REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1503

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 4, is the 1500 hours of practical experience required meant to fulfil the one year of experience required by G.S. 90-85.15(b)(2)?*

*In (b)(2), line 16, for my knowledge, what is the difference between "a location holding a pharmacy permit" and "a location approved by the Board for that purpose"? I'm assuming "that purpose" is obtaining practical experience, correct?*

*In (d), p.2, line 15, what kind of "proof of eligibility" will the Board require? Can you provide some examples of what will be accepted?*

*In (e), line 19, the Rule states that the registration must be renewed "during the month prior to the September 1 on which the registration expires." Does "month" mean 30 days, or does it mean you will be accepting renewal applications from August 1 to August 31?*

*In (f), line 24, omit the comma between "intern" and "and".*

*In (g), line 34, what does the phrase "training in pharmacy" refer to? Is this practical experience?*

*Also generally to (g), I am confused by the meaning of this sentence. How can the Board accept training gained in another state pursuant to an internship registration in this State?*

*In (h) and (i), on pp 2-3, the Rule refers to a "pharmacist preceptor," a "supervising pharmacist," and a "pharmacist-manager." Other than "pharmacist-manager," I don't believe these terms are defined in your Rules or in G.S. 90-85.3. Are these all different roles?*

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

*In (i), p.3, lines 3 and 6, the Rule states that a pharmacist preceptor or pharmacist-manager could be subject to discipline, but does not refer to "supervising pharmacist." Is there a reason this term was left out of (i)?*

*In (i), lines 4 and 6, please add the oxford comma between "rules" and "or".*
*In (i), lines 4 and 6, does "regulations" refer to federal regulations?*

*In (i), lines 5 and 8, the preceptor or manager who is subject to discipline forfeits his or her right to supervise interns "for a period of time determined by the Board." How is this determined?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1503 is amended as published in 36:12 NCR 1049 as follows:

**21 NCAC 46 .1503 EXPERIENCE IN PHARMACY AND PHARMACY INTERNSHIP**

(a) An applicant for license must show that ~~he~~ the applicant has received 1500 hours of practical experience under the supervision of a licensed pharmacist which has been acquired while enrolled in a school of pharmacy accredited by the Accreditation Council for Pharmacy Education. ~~after the satisfactory completion of two years of college work. The Board shall accept hours of experience certified by the school from which the applicant has graduated.~~

(b) All practical pharmacy experience gained within the State of North Carolina ~~to be acceptable~~ must be acquired ~~under the general conditions approved by the Board~~ as follows:

(1) All practical pharmacy experience must be validated through registration in the internship program administered by the Board. A person does not receive credit for any practical experience unless and until that person is registered with the Board as a pharmacy intern.

(2) ~~Persons working under the supervision of registered pharmacists and expecting to qualify for the registered pharmacist examination must notify the Board within five days of the beginning and the ending of such employment.~~ Practical experience shall be credited only when it has been obtained in a location holding a pharmacy permit, or a location approved by the Board for that purpose, and only after the pharmacy intern notifies the Board of the location of the practical experience. If the pharmacy intern's location of employment changes, the pharmacy intern must notify the Board of the change before commencing an internship at the new location.

(3) The person acquiring practical experience shall at all times comply with the Board's rules and the laws governing the practice of pharmacy and the distribution of drugs. Failure of the pharmacist intern to do so is grounds to disqualify the experience from counting toward the minimum requirements.

~~(3)~~(4) The Board shall accept hours of experience certified by the school from which the applicant has graduated, provided that the applicant has satisfied the foregoing Subparagraphs of Paragraph (b). The Board shall not allow credit for claims of practical experience required under the pharmacy laws, unless such claims can be corroborated by records on file in the Board's office showing the beginning and the ending of the practical experience claimed as supplied by the applicant during this training period.

