Guide to North Carolina-Specific Pharmacy Regulation for New Licensees

Congratulations on becoming a North Carolina-licensed pharmacist. As you know, the Board accepts a passing score on the Uniform Multistate Pharmacy Jurisprudence Exam ("UMPJE") as a qualifier for licensure.

This guide provides an overview of state-specific regulation that is not tested by the UMPJE to new North Carolina pharmacists. Familiarity with this material is essential to safe and competent practice in the state.

This guide is not a comprehensive guide to regulation of pharmacy practice in North Carolina. Many more resources are found on the Board's website (www.ncbop.org), and you should consult those resources frequently. Board staff are also always available to assist. A guide to the Board's staff (including specific areas of responsibility and expertise) here: https://www.ncbop.org/meet-our-board.html#administrativestaff

I. Composition of the North Carolina Board of Pharmacy

A. Board Members

1. Board is composed of six members. G.S. §§ 90-85.3 & 85.6.

2. Five members are elected. Each must be a licensed pharmacist in N.C. and a resident of the state when elected and throughout their term. Elected members may serve two consecutive five-year terms.

3. The Governor appoints a public member. The public member may not be a "health care provider or the spouse of a health care provider." A "health care provider is "any licensed health care professional; any agent or employee of any health care institution, health care insurer, health care professional school; or a member of any allied health profession." G.S. § 90-85.3(i).

4. Information about each Board member: https://www.ncbop.org/meet-our-board.html

B. Executive Director

1. The Board employs an Executive Director.

2. The Executive Director serves as secretary and treasurer of the Board, performs any administrative tasks delegated by the Board, investigates and, if necessary, prosecutes violations of the Pharmacy Act. G.S. § 90-85.10

C. Board Staff

1. The Board employees licensing staff, inspection staff, and investigative staff.

2. A staff directory that includes areas of responsibility: https://www.ncbop.org/meet-our-board.html

II. Licenses, Registrations, and Permits

A. Individual Practitioners

1. Licensing of Pharmacists

   a. Qualifications: https://www.ncbop.org/licensurebyexam.html and https://www.ncbop.org/licensurebyreciprocity.html

   b. Any pharmacist located in North Carolina performing acts that are the practice of pharmacy must hold a North Carolina license to practice pharmacy.

   c. A pharmacist employed by a pharmacy that holds an out-of-state pharmacy permit may provide services connected to dispensing from that pharmacy without holding an individual license to practice pharmacy. G.S. § 90-85.21A

   d. An out-of-state pharmacist providing only remote medication order processing services to a North Carolina pharmacy pursuant to 21 NCAC 46.1816 must hold either an individual license to practice pharmacy or an NABP Verify credential. More information: https://www.ncbop.org/downloads/GuideToInterPharmacyRMOP.pdf

   e. A pharmacist license must be renewed annually. To renew, the pharmacist must acquire 15 hours of continuing education, five (5) of which must be obtained through contact programs. 21 NCAC 46.2201. Immunizing pharmacists (discussed below) must, in addition, complete three hours of continuing education designed to maintain competency in vaccine administration every two years. G.S. § 90-85.3(i1)

2. Registration and Certification of Technicians

   a. A pharmacy technician is a person who may, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing medications. G.S. § 90-85.3(q2)

   b. More information about technician qualifications and authority: https://www.ncbop.org/pharmacy-technicians.html

   c. "Registered technicians" may only maintain a registration with the Board while actively practicing pharmacy.

   d. "Certified technicians" may maintain a registration with the Board whether actively practicing or not. The Board recognizes two certification credentials – Pharmacy Technician Certification Board ("PTCB") and National Health Career Association's ExCPT exam.

   e. By default, a pharmacy may maintain a 2:1 technician:pharmacist ratio. That ratio may be increased if: (i) each additional technician is certified; and (ii) the Board approves the increase. G.S. § 90-85.15A. More detail: https://www.ncbop.org/downloads/PTRatioFormalguidancedocument%2011NOV21version.pdf

