

TITLE 21 - OCCUPATIONAL LICENSING BOARDS AND COMMISSIONS

CHAPTER 46 – BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the Board of Pharmacy intends to amend the rules cited as 21 NCAC 46 .1606 and .1607.

Link to agency website pursuant to G.S. 150B-19.1(c): www.ncbop.org/rulemakings.htm

Proposed Effective Date: April 1, 2022

Public Hearing:

Date: February 8, 2022

Time: 10:00 a.m.

Location: *The public hearing will be held remotely. The public can participate on Teams at <https://tinyurl.com/jsuk4bjk> or may call 336-604-5350, conference ID 903 191 899#.*

Reason for Proposed Action: *The current rules require the pharmacist-manager for each permit applicant to meet personally with Board staff before the Board will grant a permit. These meetings have traditionally been a means of imparting knowledge about North Carolina pharmacy law and Board procedures. These meetings are an inefficient way to provide that information, and the result of that burden has been that out-of-state permit applicants often have not named their actual pharmacist-manager as the pharmacist-manager on their North Carolina applications, thereby creating a disconnect between the person who is legally responsible for their compliance with North Carolina law and the person who actually supervises the pharmacy. The principal purposes of the proposed changes are to substitute an on-line educational module in place of the in-person meeting, and to require that the pharmacist-manager on the North Carolina permit match the pharmacist-manager in the pharmacy's home state. In addition, Rule .1607 concerning out-of-state pharmacy permits has not been revised in 15 years. The Board has proposed general updates to that Rule largely in order to (a) clarify and emphasize certain matters that have been subject to periodic questions from the regulated entities, (b) more accurately reflect modern Board procedures and practices, (c) remove repetitive requirements contained elsewhere, and (d) refer to other laws and rules covering certain matters, rather than attempting to restate them, which has resulted in incomplete, inconsistent and confusing descriptions of those laws.*

Comments may be submitted to: Jay Campbell, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; fax (919) 246-1056; email ncboprulmaking@ncbop.org

Comment period ends: February 14, 2022

Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission after the adoption of the Rule. If the Rules Review Commission receives written and signed objections after the adoption of the Rule in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

- State funds affected
- Local funds affected
- Substantial economic impact (\geq \$1,000,000)
- Approved by OSBM
- No fiscal note required

SECTION .1600 - LICENSES AND PERMITS

21 NCAC 46 .1606 ~~REQUIREMENT OF PERSONAL APPEARANCE~~ NORTH CAROLINA-SPECIFIC EDUCATION FOR PERMIT APPLICANTS

Prior to issuance of any original pharmacy permit or device and medical equipment permit, ~~the following persons must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff:~~

- (1) the pharmacist-manager for the applicant pharmacy or ~~pharmacy;~~ and
- (2) the person in charge of the facility applying for the device and medical equipment ~~permit.~~ permit shall complete an educational module on the North Carolina Pharmacy Practice Act and its regulations that govern the operation of permits. That educational module is available in the on-line permit application section of the Board's Licensure Gateway. The pharmacist-manager or person in charge must personally complete the educational module and may not delegate this responsibility to any other person.

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~~ 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 medical equipment into this State unless and until it receives a permit from this 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 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.

~~(b)(c)~~ Pursuant to G.S. 90-85.21A, an out-of-state pharmacy must comply with the provisions of the Pharmacy Practice Act and its regulations, as well as the provisions of the laws of the state in which the pharmacy is located. In addition, these Such pharmacies shall:

- ~~(1)~~ Maintain, in readily retrievable form, records of prescription drugs dispensed to North Carolina residents;
- ~~(2)~~(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;
- ~~(3)~~(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 medical equipment; affixed to each container of dispensed drugs;
- ~~(4)~~(3) Comply with all USP and FDA requirements regarding the storage, packaging, and shipping of drugs, devices and medical equipment; prescription medications;
- ~~(5)~~(4) Develop policies governing:
 - (A) normal delivery protocols and times;
 - (B) the procedure to be followed if the patient's ~~medication~~ 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 an acute illness, which shall include a procedure for delivery of the ~~drug, device, or medical equipment~~ medication 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~~ medication at the earliest possible time; and
 - (D) the procedure to be followed when the out-of-state pharmacy is advised that the patient's ~~medication~~ drug, device, or medical equipment has not been received within the normal delivery time and that the patient is out of ~~medication~~ the drug, device, or medical equipment and requires interim dosage until the pharmacy can provide the drug, device, or medical equipment; mail prescription drugs become available;
- ~~(6)~~(5) Disclose the location, names, and titles, of all ~~officers principal corporate officers, if incorporated, and if unincorporated, partners, or owners (whether direct or indirect)~~ of the pharmacy. Disclose the names and license numbers of all pharmacists dispensing ~~drugs, devices, or medical equipment~~ prescription legend drugs to an ultimate user in this State, the names and, if available, license or registration numbers of all ~~supportive pharmacy~~ pharmacy personnel employed by the out-of-state pharmacy who assist such pharmacists in such 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 ~~principal office, pharmacist-manager of any location dispensing prescription legend drugs to an ultimate user in this State, principal corporate officer if incorporated, and if unincorporated, partner pharmacist-manager, officer, or owner (whether direct or indirect)~~ of the pharmacy. A new ~~registration 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 of this Section, and any dispensing into the State of North Carolina following one of those events is unlawful and grounds for denial of a new permit; for a change of ownership of an established pharmacy to a successor business entity which results in a change in the controlling interest in the pharmacy;
- ~~(7)~~(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; located.~~ Such evidence shall consist of one of the following:
 - (A) a copy of the current license, permit, or registration certificate issued by the regulatory or licensing agency of the state in which the pharmacy is located; or
 - (B) a letter from the regulatory or licensing agency of the state in which the pharmacy is located certifying the pharmacy's compliance with the pharmacy laws of that state;
- ~~(8)~~(7) Designate a ~~resident~~ registered office and registered agent in North Carolina for service of ~~process.~~ 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; Any such out of state pharmacy that does not so designate a resident agent shall be deemed to have appointed the Secretary of State of the State of North Carolina to be its true and lawful attorney upon whom process may be served. All legal process in any action or proceeding against such pharmacy arising from shipping, mailing or delivering prescription drugs in North Carolina shall be served on the resident agent.