~~(4) Practical experience shall be credited only when it has been obtained in a location holding a pharmacy permit, or a location approved by the Board for that purpose.~~

(c) A person is eligible to register or renew and be employed as a pharmacy intern only if, and so long as, the person is:

(1) Currently enrolled in a pharmacy school accredited by the Accreditation Council for Pharmacy Education. In order to qualify as "enrolled" in a pharmacy school, the student must be attending pharmacy school at the time, or on a break between academic terms;

(2) A graduate of a foreign school of pharmacy who has successfully completed the Foreign Pharmacy Graduate Equivalency Examination offered by the National Association of Boards of Pharmacy and the Test of English as a Foreign Language and who is acquiring the practical experience required for licensure;

(3) A pharmacist licensed in another state who is gaining practical experience required for a license by reciprocity under Rule .1602 of this Chapter;

(4) A pharmacist with an inactive North Carolina license who is gaining practical experience required for reinstatement of a license under Rule .1612 of this Chapter;

(5) A graduate of a school of pharmacy who has not been licensed in any State, who has not been denied a license in any State, who has an active application for licensure to practice pharmacy in North Carolina and who has met all requirements for licensure other than taking and passing the North American Pharmacist Licensure Examination and the Multistate Pharmacy Jurisprudence Examination, and who is gaining practical experience to prepare for the examination in order to achieve licensure.

(d) In order to register or renew as a pharmacy intern, an applicant must submit proof of eligibility under Paragraph (c) of this Rule. The applicant further must provide releases for the Board to verify the applicant's eligibility, including confirming enrollment in or graduation from pharmacy school.

(e) Pharmacy intern registrations are valid until the September 1 immediately following registration. If the person remains eligible for registration as a pharmacy intern, the registration must be renewed during the month prior to the September 1 on which the registration expires. If the registration expires for a pharmacy intern, that person is not eligible to work as a pharmacy intern in the State of North Carolina unless and until the registration is reinstated after a new application.

(f) If a pharmacy intern ceases to be eligible to be registered and employed as a pharmacy intern under Paragraph (c) of this Rule, that person must immediately cease working as a pharmacy intern, and must notify the Board within five calendar days of a change in status and request that the person's registration be made inactive.

~~(c) The pharmacist intern, or student, and the pharmacist preceptor, or supervising pharmacist, shall at all times comply with the Board's rules and the laws governing the practice of pharmacy and the distribution of drugs. Failure of the pharmacist intern to do so is grounds to disqualify the period of experience from counting toward the minimum requirements. A pharmacist preceptor who causes or permits a pharmacist intern to violate the Board's rules or the laws governing the practice of pharmacy and the distribution of drugs forfeits his right to supervise such experience for a period of time determined by the Board. A pharmacist who has been found in violation of laws, rules, or regulations governing the practice of pharmacy and the distribution of drugs cannot serve as a preceptor without the approval by the Board.~~

~~(d)~~(g) The Board may accept training in pharmacy gained in another state pursuant to internship registration in this or another state if the Board is satisfied that such training is equivalent.

(h) A registered pharmacy intern working under a pharmacist preceptor or supervising pharmacist may, while under supervision of that pharmacist, perform all acts constituting the practice of pharmacy. Because the pharmacy intern

may perform all acts constituting the practice of pharmacy under supervision under this provision, doing so without being registered with the Board is the unlicensed practice of pharmacy.

(i) A pharmacist preceptor or pharmacist-manager who causes or permits a pharmacy intern to violate any laws, rules or regulations applicable to the practice of pharmacy or the distribution of drugs forfeits his or her right to supervise pharmacy interns for a period of time determined by the Board and is subject to additional disciplinary action. A pharmacist preceptor or pharmacist-manager who violates any laws, rules or regulations applicable to the supervision of pharmacy interns forfeits his or her right to supervise pharmacy interns for a period of time determined by the Board and is subject to additional disciplinary action. This includes, but is not limited to, making false representations or withholding material information about the pharmacy intern's practical experience or employing a pharmacy intern who is not registered with the Board. A pharmacist who has been found in violation of laws, rules, or regulations governing the practice of pharmacy and the distribution of drugs cannot serve as a preceptor without the approval by the Board.

(j) The Board may consider any of the acts set forth in G.S. 90-85.38(a) that are committed by a pharmacy intern in considering whether to grant that person a license to practice pharmacy or what conditions are appropriate to ensure that the person can practice pharmacy safely.

