

COMMON PRACTICE AND PROCEDURE FOR ISSUING PHARMACY PERMITS

PLEASE READ THOROUGHLY BEFORE COMPLETING APPLICATION.

Application Fee for Pharmacy is \$500.00

THE BOARD ONLY ACCEPTS VISA, MASTERCARD, AMERICAN EXPRESS and DISCOVER.

Fees are non-refundable and processed when application is received in the Board office.

By North Carolina General Statute G.S. 90-85.21 and 90-85.21A, all places where drugs are dispensed must obtain a permit from the Board of Pharmacy. Permits are issued to the pharmacist manager whom the Board holds responsible for the operation of the pharmacy in conformance with all laws and regulations after the permit is issued. Transfer of Ownership and Reregistration information for existing permits is located on the bottom of last page, you should follow these instructions below for all original permits.

STEP 1 – Complete the entire permit application including the affidavit along with the credit card form:

The following additional material is required with the application for review before issuance of a permit:

___ Photographs as instructed below:

1. A photograph or photographs of the actual existing exterior of the building in which the pharmacy is currently located, including identifiable parts of adjacent building(s), if any.
2. Signage of or on the exterior of the Pharmacy.
3. Interior photograph(s) of the prescription area of the pharmacy as viewed by a customer/inspector as well as photograph(s) of the dispensing/processing area of the pharmacy.
4. A photograph(s) of and/or assurance that all required equipment is present. It should include equipment in the pharmacy adequate to meet the pharmaceutical care needs of the patient as well as the pharmacy's services that are pharmacy is providing.
5. Photograph(s) of the compounding area with adequate equipment present (if compounding this is required).

___ Copy of Current License (permit) or Letter from Regulatory Agency:

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. Such evidence shall consist 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; and/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; *As outlined in 21 NCAC 46.1607 (7) (A) & (B)* [SECTION .1600 - LICENSES AND PERMITS](#)

___ **Current Operational Inspection Report REQUIRED.** USP Compounding Compliance Inspection report is required if compounding. The Board will accept a compliant inspection from the State Board in which you are permitted or a NABP VPP Inspection. If the inspection report shows non-compliance, documentation from that corrective action has been taken and is acceptable from either the State Board or NABP.

___ Verification or assurance of Reference Material. Online References are acceptable. A photograph of the reference library required by Board regulation clearly showing titles of publications on hand or assurance that references are available online. See <http://www.ncbop.org/LawsRules/rules.1600.pdf> (or reference material under additional information below on the last page).

___ Completed Label, **not a blank label.** Label should be an example of what is placed on a patient's bottle with all the required label information. Dispensing pharmacist's initials *only* are NOT acceptable. See FAQ- Pharmacist FAQ on Board's website: Prescription Labeling for required information- http://www.ncbop.org/faqs/Pharmacist/faq_PrescriptionLabelling.htm

___ Secretary of State or Registered Agent Information: Item #10 on the application and I am registered with the State or have a Registered Agent, I have attached the appropriate documentation. 21NCAC 46.107 (8) <http://www.ncbop.org/LawsRules/rules.1600.pdf>

___ I answered "Yes" to Item 6 (page 2), I have enclosed the attached material required. If yes, please provide the Board with appropriate documentation, including but not limited to the charging document, consent order and any disposition of the charge.

___ I answered "Yes" to certain questions on the Affidavit then additional documentation may be required, refer to each question for additional information. <http://www.ncbop.org/Forms%20and%20Applications%20-%20Pharmacies/PharmacyServicesAffidavit.pdf>

I have completed the checklist and made a copy of my application for future reference if needed.

STEP 2 – Submitted Applications- Once your application is received:

-Allow at least 6 weeks to review applications. Make sure that you provided a valid email address in Certificate B of the application. Email is the primary source of communication (vital). If additional information has been requested or if application is incomplete, expect a longer review time. Incomplete applications should allow six weeks once required documentation is received and considered complete.

-You will receive notification informing you the application has been received along with an application number (allow at least 7 to 10 business days for notification), as well as the status of your application once it has been reviewed. If additional information is required, you will be notified.

-Make sure to reference your Application number when contacting the Board for a submitted application.

-Note: Individuals who sign as pharmacist managers are indicating their intent to remain in the position for the foreseeable future as expressed in Certificate B of the application and the Board will rely on this representation in processing the application. (See specifically G. S. 90-85.38(a) (1) and (b).) The pharmacist manager is the point of contact for the Board and the individual held responsible for the permit.

I have had a change to my application (address, pharmacist manager, etc.) What do I need to do?

Send in an updated, revised completed application with an attachment to notify the Board of a previous application filed and what has been revised.

What I should not be doing: Calling the Board to see if the application was delivered (we recommend you send your application a trackable method if you want to verify that information). Calling to expedite my application; the Board is reviewing applications in the order they are received in the office. You should allow at least six weeks for the review process by the review team.

