#### 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 submitted online.
The Pharmacist Manager is required to submit the online application.

A valid email address is required for the Pharmacist Manager and the facility.

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.

<u>STEP 1 – Application Submission Procedures</u> - Navigate to the Licensure Gateway, click on FACILITY MANAGEMENT, and then click on NEW PHARMACY -complete the application, upload the required documentation including the credit card payment: (*To view an example of the pharmacy application, please click here.*) Make sure to thoroughly review the application, for accuracy, prior to submission.

<u>Please note:</u> Once the application has been started, it needs to completed in one sitting. Since you will not be able to save the application, be sure all the documents are readily available to upload. All uploads must be less than 8MB. Once the application has been submitted, the checklist items will remain "incomplete" until Board staff reviews and completes.

• The EIN number (Federal Tax ID) and the NABP Business e-profile number are required. Please visit NABP (<a href="www.nabp.pharmacy">www.nabp.pharmacy</a>) to create a business e-profile. The DEA number is required on the application if you are dispensing controls.

#### 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 or registration as a pharmacy in compliance with the laws of the state in which the pharmacy is located. 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 certifying the pharmacy's compliance with the pharmacy laws of that state; outlined in 21 NCAC 46.1607 (7) (A) & (B) SECTION .1600 - LICENSES AND PERMITS

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

<u>Completed Label</u>, 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

<u>Secretary of State or Registered Agent Information</u>: 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) <a href="https://www.ncbop.org/LawsRules/rules.1600.pdf">https://www.ncbop.org/LawsRules/rules.1600.pdf</a>

<u>"Yes" to Item 6 (page 2) Disciplinary Question</u>, If yes, please provide the Board with appropriate documentation, including but not limited to the charging document, consent order and any disposition of the chargee.

If "Yes" to certain questions on the Application then additional documentation may be required, refer to each question for additional information.

<u>STEP 2 – Submitted Applications-</u> Once the fee has been paid and the application has been submitted, the Pharmacist-Manager will receive an automated email with the application confirmation number. This confirmation will be used to log in and check the status of the application.

- -Allow at least 6 weeks to review applications. Make sure that you provided a valid email address on the application for the Pharmacist Manager and the Pharmacy. Email is the primary source of communication (vital). If additional information is requested or if the application is incomplete, expect a longer review time. Incomplete applications should allow six weeks once required documentation is received and considered complete.
- If additional information is required, you will be notified by email of additional action needed for the application.
- -Make sure to reference your confirmation number or permit number when contacting the Board for a submitted application or any inquiries, updates, or changes.
- -Note: Individuals who sign as pharmacist managers are indicating their intent to remain in the position for the foreseeable future as <u>expressed in Certificate B of the application and the Board will rely on this representation in processing the application.</u> (See specifically G. S. 90-85.38(a) (1) and (b).) <u>The pharmacist manager is the point of contact for the Board and the individual held responsible for the permit.</u>

I have had a change to my application (address, pharmacist manager, etc.) What do I need to do? Sign into the portal and make the correction as needed. This could delay your application process.

<u>What I should not be doing:</u> 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 ISSUANCE INFORMATION

- Once the pending application is approved, an approval email will be sent to the PM instructing them to log in to view the
  PM Education Video. You must click the link in the email to access the video, at the end of the video the PM will be required
  to attest that they have completed this process.
- The Educational video consist of Informative information on NC Laws and Rules, Procedures, and related material concerning permits. The 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.
- Once the Educational video has been reviewed and attested to, the permit number will be emailed to the Pharmacist-Manager. Once the permit number is issued this will be your new log-in information to access your profile.
- · Permit certificates can be printed directly from the Board's website using the pharmacy's new permit number.
- !! If the permit has not been issued within six (6) months of the receipt of the application, the application will be deemed void and a new application must be completed. PLEASE NOTE: It is Board policy that fees are non-refundable.
- Review the Resource Materials for New Permits here: http://www.ncbop.org/resourcesfornewpermitholders.htm

!! 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. For out ot state pharmacies you should already have your DEA number if you dispense controls and that should be filled in on the application. You can apply/renew online at <a href="http://www.deadiversion.usdoj.gov/">http://www.deadiversion.usdoj.gov/</a>.
- **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 <a href="http://www.ncbop.org/LawsRules/rules.1600.pdf">http://www.ncbop.org/LawsRules/rules.1600.pdf</a>. The reference library should comply with rule 46 .1601 (4) (A E) (see below). Evidence of items ordered will be acceptable.
- **-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.
- Once the permit is obtained keep your information updated with the Board by logging in under the permit profile at the gateway portal. Make sure to reference your permit number when contacting the Board for any inquiries, updates or changes to the permit. FAQs Click here for FAQs concerning Pharmacy Applications and Accessing/Updating Information for Existing Pharmacy Permits

# A NEW PERMIT is REQUIRED for a Change of Ownership or Relocation of the Facility.

### Notice Concerning Transfer of Ownership Applications

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. <a href="http://www.ncbop.org/LawsRules/rules.1600.pdf">http://www.ncbop.org/LawsRules/rules.1600.pdf</a>

**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

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