(k) The practical experience hours gained prior to the effective date of any amendment to this Rule are governed by the requirements of this Rule in effect at the time the hours were obtained.

*History Note:* *Authority G.S. 90-85.6; 90-85.14; 90-85.15; 90-85.38;*
*Eff. April 1, 1983;*
*Amended Eff. March 1, 2004; September 1, 1993; April 1, 1992; October 1, 1990; May 1, 1989;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017. 2017;*
*Amended Eff. May 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1606

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*On line 10, please replace "its" with "the" or "the Board's".*

*On lines 11-12, the Rule states that the educational module is available in the online permit application section of the Board's Licensure Gateway. I looked at your Rules regarding permitting, and I didn't see anything (other than applications are to be submitted on forms provided by the Board), indicating whether the Board still accepts paper applications. If so, will this module be available to someone who hasn't otherwise made an online application?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1606 is amended as published in 36:12 NCR 1052 as follows:

**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.

*History Note:* *Authority G.S. ~~90-18.1; 90-18.2; 90-85.3(a),(r);~~ 90-85.6; 90-85.21; 90-85.21A; 90-85.22;*
*Eff. April 1, 1994;*
*Amended Eff. April 1, 2003; April 1, 1999; September 1, 1995;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;*
*Amended Eff. May 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1607

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*Were the changes made post-publication made in response to public comment? Are they substantial changes as defined by G.S. 150B-21.2(g)?*

*Throughout the Rule, consider correcting usage with respect to "medical equipment." For instance, in (a), line 5-6, the Rule says "…a dispensed legend drug, device, or medical equipment…." Perhaps consider something along the lines of a "**piece** of medical equipment" or an "**article** of medical equipment"?*

*In (b), line 7, is it necessary to say "**even a single** dispensed legend drug…"?*

*In (b), line 8, please consider revising "unless and until" to either "unless" or "until".*

*In (b), line 8, replace "this Board" with "the Board".*

*In (b), line 9, delete the comma following "application."*

*In (b), line 10, the Rule requires the applicant to update any application within 24 hours of "any dispensing" that occurs during the pendency of the application. Do you mean "any dispensing **in this State**"?*

*In (c), line 14, please change "G,S.," to "G.S."*

*For the list at (c)(1)-(8), please format so that the list comprises a single sentence—capitalize only the first word of the sentence in (c), use lowercase to begin each subsequent item, end the second to last item with "and" or "or," and punctuate with semicolons following each item except the last, which gets a period. Otherwise, you may format such that each item is itself a complete sentence, in which case you can keep the first word of each item capitalized, but should end each item with a period, and remove the "and" following the second to last item.*

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

*In (c)(3), line 25, add an oxford comma between "devices" and "and".*

*In (c)(4)(B), line 30, and in (c)(4)(D), p. 2, lines 2-3, please define "normal delivery time".*

*In (c)(4)(C), line 31, please define "acute illness".*

*In (c)(5), p. 2, line 7, please remove the parentheses and incorporate the parenthetical material into the body of the Rule.*

*In (c)(5), line 11, please consider removing both instances of "such", as they are unnecessary and the use of the word "such" is discouraged.*

*In (c)(5), line 12, please revise "this Board" to "the Board".*

*In (c)(5), line 20, add an oxford comma after "devices".*

*In (d), line 19, under what circumstances may the Board accept or not accept inspection reports by the out-of-state licensing entity?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1607 is amended with changes as published in 36:12 NCR 1052 as follows:

**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 to the requirements contained in G,S., 85-21A, [~~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 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; and ~~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. [~~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.~~]

~~(c)~~(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 as set forth in the Pharmacy Practice Act. [~~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.~~

*History Note:* *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;*
*Eff. July 1, 1994;*
*Amended Eff. March 1, 2006;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;*
*Amended Eff. May 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1612

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a), line 6, the Rule states that licenses/registrations that are not renewed by March 1 "of the succeeding year" lapse. This may seem obvious, but I would suggest for clarity, editing to say "the year following issuance" or something similar, so it's clear what this language is referring to.*