STEP 3 – Permit Meeting

- **Permit meeting is required for all original permit applications normally at the Board's office.**

Permit meetings begin promptly at 10:00 am on the first Monday and the Monday prior to the third Tuesday of each month (unless otherwise noted). Check-in time for the meeting is at 9:45 am. Permits are issued to the pharmacist manager who must be present at the time of issuance for clarification of any matters in question (this includes Out-of-State). Any questions regarding security must be resolved before a permit is issued. See calendar information below. **Late arrivals will not be allowed into the permit meeting. Accordingly, if you cannot arrive at the Board office before 10:00 am on the meeting date, your permit application will not be considered, and you will have to attend a future permit meeting.**

-**Informative meeting on NC Laws and Rules, Procedures, and for clarification of any matters concerning the application for permit.** The office review shall include, but not be limited to, the items specified in Board regulation 46 .1601 or .1607, as applicable, proper pharmacist coverage and security. If all items are found in compliance, a permit number will be issued at that time. The reference library should be in compliance with rule 46 .1601- *see additional information below*. A change in pharmacist managers between submission and the office review can produce an indefinite delay in issuance of a permit number. <http://www.ncbop.org/LawsRules/rules.1600.pdf>

-**Applications must be in the Board office at least six (6) weeks prior to the meeting you would like to attend and be complete in all pertinent parts before issuance of the permit will be considered. This is an estimated not guaranteed time.**

- **DO NOT** plan to attend a permit meeting until you have received notification to do so, an acknowledgement will be sent if approved.

- **Reviewed the Calendar of Events of the Board's website for permit meeting dates. I do not need to schedule in advance once I receive my acknowledgement** (permit meetings are set meetings). In case of Adverse Weather, check the website or call to see if the Board has rescheduled the meeting). *Calendar of Events* <http://www.ncbop.org/calendar.htm>

- **Permit meeting normally lasts about an hour and half.** No tests are given. Informative and clarification as explained above.

- **Review the Resource Materials for New Permits here:** <http://www.ncbop.org/resourcesfornewpermitholders.htm>

- **Permit number issued at permit meeting and are effective that day** (unless additional information is required). Receipt and issuance of pharmacy permits will be presented to the members of the Board at each regular meeting. Under the provisions of the Administrative Procedures Act and Board regulations, any Board Member may call for a hearing on the issuance of any individual permit.

- Permit certificates are normally available within 7 business days after attending the permit meeting on the Board's website.

! If the permit has not been issued within six (6) months of the receipt of the application in Board offices, the application will be deemed void and a new application must be completed. PLEASE NOTE: It is Board policy that fees are non-refundable.

Additional Information

- **If the dispensing of controlled substances is anticipated, a DEA Registration is also necessary.** Applications for DEA Registration are available from their Regional Office in Atlanta: 75 Spring Street, Suite 800, Atlanta, GA 30303, (888) 219-8689, Fax # (404) 893-7095, or you can apply/renew online at <http://www.deadiversion.usdoj.gov/>.

- **To obtain a NCPDP number, contact: National Council for Prescription Drug Programs, 9240 E. Raintree Drive, Scottsdale, AZ 85260. Phone 480-477-1000, Fax 480-767-1043.**

-**Reference Material-** See <http://www.ncbop.org/LawsRules/rules.1600.pdf>. The reference library should be in compliance with rule 46 .1601 (4) (A - E) – (see below). Evidence of items ordered will be acceptable.

(4) The pharmacist-manager shall be responsible for obtaining and maintaining a reference library in the pharmacy. The library shall include current references, either hard copy or electronically accessible, covering:

(A) State and federal statutes and rules relating to the practice of pharmacy and the legal distribution of drugs;

(B) Drug interactions, adverse effects, therapeutic use, dosing and toxicology;

(C) Patient-oriented reference materials for counseling in proper drug usage as specified in 21 NCAC 46 .2504;

(D) Equivalent drug products as defined in G.S. 90-85.27; and

(E) Any reference materials otherwise required by state or federal law, including any otherwise required in these Rules.

-**Renewal information:** Permits expire 12/31 of each calendar year. Permits are required to be renewed online through the Board's website. The renewal period starts November 1st and the renewal fee is \$200.00.

NEW PERMIT REQUIRED for a change of ownership or relocation of the facility.

Rule .1603 states that a new permit is required for a new location, change to a different or successor business entity, or a change of majority control. Can be accomplished administratively in the Board office after submission of an application with the required fee without an appearance by the pharmacist manager. <http://www.ncbop.org/LawsRules/rules.1600.pdf>

TRANSFER OF OWNERSHIP: A change of majority control- a change to a different or successor business entity, or a change resulting in a different person or entity owning more than 50 percent interest in the permit holder or any entity in the chain of ownership above the permit holder, except as provided in 21 NCAC 46 .1604 of this Section. A new permit is required if there is a change in the authority to control or designate a majority of the members or board of directors of a nonprofit corporation holding a pharmacy permit or any nonprofit corporation in the chain of ownership above the permit holder.

Review the following instructions:

[Transfer of ownership information/instructions](#)

RE-REGISTRATION: CHANGE OF ADDRESS OR PERCENTAGE OF OWNERSHIP CHANGE WITHIN AN EXISTING GROUP OF STAKEHOLDERS: Re-registration is required when there is a change of location or a percentage of ownership change within an existing group of stakeholders. Permit numbers remain the same however the permit is reregistered to the permit holder.

Review the following instructions:

[Address change information/instructions](#)

[Percentage of ownership change within an existing group of stakeholders - information/instructions](#)

I have had a change to my application after submitting (pharmacist manager, etc.)- Send in an updated, revised completed application with an attachment to notify the Board of a previous application filed and what has been revised.

Email- Wendy Watson, Permitting Specialist if I need clarification or have additional questions: wwatson@ncbop.org