RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: Commissioner of Agriculture

RULE CITATION: 02 NCAC 09M .0101

RECOMMENDED ACTION:

Approve, but note staff's comment

X Object, based on:

X Lack of statutory authority

X Unclear or ambiguous

Unnecessary

Failure to comply with the APA

Extend the period of review

COMMENT:

G.S 106-140.1(h) provides authority to the Commissioner of Agriculture to charge an "annual registration fee of up to five hundred dollars ($500.00) for companies operating as manufacturers, wholesalers, or repackagers." The proposed Rule change in Paragraph (b) seeks to add a fee for "outsourcing facilities." G.S. 106-140.1(h) specifically defines "manufacturers," "repackagers" and "wholesalers" with no mention of "outsourcing facilities." As the outsourcing facility registration fee is not specifically allowed, nor is the term "outsourcing facility" specifically defined by G.S. 106-140.1, it is counsel's opinion that there is not authority to charge the annual registration fee for outsourcing facilities.

Further, in Paragraph (e) the Commissioner is proposing language to add a definition of "outsourcing facility" as set forth in 21 USC 353b(d)(4). The Submission for Permanent Rule Form indicates that "outsourcing facilities that compound and distribute drugs for office use are actually operating as a 'manufacturer' and 'wholesale distributer'"; however, the definition of "outsourcing facility" contained in Paragraph (e) of this Rule does not make it clear that outsourcing facilities can be acting as "manufacturers" or "wholesale distributers." Also, the fee for manufacturers is five hundred dollars ($500.00) while the fee for wholesalers is three hundred and fifty dollars ($350.00); therefore, while the proposed amendment would require a five hundred dollar ($500.00) fee for outsourcing facilities, it is unclear what fee will be charged if it is determined that an outsourcing facility is actually operating as a wholesaler. Further, it unclear whether an

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outsourcing facility can be considered a “repackager.” It is also unclear and how it is determined whether an outsourcing facility will be considered a “manufacturer,” “repackager,” or “wholesaler.” As such, it is also counsel’s opinion that Paragraph (e) of this Rule is unclear and ambiguous.

§ 106-140.1. Registration of producers of prescription drugs and devices.

(a) On or before December 31 of each year, every person doing business in North Carolina and operating as a wholesaler, manufacturer, or repackager, as those terms are defined in subsection (j) of this section, shall register with the Commissioner his name and business location(s) in North Carolina. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(b) Every person, upon first operating as a wholesaler, manufacturer or repackager in North Carolina shall immediately register with the Commissioner his name, place of business, and such establishment. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(c) Every person duly registered in accordance with subsections (a) and (b) of this section shall register with the Commissioner any additional establishment that he owns or operates in the State of North Carolina prior to doing business as a manufacturer, wholesaler or repackager.

(d) The Commissioner may assign a registration number to any person or any establishment registered in accordance with this section.

(e) The Commissioner shall make available for inspection to any person so requesting any registration filed pursuant to this section.

(f) The following classes of people are exempt from the registration requirements of this section:

(1) Pharmacists as defined in G.S. 90-85.3(q) holding a valid permit as defined in G.S. 90-85.3(m);

(2) Practitioners licensed or registered by law to prescribe or administer drugs and who manufacture, prepare, compound, or process drugs or devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale.

(4) Other classes of persons the Commissioner may by rule exempt from the application of this section upon a finding that registration by these classes of persons in accordance with this section is not necessary for the protection of the public health.

(5) Wholesale distributors of prescription drugs licensed under G.S. 106-145.3.

(g) Every establishment in the State of North Carolina registered with the Commissioner pursuant to this section shall be subject to inspection pursuant to G.S. 106-140.

(h) The Commissioner shall adopt rules to implement the registration requirements of this section. These rules may provide for an annual registration fee of up to five hundred dollars ($500.00) for companies operating as manufacturers, wholesalers, or repackagers. The Department of Agriculture and Consumer Services shall use these funds for the implementation of the North Carolina Food, Drug and Cosmetic Act.

(i) For the purposes of this act, name means the name of the partnership if a partnership and the name of the corporation if a corporation.

(j) As used in this section:

(1) The term "manufacturer" means a person who prepares, derives, or produces a prescription drug. Pharmacists are specifically excluded from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(2) The term "prescription drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription."

(3) The term "repackager" means a person who repacks, relabels, or manipulates a prescription drug which was in a unit packaged and sealed by a manufacturer. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(4) The term "wholesaler" means a person acting as a jobber, wholesale merchant, salvager, or broker, or agent thereof, who sells or distributes for resale a prescription drug. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it. (1987, c. 737, s. 2; 1989, c. 226, s. 2; 1989 (Reg. Sess., 1990), c. 1024, s. 20; 1991, c. 699, ss. 3, 4; 1997-261, s. 109.)

02 NCAC 09M .0101 is proposed for amendment as published in 29:16 NCR 1934-1935 as follows:

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.

History Note: *Authority G.S. 106-140.1;*
Eff. June 1, 1988;
Amended Eff. July 1, 2015; January 1, 1992.