21 NCAC 46 .1607 OUT-OF-STATE PHARMACIES

(a) In order to protect the public health and safety and implement G.S. 90-85.21A, the following provisions apply to out-of-state pharmacies that ship, mail, or deliver in any manner a dispensed legend drug, device, or medical equipment into this State.

(b) An out-of-state pharmacy may not ship, mail, or deliver in any manner even a single dispensed legend drug, device, or piece of medical equipment into this State until it receives a permit from the Board. All unpermitted dispensing must be disclosed on any permit application, and any permit applicant must update any application within 24 hours of any dispensing into this State that occurs while a permit application is pending. The Board may deny a permit based on that dispensing or on a failure to disclose it.

(c) In addition to the requirements contained in G.S. 85-21A, these pharmacies shall:

(1) supply all information requested by the Board in carrying out the Board's responsibilities under the statutes and rules pertaining to out-of-state pharmacies;

(2) during the pharmacy's regular hours of operation but not less than six days per week, for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients and pharmacists at the pharmacy who have access to the patient's records. This toll-free number must be disclosed on the label for each dispensed drug, device, or piece of medical equipment;

(3) comply with all USP and FDA requirements regarding the storage, packaging, and shipping of drugs, devices, and medical equipment;

(4) develop policies governing:

(A) normal delivery protocols and times;

(B) the procedure to be followed if the patient's drug, device, or medical equipment is not available at the out-of-state pharmacy, or if delivery will be delayed beyond the normal delivery time;

(C) the procedure to be followed upon receipt of a prescription for a condition that requires treatment before the drug, device, or medical equipment would be delivered in the normal delivery time, which shall include a procedure for delivery of the drug, device, or medical equipment to the patient from the out-of-state pharmacy at the earliest possible time (such as courier delivery), or an alternative that assures the patient the opportunity to obtain the drug, device, or medical equipment at the earliest possible time; and

(D) the procedure to be followed when the out-of-state pharmacy is advised that the patient's drug, device, or medical equipment has not been received within the normal delivery time and that the patient is out of the drug, device, or medical equipment and requires interim dosage until the pharmacy can provide the drug, device, or medical equipment;

(5) disclose the location, names, and titles, of all officers and direct and indirect owners of the pharmacy. Disclose the names and license numbers of all pharmacists dispensing drugs, devices, or medical equipment to an ultimate user in this State, the names and, if available, license or registration numbers of all pharmacy personnel employed by the out-of-state pharmacy who assist pharmacists in dispensing. The pharmacist-manager for the out-of-state permit issued by this Board must be the same person as the pharmacist-manager (whether called a pharmacist-manager, a person-in-charge or otherwise) of the pharmacy on the permit issued by the pharmacy's home state. A report containing this information shall be made on an annual basis and within 30 days of each change of any pharmacist-manager, officer, or owner (whether direct or indirect) of the pharmacy. A new permit shall be required under the circumstances set out in Rule .1603 of this Section, and a new permit must be secured before any legend drugs, devices, or medical equipment may be dispensed into the State of North Carolina following any of the enumerated changes in circumstances. The existing permit becomes void upon one of the events in Rule .1603, and any dispensing into the State of North Carolina following one of those events is unlawful and grounds for denial of a new permit;

(6) submit evidence of possession of a valid license, permit, or registration as a pharmacy in compliance with the laws of the state in which the pharmacy is located;

(7) designate a registered office and registered agent in North Carolina for service of process pursuant to Article 4 of Chapter 55D of the North Carolina General Statutes. The Board may serve or deliver any notice or other document provided for under the Pharmacy Practice Act or these Rules on that registered agent. The Board may further serve or deliver any notice or other document provided for under the Pharmacy Practice Act or these Rules on the Secretary of State when the

Secretary of State becomes an agent of the entity pursuant to Article 4 of Chapter 55D of the North Carolina General Statutes; and

(8) notify the Board within five days of receipt of any order or decision by a Board of Pharmacy or other state or federal agency imposing discipline of any sort on the pharmacy, or receipt of any warning letter from the Food and Drug Administration.

(d) The facilities and records of an out-of-state pharmacy shall be subject to inspection by the Board. The Board also may require submission of inspection reports by the licensing entity of the state in which the pharmacy is located or records transmitted by the pharmacy to the Board offices.

(e) Any person who ships, mails, or delivers prescription drugs to North Carolina residents from more than one out-of-state pharmacy location shall register each pharmacy separately.

(f) An out-of-state permit holder may be disciplined as set forth in the Pharmacy Practice Act. The suspension or revocation of the pharmacy's home state permit will result in the immediate suspension or revocation of the out-of-state permit issued by this Board.

(g) An out-of-state pharmacy permit shall expire on December 31 of each year.

(h) The fees provided for in G.S. 90-85.21A as maximum fees which the Board is entitled to charge and collect are hereby established as the fees for each original permit and for annual renewal of each permit.

History Note: *Authority G.S. 90-85.6; 90-85.15A; 90-85.21A; 90-85.22; 90-85.26; 90-85.30; 90-85.32;*
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