

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 .1503, .1612, .1613, and .1615.

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 Pharmacy Practice Act requires all applicants for initial licensure and certain reinstatement and reciprocity candidates to complete practical experience in order to be licensed, and further requires the Board of Pharmacy to adopt regulations to "assure that the person successfully completing the program will have gained practical experience that will enable him to safely and properly practice pharmacy." NCGS 90-85.14. Those gaining practical experience are regularly and collectively referred to as "pharmacy interns." The Board has proposed to amend Rule .1503 to provide for a uniform system by which those gaining practical experience can sign up with the Board and can easily document and verify their practical experience hours through an on-line system. Moreover, in recent years, a handful of individuals have falsely claimed to be pharmacy students or recent graduates who were entitled to work as pharmacy interns, who are allowed to engage in all acts constituting the practice of pharmacy under the supervision of pharmacists. These individuals who lacked pharmacy educational training thereby created a risk of harm to the public safety, health and welfare in order to defraud their employers. This was made easier because, previously, in order to verify whether an individual was entitled to work as a pharmacy intern, that individual's prospective employer would have to contact pharmacy schools directly. The new uniform system will make it easier to ensure that only those who are entitled to work as pharmacy interns are able to do so. In addition to amending Rule .1503, the Board has proposed to adopt conforming amendments to other rules to appropriately reference and account for the changes to Rule .1503.*

Comments may be submitted to: Jay Campbell, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; fax (919) 246-1056; email ncboprulemaking@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 .1500 - ADMISSION REQUIREMENTS: EXAMINATIONS

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.
- ~~(e)~~ 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.

Authority G.S. 90-85.6; 90-85.14; 90-85.15; 90-85.38.

SECTION .1600 - LICENSES AND PERMITS

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.~~

~~(e)~~ (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.

~~(f)~~ (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.~~

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.

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.

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.

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.~~

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.