3. Registration of Pharmacy Interns

    a. A "pharmacy intern" is "any person who is registered with the Board under the internship program of the Board to acquire pharmacy experience or enrolled in approved academic internship programs." A qualified pharmacy intern "may, while under supervision [of a licensed pharmacist], perform all acts constituting the practice of pharmacy." 21 NCAC 46.1317(29)

    b. Any person who wishes to serve as a pharmacy intern and obtain practical experience in North Carolina must register with the Board. A person may not, and will not, receive credit for any practical experience required for licensure and obtained in North Carolina unless and until registered as a pharmacy intern. 21 NCAC 46.1503.

    c. More information about intern qualifications and registration requirements: https://www.ncbop.org/pharmacy-intern.html

4. Regulation of Others Who Practice Pharmacy

    a. Physicians may dispense drugs to their own patients. G.S. § 90-85.21(b). Dispensing physicians must register with the Board of Pharmacy and comply with all laws governing the practice of pharmacy. More information: https://www.ncbop.org/non-pharmacist-dispensers.html

    b. Dispensing physician assistants and nurse practitioners may dispense drugs from a place holding a North Carolina pharmacy permit. 21 NCAC 46.1703(c). Dispensing PAs/NPs are subject to oversight by the pharmacist-manager of the pharmacy from which they dispense. 21 NCAC 46.1703(d) & (e); 21 NCAC 46.1706. More information: https://www.ncbop.org/non-pharmacist-dispensers.html#licpanp

    c. Optometrists may dispense drugs to treat conditions of the eye to their patients. They may not compound drugs or dispense controlled substances. Dispensing optometrists much register with the Board of Pharmacy, and their dispensing activities are regulated by the Board of Pharmacy. G.S. § 90-127.4. More information: https://www.ncbop.org/non-pharmacist-dispensers.html#licoptometrist

    d. Registered nurses may dispense drugs from an approved formulary to health department patients. G.S. § 90-85.34; 21 NCAC 46.2401

    e. Veterinarians may dispense drugs to their own patients. Their dispensing activities are regulated by the North Carolina Veterinary Medical Board.

B. Pharmacies

1. What is a pharmacy?

    a. A "pharmacy" is "any place where prescription drugs are dispensed or compounded." G.S. § 90-85.3(p)

    b. The Board also permits and regulates device and medical equipment facilities. A permitted pharmacy, however, may dispense all devices and medical equipment without having to separately obtain a device and medical equipment facility permit. G.S. § 90-85.22. More

information: https://www.ncbop.org/dme-permits.html

2. The Role of the Pharmacist-Manager

   a. The North Carolina Pharmacy Practice Act and rules place responsibility on the "pharmacist-manager" for compliance with legal requirements.

   b. The pharmacist manager is "the person who accepts responsibility for the operation of the pharmacy in conformance with all statutes and regulations pertinent to the practice of pharmacy and distribution of drugs by signing the permit application, its renewal or addenda thereto." 21 NCAC 46.1317(25).

   c. General responsibilities. 21 NCAC 46.2502. Some emphasis points:

      - Person to whom a pharmacy permit is issued. Responsible for maintenance of the permit and obtaining a new permit when required by law. More information: https://www.ncbop.org/pharmacy-permits.html#pharmacy-faq-permitmgmt

      - Ensure qualified personnel, equipment, and references are secured to provide safe, competent pharmacy care. 21 NCAC 46.1601; 21 NCAC 46.1411

      - May only serve as pharmacist-manager for one pharmacy. 21 NCAC 46.2502(g). Exception: May serve as a pharmacist-manager for multiple "limited service" pharmacy permits or as pharmacist-manager for two full pharmacy permits if one of the two is newly permitted and has not begun providing patient services.

      - Controls all access to the pharmacy. 21 NCAC 46.2502(e).

