

**Proposed Amendment to 02 NCAC 09 M .0101  
To be published in the NC Register 02/16/15**

**TEXT OF PROPOSED RULE:**

**02 NCAC 09M .0101 MANUFACTURER REGISTRATION**

- (a) Every person doing business in North Carolina and operating as a prescription drug manufacturer, outsourcing facility, repackager or wholesaler shall submit a completed prescription drug registration form to the department. A separate registration form shall be submitted for each establishment operating in the State of North Carolina. Each registration form shall be signed by the owner or individual in charge.
- (b) A fee of five hundred dollars (\$500.00) for ~~manufacturers~~, manufacturers, outsourcing facilities, or repackagers and a fee of three hundred fifty dollars (\$350.00) for wholesalers shall be submitted with each registration or renewal form.
- (c) On or before December 31 of each year, every person registered in accordance with Paragraph (a) of this Rule shall submit a renewal form furnished by the division.
- (d) Prescription Drug Registration Forms may be obtained from the Food and Drug Protection Division.
- (e) “Outsourcing facility” is defined as a facility at a single geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility with the Food & Drug Administration, and complies with the requirements as provided in 21 USC 353b; exemptions provided by 21 USC 353b(a) with respect to labeling, new drug registration and distribution supply chain requirements shall also apply to compounded drugs distributed in North Carolina by an outsourcing facility.

**EXPLANATION/REASON FOR PROPOSED RULE:**

This amendment addresses a change in the Federal Food Drug and Cosmetic Act that provides for the establishment, registration and regulation of voluntary outsourcing facilities that are engaged in the compounding of sterile drugs.

**HOW TO DEMAND A PUBLIC HEARING:**

Any person may request a public hearing on the proposed rule by submitting a request in writing no later than March 3, 2015, to Christina Waggett, Rulemaking Coordinator, NC Department of Agriculture, 1001 Mail Service Center, Raleigh, NC 27699-1001.

**INSTRUCTIONS ON HOW AND WHERE TO SUBMIT COMMENTS ON THE PROPOSED RULE:**

Written comments may be submitted to Christina Waggett, Rulemaking Coordinator, 1001 Mail Service Center, Raleigh, NC 27699-1001. Written comments may also be received via email (christina.waggett@ncagr.gov).