*In (d), line 17, please add the oxford comma following "permit."*

*In (e), lines 21 and 22, the Rule requires applicants for restatement to obtain continuing education "in addition to that required by Rule .2201" and "practical pharmacy experience," among other things. How much extra CE will the Board require, and how will that number be determined? Further, how much practical pharmacy experience is required? Is the requirement that the applicant fulfil the 1500 hours mentioned in R .1503?*

*In (f), line 26, how will the Board determine what length of time is necessary to restrict the license?*

*In (g), line 27, the Rule requires submission of a "signed release form." Release of what?*

*In (g), line 28, what "other forms" will be necessary for a criminal history check?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1612 is amended as published in 36:12 NCR 1049 as follows:

**21 NCAC 46 .1612 REINSTATEMENT OF LICENSES AND PERMITS**

(a) ~~All licenses and registrations issued to individuals~~ Pharmacist licenses, pharmacy technician registrations, dispensing physician registrations, dispensing physician assistant registrations, and dispensing nurse practitioner registrations that are not renewed by March 1 of the succeeding year, lapse and are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.24 in order to be reinstated.

(b) All pharmacy permits and device and medical equipment ~~permits and registrations issued to locations~~ that are reinstated after March 1 and prior to April 1 of the succeeding year are subject to the maximum reinstatement and renewal fees set out in G.S. 90-85.21A and 90-85.24. After March 31, ~~permits and registrations issued to locations~~ holders of lapsed permits shall submit new applications and are subject to the maximum original registration fees. ~~This Rule also applies to licenses, registrations, and permits reinstated following voluntary surrender or disciplinary action by the Board.~~

~~(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.~~

(c) Pharmacy intern registrations are governed by Rule .1503 of this Chapter.

(d) In order to apply to have a license, permit or registration reinstated following a voluntary surrender or disciplinary action, the applicant must complete a reinstatement application and pay the maximum reinstatement fee allowed by G.S. 90-85.24.

~~(c)~~(e) The Board shall require applicants for reinstatement of a lapsed license who have not practiced pharmacy within two years prior to application for reinstatement to obtain continuing education in addition to that required by Rule .2201 of this Chapter, practical pharmacy experience, successfully complete one or more parts of the Board's licensure examination, or a combination of the foregoing, as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

~~(d)~~(f) The Board shall also restrict licenses reinstated pursuant to G.S. 90-85.19 for such period of time as the Board deems necessary to ensure that the applicant can safely and properly practice pharmacy.

(g) All applicants for reinstatement of a license shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application. If the applicant withdraws the reinstatement application or the Board denies it, no fees will be refunded to the applicant.

*History Note:* *Authority G.S. 90-85.6; 90-85.15A; 90-85.17; 90-85.19; 90-85.21; 90-85.21A; 90-85.22; 90-85.24;*
*Eff. April 1, 1999;*
*Amended Eff. March 1, 2006; July 1, 2005;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, ~~2017.~~ 2017;*

*Amended Eff. May 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1613

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*In (a)(1), does the reference to "pharmacist vaccinator" include "immunizing pharmacists" as defined by G.S. 90-85.15B? If so, do you need a citation to that statute in the History Note?*

*In (a)(3), line 14, please change "U.S. Code" to "U.S.C."*

*In (a)(4), line 15, please add the oxford comma following "revoked".*

*In (b), line 17, I believe "fee" should be plural.*

*In (b)(5), what kind of proof of eligibility will the Board require?*

*In the History Note, I am a little confused by the reference to G.S. 90-85.21(b). Did you mean 90-85.21B?*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1613 is amended as published in 36:12 NCR 1049 as follows:

**21 NCAC 46 .1613 EXTENSION PERIOD FOR CERTAIN MEMBERS OF THE ARMED FORCES**

(a) Definitions:

(1) "Eligible licensee" means a pharmacist who holds a license in good standing from the Board of Pharmacy, who serves the armed forces of the United States, and who is eligible for an extension of time in which to file a tax return pursuant to G.S. 105-249.2. "Eligible licensee" includes a pharmacist who holds a Clinical Pharmacist Practitioner credential or who is a pharmacist vaccinator.