      - Make determinations on emergency closures and ensure communications to the Board and the public required by 21 NCAC 46.2516 are made. More information: https://www.ncbop.org/downloads/EmergencyClosureFAQ.pdf

      - Pharmacist-manager must be present for half of the hours the pharmacy is open or 32 hours per week, whichever is less. 21 NCAC 46.2502(b).

      - May serve as a "temporary" pharmacist manager for a maximum of 90 days. A temporary pharmacist-manager need only be in the pharmacy 20 hours per week. 21 NCAC 46.2502(b).

      - When there is a change in the pharmacy owner or the pharmacist-manager, the successor pharmacist-manager must inventory all controlled substances within ten (10) days and maintain a copy of that inventory for three years. 21 NCAC 46.2502(c).

      - The pharmacist-manager must prepare a "plan to safeguard prescription records and pharmaceuticals in the event of a natural disaster such as a hurricane or flood." 21 NCAC 46.2502(j).

      - North Carolina requires that the pharmacist-manager "report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or

contributed to the death of a patient or customer." 21 NCAC 46.2502(l).

3. In-State Pharmacies.

   a. "[E]ach pharmacy in North Carolina shall annually register with the Board . . ." G.S. § 90-85.21(a).

   b. This includes all hospitals or other healthcare facilities "providing services which embrace the practice of pharmacy . . ." 21 NCAC 46.1401(a). But the registration requirement does not extend to "those health care facilities in which there occurs only the administration of drugs." 21 NCAC 46.1401(b).

   c. Health-system "satellite pharmacies" must obtain a separate registration if not located in the same building as the permitted pharmacy or in a building located on property contiguous to the permitted pharmacy. If the majority of the satellite's activity is dispensing or compounding drugs for a patient's use outside the facility, it must have its own permit. 21 NCAC 46.1401.

4. Out-of-State Pharmacies.

   a. "Any pharmacy operating outside the State which ships, mails, or delivers in any manner a dispensed legend drug into this State shall annually register with the Board." G.S. § 90-85.21A(a).

   b. An out-of-state pharmacy's pharmacist-manager for the North Carolina permit must be the same person who acts as pharmacist-manager in the pharmacy's home state. 21 NCAC 46.1607(c)

   c. The Board has established specific additional rules governing the permitting of out-of-state pharmacies. 21 NCAC 46.1607. Some highlights:

      - Must maintain at least six days per week for a minimum of 40 hours per week a toll-free telephone service to facilitate communication between pharmacists and patients. This number must be on the prescription label. 21 NCAC 46.1607(b)(4).

      - Maintain in readily retrievable form records of prescription drugs dispensed to North Carolina residents. 21 NCAC 46.1607(b)(2).

      - Develop protocols for dispensing where the patient's medication is not in stock at the out-of-state pharmacy or delivery will be delayed, dispensing prescriptions for acute illness, and providing interim dosage when the pharmacy is notified that the patient's medication did not arrive within normal delivery time and the patient is out of medication. 21 NCAC 46.1607(b)(6).

      - Be licensed in the state of residence and comply with all laws in that state. 21 NCAC 46.1607(b)(8); (d).

      - Out-of-state pharmacies also must 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." 21

NCAC 46.1607(g).

5. Physical Requirements

   a. Pharmacies Generally

      - Must post the specific hours that a pharmacist is on duty (unless a hospital, nursing home, or similar healthcare facility). 21 NCAC 46.1601(a)(2).

      - Must maintain "equipment in the pharmacy adequate to meet the pharmaceutical care needs of the pharmacy's patients." 21 NCAC 46.1601(a)(3).

      - Must maintain a "reference library" that addresses legal requirements, therapeutic references, patient reference materials, and equivalent drugs. 21 NCAC 46.1601(a)(4).

      - Pharmacy is "equipped with sanitary appliances including lavatory facilities with hot and cold running water; is well lighted; and is kept in a clean, orderly, and sanitary condition." 21 NCAC 46.1601(a)(5).

