21 NCAC 46 .1416 REPACKAGING

(a) Drugs which are prepackaged from within a health care facility pharmacy for subsequent dispensing or administration shall be labeled to include:

(1) the generic or trade name, strength, and quantity of drug;
(2) identification of the manufacturer, and lot or control number;
(3) the expiration date of the drug being repackaged; and
(4) cautionary notations, if applicable.

(b) A batch number assigned by the pharmacy may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy maintains a readily retrievable record which identifies, by batch number, the manufacturer, manufacturer's expiration date, and lot number of the drug.

(c) The pharmacy shall have and use facilities, personnel, operational practices, packaging material, and control procedures to assure that the purity, integrity, safety, and effectiveness of the drugs are not affected by such repackaging. All repackaging must be performed by or under the supervision of a pharmacist.

History Note: *Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33;*
Eff. May 1, 1997;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.