) to be included on the label. Noting such information on the patient's chart or record maintained by the physician is sufficient.

This rule is intended to implement Iowa Code sections 147.55, 148.6, 272C.3 and 272C.4.

653—13.6 (79GA,HF726) **Standards of practice—automated dispensing systems.**

A physician who dispenses prescription drugs via an automated dispensing system or a dispensing system that employs technology may delegate nonjudgmental dispensing functions to staff assistants in the absence of a pharmacist or physician provided that the physician utilizes an internal quality control assurance plan that ensures that the medication dispensed is the medication that was prescribed. The physician shall be

physically present to determine the accuracy and completeness of any medication that is reconstituted prior to dispensing.

13.6(1) An internal quality control assurance plan shall include the following elements:

a. The name of the physician responsible for the internal quality assurance plan and testing;

b. Methods that the dispensing system employs, e.g., bar coding, to ensure the accuracy of the patient's name and medication, dosage, directions and amount of medication prescribed;

c. Standards that the physician expects to be met to ensure the accuracy of the dispensing system and the training and qualifications of staff members assigned to dispense via the dispensing system;

d. The procedures utilized to ensure that the physician(s) dispensing via the automated system provide(s) patients counseling regarding the prescription drugs being dispensed;

e. Staff training and qualifications for dispensing via the dispensing system;

f. A list of staff members who meet the qualifications and who are assigned to dispense via the dispensing system;

g. A plan for testing the dispensing system and each staff member assigned to dispense via the dispensing system;

h. The results of testing that show compliance with the standards prior to implementation of the dispensing system and prior to approval of each staff member to dispense via the dispensing system;

i. A plan for interval testing of the accuracy of dispensing, at least annually; and

j. A plan for addressing inaccuracies, including discontinuing dispensing until the accuracy level can be reattained.

13.6(2) Those dispensing systems already in place shall show evidence of a plan and testing within two months of August 31, 2001.

13.6(3) The internal quality control assurance plan shall be submitted to the board of medicine upon request.

This rule is intended to implement Iowa Code section 147.107 and 2001 Iowa Acts, House File 726, section 5(10), paragraph *"i."*