657—20.11(126) Bulk compounding.

20.11(1) *Master formula record.* Pursuant to the provisions of subrule 20.3(3), pharmacies may compound drugs in bulk quantities for subsequent prescription labeling and dispensing. For each drug product compounded in bulk quantity, a master formula record containing the following information shall be prepared:

a. Name of the product;
b. Specimen or copy of label;
c. List of ingredients and quantities;
d. Description of container used;
e. Compounding instructions, procedures and specifications.

20.11(2) *Production record.* For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

a. The information from the master formula record;
b. Records of each step in the compounding process including:
(1) Preparation date;
(2) Identification of ingredients (including lot numbers);
(3) Quantities of ingredients used;
(4) Initials of person completing each step;
(5) Initials of pharmacist verifying each step;
c. Expiration/beyond-use date;
d. Internal control number;
e. Total yield.

20.11(3) *Label information.* For each batch of drug product compounded, labels containing the following information shall be prepared and affixed to each container:

a. Drug product name or formula;
b. Dosage form;
c. Strength;
d. Quantity per container;
e. Internal control number;
f. Expiration/beyond-use date.