      - The pharmacy must be "physically separated" from other business if the pharmacy will be operated as a department in or a part of any other business serving the general public (except hospitals, nursing homes, and similar institutions). 21 NCAC § 1601(c).

   b. Health Care Facilities

      - "Sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well lighted and enclosed spaces." 21 NCAC 46.1412

      - "Sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations." 21 NCAC 46.1412.

      - Must comply with all physical requirements for a pharmacy generally.

6. Remote Pharmacy Operations

   a. North Carolina law authorizes pharmacies to enter into remote medication order processing and central fill arrangements. 21 NCAC 46.1816.

   b. Pharmacies may also deploy their own employees to provide certain remote services outside of the pharmacy. 21 NCAC 46.2515.

   c. More information: https://www.ncbop.org/downloads/GuideToInterPharmacyRMOP.pdf

7. Direct-to-Patient Dispensing Systems

   a. Board Rule .1821 (21 NCAC 46.1821) authorizes pharmacies to deploy direct-to-patient dispensing systems.

b. More information: https://www.ncbop.org/downloads/DTPSystemFAQsAndPermitInstructions.pdf

8. Limited Service Permits

a. Board rule recognizes "limited service" permits for certain specialized and, as the name suggests, limited pharmacy practices. 21 NCAC 46.1616

b. A pharmacist-manager may serve in that capacity for more than one pharmacy if the "other" permit is a limited-service permit.

c. Eligibility for a limited-service permit is based on the Board's determination that the types of practice involved are such that the pharmacist-manager's division of time and effort across multiple pharmacies raises a low risk of harm to the public health and safety.

d. Pharmacist-manager responsibilities are somewhat reduced for limited-service permits, though the specifics depend on the type of limited-service permit.

e. More information: https://www.ncbop.org/downloads/LtdServicePermitRulesFAQNov2021.pdf

III. North Carolina-Specific Scope of Practice

A. Practice of Pharmacy The practice of pharmacy is not limited to the dispensing of prescription drugs. Practice is defined at G.S. § 90-85.15B. It includes:

1. A pharmacist is responsible for interpreting and evaluating drug orders, including prescription orders; compounding, dispensing, and labeling prescription drugs and devices; properly and safely storing drugs and devices; maintaining proper records; and controlling pharmacy goods and services.

2. A pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses, and significant problems of drugs and devices; assess, record, and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record, and report drug therapy and device usage; perform drug utilization reviews; and participate in drug and drug source selection and device and device source selection as provided in G.S. § 90-85.27 through G.S. § 90-85.31.

B. Immunizing Pharmacists An immunizing pharmacist is authorized and permitted to administer vaccines, long-acting injectables, and drugs pursuant to certain state-wide protocols. G.S. § 90-85.15B

1. An "immunizing pharmacist" (G.S. § 90-85.3(i1)):

a. Holds a current provider level cardiopulmonary resuscitation certification issued by the American Heart Association or the American Red Cross, or an equivalent certification.

b. Has successfully completed a certificate program in vaccine administration accredited by the Centers for Disease Control and Prevention, the Accreditation Council for Pharmacy Education, or a similar health authority or professional body approved by the Board.

c. Maintains documentation of three hours of continuing education every two years, designed to maintain competency in the disease states, drugs, and vaccine administration.

d. Has successfully completed training approved by the Division of Public Health's Immunization Branch for participation in the North Carolina Immunization Registry.

e. Has notified the North Carolina Board of Pharmacy of immunizing pharmacist status.