~~In addition, a copy of such service of process shall be mailed to the out-of-state pharmacy by certified mail, return receipt requested, at the address of the out-of-state pharmacy as designated on the registration form filed with the Board. Any out-of-state pharmacy which does not register in this State, shall be deemed to have consented to service of process on the Secretary of State as sufficient service.~~

(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; and

(9) Within five days of receipt, provide the Board with any inspection report from any other state's board of pharmacy or other agency that regulates the pharmacy, the Food and Drug Administration, or the National Association of Boards of Pharmacy.

~~(e)(d)~~ The facilities and records of an out-of-state pharmacy shall be subject to inspection by the Board; provided however, the Board may accept in lieu thereof ~~satisfactory~~ inspection reports by the licensing entity of the state in which the pharmacy is ~~located~~. located or records transmitted by the pharmacy to the Board offices.

~~(d) An out-of-state pharmacy shall comply with the statutes and regulations of the state in which the pharmacy is located.~~

(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 pursuant to G.S. 90-85.38(b) based on the conduct of its pharmacy personnel, even if those pharmacy personnel are not licensed or registered with the Board. 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. Prior to original registration, a pharmacist who is an authorized representative of the pharmacy's owner must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff. Such authorized pharmacist may represent all pharmacies having the same ownership.

~~(g) An out-of-state pharmacy shall report to the Board information that reasonably suggests that there is a probability that a prescription drug or device dispensed from such out-of-state pharmacy has caused or contributed to the death of any patient. The report shall be filed in writing on a form provided by the Board within 14 days of the pharmacy becoming aware of the death. The Board may not disclose the identity of any person or entity making the report, except when it is necessary to protect life or health of any person. No such report in possession of the Board shall be discoverable or admissible into evidence or otherwise used in any civil action involving private parties, except as otherwise required by law.~~

~~(h) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew registration to an out-of-state pharmacy if such pharmacy has:~~

- ~~(1) made false representations or withheld material information in connection with obtaining registration;~~
- ~~(2) been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs;~~
- ~~(3) made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person;~~
- ~~(4) failed to comply with this Rule;~~
- ~~(5) been the subject of a negligence complaint resulting from the dispensing of prescription drugs to a resident of North Carolina and based on an investigation of such complaint been found to be negligent:~~
 - ~~(A) by the Board of Pharmacy of the state in which the pharmacy is located;~~
 - ~~(B) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located failed to initiate an investigation of such complaint within 45 days after referral of the complaint from the North Carolina Board of Pharmacy; or~~
 - ~~(C) by the North Carolina Board of Pharmacy if the Board of Pharmacy of the state where the pharmacy is located initiates an investigation of such complaint within 45 days, but later advises the North Carolina Board that it will not make a determination of negligence or that it has made no determination of the issue of negligence within one year after referral of the complaint and has discontinued any active investigation or proceeding for such determination. In any disciplinary proceeding based on negligence, the standard of practice shall be that applicable in the state in which the pharmacy is located. In disciplinary proceedings pursuant to Part (h)(5)(A) of this Rule, the Board shall adopt the findings of negligence by the Board of Pharmacy of the state in which the pharmacy is located as part of the Board's final decision without producing its own evidence of negligence.~~

~~(i) An out-of-state pharmacy shall notify the Board within five days of receipt of any order or decision by a Board of Pharmacy imposing disciplinary action on the pharmacy. Notwithstanding the provisions of Paragraph (h) of this Rule, if the permit or registration in the state where the pharmacy is located is suspended or revoked, then the pharmacy's registration in North Carolina will be immediately suspended or revoked for the same period of time.~~

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

~~(k)(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 registration permit and for annual renewal of each permit. ~~registration.~~

Authority G.S. 90-85.6; 90-85.15A; 90-85.21A; 90-85.22; 90-85.26; 90-85.28; 90-85.29; 90-85.30; 90-85.32.