650—16.4(153) Dispensing—requirements for containers and labeling.

16.4(1) Containers. A prescription drug shall be dispensed in a container which meets the requirements of the Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471-1476 which relates to childproof closure, unless otherwise required by the patient. Containers must also meet the requirements of Section 502G of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §301 et seq. which pertains to light resistance and moisture-resistance needs of the drug being dispensed.

16.4(2) Labeling. A label shall be affixed to the container in which a prescription drug is dispensed bearing the following information:

1. Name and address of the dentist.
2. Name of the patient.
3. Date dispensed.
4. Directions for use.
5. Name, quantity, and strength of medication.
6. If it is Schedule II, III, or IV controlled substance, the federal transfer warning statement must appear on the label as follows: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."
7. Cautionary statements, if any.

16.4(3) Prescription sample drugs dispensed in the original container or package and provided without charge shall be deemed to conform to labeling and packaging requirements.