2. Detailed information on an immunizing pharmacist's scope of authority to administer vaccines: https://www.ncbop.org/downloads/ExpandedVaccineAuthorityFAQ.pdf

3. Detailed information on an immunizing pharmacist's scope of authority to administer long-acting injectables: https://www.ncbop.org/downloads/LAIAdministrationGuidance.pdf

4. Detailed information on an immunizing pharmacist's scope of authority to dispense, deliver, and administer drug therapy under certain statewide protocols: https://www.ncbop.org/downloads/GS90-85.15BGuidance%20Document.pdf

C. Clinical Pharmacist Practitioners

1. Authorized by the Pharmacy and Medical Boards to enter into collaborative practice agreements with supervising physicians.

2. More information about Clinical Pharmacist Practitioner qualifications and authority: https://www.ncbop.org/clinical-pharmacist-practitioner.html

D. Pharmacy Technicians

1. May, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing prescription drugs. G.S. § 90-85.3(q2)

2. Properly trained and supervised pharmacy technicians may administer certain vaccines to patients. Detailed information on the qualifications and scope of authority: https://www.ncbop.org/downloads/ExpandedVaccineAuthorityFAQ.pdf

IV. Miscellaneous North Carolina-Specific Practice Standards

A. Dispensing

1. Receipt of Valid Prescription Orders

a. A pharmacist has the right to refuse to dispense a prescription if the pharmacist has concerns about the prescription's validity, safety, or clinical appropriateness. 21 NCAC 46.1801.

b. Only a pharmacist or bona fide employee of the pharmacy may receive prescriptions for filling or refilling. 21 NCAC 46.1804(a).

c. A prescription order "shall include, but not be limited to" (21 NCAC 46.2301):

- date of issue
- name and address of patient (which information may be stored in a readily retrievable data file used by the pharmacy)
- name, address, and telephone number of prescriber (which information may be stored in a readily retrievable data file used by the pharmacy)
- prescriber's DEA number in case of controlled substance prescriptions (which information may be stored in a readily retrievable data file used by the pharmacy)
- name, strength, dosage form and quantity of drug prescribed
- refills authorized (which information may be stored in a readily retrievable data file used by the pharmacy)
- route of administration for drug prescribed (which information may be stored in a readily retrievable data file used by the pharmacy)
- directions for use.

2. Automated Dispensing Devices/Auxiliary Medication Inventories

   a. Pharmacies may deploy automated devices to provide medications for subsequent dispensing or administration to a patient by a licensed health care provider. More detail: https://www.ncbop.org/faqs/general-pharmacy-faqs.html#faqads

   b. Pharmacies may deploy direct-to-patient dispensing devices. More detail: https://www.ncbop.org/downloads/DTPSystemFAQsAndPermitInstructions.pdf

3. Health Care Facility-Specific Issues

   a. Dispensing is allowable "only upon receipt of a medication order" in a system allowing for a means of verifying the order's authenticity. Oral orders are allowable, so long as they are put into writing immediately and signed at an appropriate time. 21 NCAC 46.1414(a)(1).

   b. The medication order "shall be received and reviewed by a pharmacist and, at a minimum, shall contain" (21 NCAC 46.1414(a)(2)):

      - patient's name, location and other necessary identifying information such as history or medical records number
      - medication name, strength, dosage form, route of and directions for administration
      - date the order was written
      - prescriber's signature (may include electronic signature or verification)

   c. Pharmacists must enter medication orders into a patient medication profile, which "shall, at a minimum, contain" (21 NCAC 46.1414(a)(3)):

- patient's name, location and important clinical data such as age, height, weight, sex, and allergies
- medication name, strength, dosage form, route of and directions for administration
- medication start date
- medication d/c date
- identification of pharmacist responsible for or verifying technician entry of the medication order.