(2) "Eligible registrant" means a pharmacy intern, pharmacy technician, dispensing physician, dispensing nurse practitioner or dispensing physician assistant who holds a registration in good standing from the Board of Pharmacy, who serves the armed forces of the United States, and who is eligible for an extension of time in which to file a tax return pursuant to G.S. 105-249.2.

(3) "Extension period" means the time period specified in 26 U.S. Code 7508.

(4) "Good standing" means a license or registration that is not suspended, revoked or subject to a current disciplinary order.

(b) Extension of time to pay license or registration renewal fee and waiver of continuing education requirements:

(1) An eligible licensee or registrant shall notify the Board of eligibility for the extension period before his or her current license or registration expires. Upon such notification, the Board shall maintain the license or registration in active status through the extension period.

(2) If an eligible licensee or registrant fails to notify the Board of eligibility for the extension period before his or her current license or registration expires, upon receipt and acceptance of a renewal application within the extension period and presentation of proof that the licensee or registrant was an eligible licensee or registrant on the date that is the deadline for renewal, the expired license or registration shall be deemed retroactively to have not expired.

(3) Notwithstanding 21 NCAC 46 .1612(a) and .3301(a), an eligible licensee or registrant who submits a renewal application and pays the renewal fee required by the Board within the extension period shall not be deemed to hold a lapsed license or registration subject to reinstatement fees.

(4) Notwithstanding 21 NCAC 46 .2201, .3101(d) and .2507(d), an eligible licensee may renew his or her license within the extension period despite failing to complete the specified continuing education requirements.

(5) A licensee or registrant shall provide proof of eligibility for the extension period when the licensee or registrant submits the renewal application.

*History Note:* *Authority G.S. 90-18.1; 90-18.2; 90-85.6; 90-85.15A; 90-85.17; 90-85.21(b); 90-85.24; 90-85.26A; 93B-15;*
*Eff. April 1, 2010;*

*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. October 3, 2017.* ~~*2017.*~~ *2017;*

*Amended Eff. May 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: North Carolina Board of Pharmacy

RULE CITATION: 21 NCAC 46 .1615

**DEADLINE FOR RECEIPT: Friday, April 8, 2022.**

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

*Is (b) necessary? I don't see that it meets the definition of a "Rule" in G.S. 150B-2(8a).*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Brian Liebman
Commission Counsel
Date submitted to agency: March 25, 2022

21 NCAC 46 .1615 is amended as published in 36:12 NCR 1049 as follows:

**21 NCAC 46 .1615 E-PROFILE NUMBER REQUIRED FOR LICENSE, PERMIT, OR REGISTRATION**

(a) As part of the application for issuance or renewal of any in-state or out-of-state pharmacy permit, device and medical equipment permit, license to practice pharmacy, pharmacy intern registration, or pharmacy technician registration issued by the Board, the permittee, licensee, or registrant must report an e-Profile number to the Board.

(b) An e-Profile number is a unique identifier for permittees, licensees, and registrants that allows for the accurate identification and collection of licensure, disciplinary, inspection, and other information in a secured electronic profile.

(c) ~~A~~ An applicant, permittee, licensee, or registrant may obtain an e-Profile number at no cost by contacting the National Association of Boards of Pharmacy by phone at (847) 391-4406; by mail at 1600 Feehanville Drive, Mount Prospect, Illinois 60056; or electronically at www.nabp.pharmacy.

~~(d) Any person or entity holding a permit, license, or registration as of the effective date of this rule must obtain an e-Profile number prior to renewal of the permit, license, or registration for 2018.~~

*History Note:* *Authority G.S. 90-85.6; 90-85.14; 90-85.15; 90-85.15A; 90-85.17; 90-85.20; 90-85.21; 90-85.21A; 90-85.22.*
*Eff. May 1, ~~2017.~~ 2017;*
*Amended Eff. May 1, 2022.*