B. Drug Product Selection

1. North Carolina law permits pharmacists to substitute an equivalent drug product unless the prescriber directs that no such substitution is permissible. G.S. § 90-85.28

2. "Interchangeable biological products" may be substituted if authorized by the prescriber. North Carolina law requires that the pharmacist "communicate to the prescriber the product name and manufacturer of the specific biological product dispensed to the patient." This "reporting" requirement is satisfied, however, by the transmission of an insurance claim (among other things). G.S. § 90-85.28(b2)

3. Narrow Therapeutic Index ("NTI") Drugs. An NTI drug must be refilled using the same drug product by the same manufacturer that the pharmacist last dispensed, unless the prescriber and patient give documented consent to the change. G.S. § 90-85.27(4a).

   a. This is not a "no generics" law. If substitution of equivalent drug product is authorized by the prescriber, the pharmacist may select an equivalent drug product. But whatever product is dispensed initially must continue to be dispensed unless the prescriber and patient give consent to a change. G.S. § 90-85.28(b1)

   b. More information, including the list of NTI Drugs: https://www.ncbop.org/faqs/general-pharmacy-faqs.html#faqprescriptionsntidrugs

C. Labeling

1. The label of every drug product dispensed shall contain "the brand name of any drug product dispensed, or in the absence of a brand name, the established name." G.S. § 90-85.29

2. Every prescription drug label must contain the generic name of the drug, even if the brand name is on the label. 21 NCAC 46.1818

3. The label must contain a discard date when dispensed in a container other than the manufacturer's original container. That date is one year from the date dispensed or the manufacturer's expiration date, whichever is earlier. G.S. § 90-85.29

4. The label must not obscure the expiration date when the drug is dispensed in the manufacturer's original container. G.S. § 90-85.29(2)

5. Hospital-Specific Issues (21 NCAC 46.1414(d); 21 NCAC 46.1616).

    a. The pharmacist dispensing the drug must ensure that all dispensed drugs within a health care facility are labeled and identified up to the point of administration.

    b. When a drug is added to a parenteral admixture, the admixture must be labeled with "a distinctive supplementary label indicating the name and amount of the drug added, expiration date, and expiration time, if applicable

    c. Repackaged drugs must be labeled to include generic or trade name, strength, and quantity; identification of the manufacturer and lot number; expiration date; and any applicable cautionary notations. Pharmacy may assign its own batch number in lieu of the manufacturer's name and lot number so long as keyed to manufacturer's information in a readily retrievable record.

D. Refills

1. "PRN" Refill Limitation. A prescription with a refill authorization designated only "PRN", "as needed", or words to similar effect may not be refilled more than one year from the date of issue unless the prescriber otherwise specifies. G.S. § 90-85.32

2. Advancing Refills. A pharmacist may, "if deemed appropriate in the pharmacist's professional judgment," dispense "drug quantities in excess of the face amount of a prescription for a non-controlled substance, up to the total amount authorized." 21 NCAC 46.1802

3. Emergency Refills.

    a. One-Time 30-Day Supply (21 NCAC 46.1809). A pharmacist may dispense a one-time, 30-day emergency refill to a patient when the pharmacist is "unable to obtain readily refill authorization from the prescriber" provided:

        - the prescription is not for a C-II
        - the medication is "essential to the maintenance of life or to the continuation of therapy in a chronic condition"
        - in the pharmacist's "professional judgment," "interruption of therapy might reasonably produce undesirable health consequences"
        - pharmacist creates a written order containing all information required for a valid prescription
        - pharmacist notifies the prescriber or the prescriber's office of the emergency dispensing within 72 hours.

    b. One-Time 90-Day Supply (21 NCAC 46.1815). If a pharmacist is unable to "obtain readily refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient," the pharmacist may dispense a one-time 90-day emergency refill subject to the same qualifications above.

E. Drug Donation

1. In certain circumstances, prescription drugs and devices may be donated to a pharmacy for redispensing.

2. Detailed information on eligibility and procedure: https://www.ncbop.org/downloads/FAQDrugSuppliesMedicalDeviceRespositoryProgramJuly2023.pdf

F. Work-Load Regulation

1. "Pharmacists shall not dispense and permit holders shall not allow a pharmacist to dispense prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety." 21 NCAC 46.1811

2. "A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than six continuous hours per work day shall be allowed during that time period to take a 30 minute meal break and one additional 15 minute break." 21 NCAC 46.2512.

3. The Board maintains a tab that every pharmacist may access in their online BOP profile to report pharmacy working conditions problems.

4. Use of Pharmacy Technicians During Pharmacist Breaks. Board's policy: https://www.ncbop.org/downloads/UseofTechniciansDuringPharmacistBreaks%20%281%29.pdf

G. Identification

1. Any "health care practitioner" in North Carolina – which includes anyone registered to engage in the practice of pharmacy – "shall wear a badge or other form of identification displaying in readily visible type the individual's name and the license, certification, or registration held by the practitioners." G.S § 90-640

2. A pharmacist need not wear this badge if involved in procedures requiring full sterile dress or other protective clothing. 21 NCAC 46.2506(a)

3. A pharmacist may limit her identification to first name only with reference to licensure if full name identification would "place the personal safety of the pharmacist in jeopardy" or would "interfere with the therapeutic relationship between the pharmacist and the client." 21 NCAC 46.2506(b)

H. Recordkeeping

1. Prescription Orders

    a. The pharmacist manager must retain prescription orders for three years. G.S. § 90-85.26

        - A pharmacy may maintain an accurate electronic copy of a paper prescription as the original so long as the pharmacy's recordkeeping system adequately backs up copies of the electronic files and can produce electronic or printed copies upon a Board request within 48 hours. Note: Federal controlled substance regulation requires all hard copies of controlled substance prescriptions must be maintained on-site for 2 years.

        - Unless otherwise specified by rule or statute, any documentation required to be created by Board rule may be created and maintained electronically. 21 NCAC 46.2508

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2. Health-Care Facility Specific Requirement. The pharmacist-manager must "develop a system of daily accountability for medication compounding and dispensing that shall permit the identification of the responsible pharmacists and pharmacy technicians." Accountability records "shall be maintained for at least 30 days." 21 NCAC 46.1414(j)

I. Compounding (21 NCAC 46.2801)

a. All compounding must comply with current United States Pharmacopeia chapters <795> and <797>, and all other chapters expressly incorporated into <795> and <797>

b. In addition to complying with all recordkeeping and labeling requirements specified or referred to by United States Pharmacopeia (USP) chapters <795> or <797>, a pharmacy that prepares, labels, or dispenses compounded drug preparations shall create and maintain a record-keeping system that enables the pharmacy immediately upon request to identify every compounded drug preparation prepared, labeled, or dispensed in the past three years.

c. The pharmacist-manager or a specific designee pharmacist "shall be knowledgeable in the specialized functions of preparing, labeling, and dispensing compounded drug preparations."

d. More information: https://www.ncbop.org/faqs/general-pharmacy-faqs.html#faqcompounding

V. North Carolina-Specific Controlled Substance Regulation

A. North Carolina Controlled Substances Act

1. The North Carolina act substantially replicates the federal Controlled Substances Act.

2. Significant variations from the federal Controlled Substances Act:

    a. Marijuana is a Schedule VI controlled substance. G.S. § 90-94. This is for purposes of applicable punishments only. Marijuana is not legal under North Carolina law, for medical

or recreational use.

b. When it is permissible to give a copy of a prescription to the patient or other appropriate person (G.S. § 90-85.36), a copy of a prescription for a controlled substance must be marked "Copy – for information only." G.S. § 90-106(g).

c. Preprinted prescription blanks for controlled substances are "prohibited." 21 NCAC 45G.0307.

d. Prescriptions for Schedule II controlled substances cannot be filled more than six months after the day they were written. This does not limit the "days' supply" to six months. Rather a prescription for a Schedule II CS cannot be filled at all after six months. G.S. § 90-106(b)

e. Pharmacists are required to obtain qualifying identification prior to dispensing certain Schedule III controlled substances. Detailed information: https://www.ncbop.org/downloads/PhotoIDControlledSubstancesFAQ.pdf

f. The Strengthen Opioid Misuse Prevention ("STOP") Act imposes requirements on the prescribing, dispensing, and monitoring of "targeted controlled substances." Detailed information: https://www.ncbop.org/downloads/GuidanceImplementationSTOPACTUpdatedJune2023.pdf

B. North Carolina Controlled Substances Reporting Act

1. North Carolina operates a Controlled Substance Reporting System ("NC CSRS") – often called a Prescription Monitoring Program in other states.

2. NC CSRS is administered by the North Carolina Department of Health and Human Services' Drug Control Unit. More information: https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-and-substance-use-services/north-carolina-drug-control-unit/nc-controlled-substances-reporting-system

3. More detail about reporting requirements for pharmacies here: https://www.ncbop.org/faqs/general-pharmacy-faqs.html#faqcontrolledsubstancescsrs

VI. Discipline

A. Pharmacists (G.S. § 90-85.38(a)). The Board may issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew a license to practice pharmacy, or require licensees to successfully complete remedial education if the licensee has done any of the following (G.S. § 90-85.38(a)):

1. Made false representations or withheld material information in connection with securing a license or permit.

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. Indulged in the use of drugs to an extent that renders the pharmacist unfit to practice pharmacy.

4. 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.

5. Failed to comply with the laws governing the practice of pharmacy and the distribution of drugs.

6. Failed to comply with any provision of this Article or rules adopted by the Board.

7. Engaged in, or aided and abetted an individual to engage in, the practice of pharmacy without a license.

8. Been negligent in the practice of pharmacy.

9. Engaged in unprofessional conduct, including the departure from or failure to comply with the requirements of G.S. 90-85.15B(c1) and (d1), when dispensing, delivering, or administering medication for patients.

B. Pharmacy Permits (G.S. § 90-85.38(b))

1. The Board may suspend, revoke, or refuse to grant or renew any permit for the same conduct that could ground discipline of a pharmacist license.

2. A pharmacy is responsible for the acts or omissions of its employee/agent pharmacists and technicians.

3. Any license or permit obtained through false representation or withholding of material information is void.

C. Technicians (G.S. § 90-85.15A(d)). The Board may issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew the registration of a pharmacy technician if the pharmacy technician has done one or more of the following:

1. Made false representations or withheld material information in connection with registering as a pharmacy technician.

2. Been found guilty of or plead guilty or nolo contendere to a felony involving the use or distribution of drugs.

3. Indulged in the use of drugs to an extent that it renders the pharmacy technician unfit to assist a pharmacist in preparing and dispensing prescription medications.

4. Developed a physical or mental disability that renders the pharmacy technician unfit to assist a pharmacist in preparing and dispensing prescription medications.

5. Been negligent in assisting a pharmacist in preparing and dispensing prescription medications.

6. Failed to comply with the laws governing pharmacy technicians, including any provision of this Article or rules adopted by the Board governing pharmacy technicians.

D. License/Registration/Permit Reinstatement (21 NCAC 46.2017)

1. A pharmacist/technician/pharmacy that loses its license/registration/permit, either by Board order or surrender, may apply for reinstatement unless prohibited by a Board order.

2. Board disciplinary orders revoking or denying a license, registration, or permit, by default, prohibit any application for a new license or permit for a period of at least five years. A Board order can set a shorter or longer term or can specify that revocation is permanent.

E. Impaired Pharmacy Personnel Program

a. The Board is authorized to "establish a program for the purpose of aiding in the recovery and rehabilitation of pharmacists who have become addicted to controlled substances or alcohol, and the Board may use money collected as fees to fund such a program." G.S. § 90-85.6 The Board may establish such a program by entering "into agreements with special impaired pharmacy personnel peer review organizations." G.S. § 90-85.41

b. The Board has such an agreement with the North Carolina Professional Health Program ("NCPHP"): https://ncphp.org/