

COMMON PRACTICE AND PROCEDURE FOR ISSUING DME PERMITS

PLEASE READ THOROUGHLY BEFORE COMPLETING APPLICATION.

Application Fees for DME 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.**

North Carolina General Statute 90-85.22, 21 NCAC 46.1608 and Board Rules 21 NCAC 46.2600 et. seq. requires all places where Devices and Medical Equipment are dispensed to register with the Board of Pharmacy.

Device and Medical Equipment Dispensing Permits may be obtained from the NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517. Permits are issued to the Person-In-Charge whom the Board holds responsible for the operation of the facility in conformance with all pertinent laws and regulations.

The General Statute and Board Rules can be found on the Board's website under Pharmacy Law/Rules:

90.85.22 [NC PHARMACY LAWS](#) **21 NCAC 46.1608** [SECTION .1600 - LICENSES AND PERMITS](#) **21 NCAC 46.2600** [SECTION .2600 - DEVICES](#)

NOTE: Board Rule 21 NCAC 46.2601 (c) -"Device and medical equipment permits shall not be issued to applicants located on residential property."

STEP 1- Complete the entire permit application along with the credit card form:

[Application for Registration and Permit to Dispense Devices and Medical Equipment](#)

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

Photographs as instructed below:

1. Photograph(s) of the actual existing exterior of the building in which the facility will be or is currently located, including identifiable parts of adjacent building(s), if any, include signage of the DME facility.
2. Interior photograph(s) of the facility including but not limited to office area, storage space for equipment, proof that the facility is equipped with a functioning lavatory where hot and cold running water or hand washing appliances or waterless hand cleaner are available.
3. Photograph(s) of all required equipment that will be present before the facility is opened. It should include equipment in the facility that is adequate to meet the services that the facility is providing. (example; if providing oxygen, equipment related to oxygen).
4. Photograph of segregated areas on the premises and in delivery vehicles for clean, dirty, and contaminated equipment.
5. Architect plans or sketches acceptable in addition to but not in place (not substituted) of required photographs.
6. Person in Charge Passport-like Photograph required on application * - see requirements under additional information (3rd page)

Note: Renovating and/or building – if the renovations or build out is not complete in this case send a couple of photographs now as it appears and bring required updated photographs to the permit meeting. Failure to bring updated pictures can result in a permit number not being issued for the facility.

Proof of Occupancy of the Addressed Facility (applies to In-State facilities only). Acceptable items would be: Lease/Rental Agreement, Deed or Deed of Trust, Property Tax Statement, Building Permit. If sending a lease agreement, the entire lease is not required, just the address page and signature page.

 I answered "Yes" to Item 8 (page 2), Attach documentation such as court orders/disposition of charges/charging documents

 I answered "Yes" to Item 9 (page 2), provide the Board with appropriate documentation; Provide an attached list of all the states in which you hold a DME permit/license

 I answered "Yes" to Item 10 (page 2), provide the Board with a copy of the Out of State license/permit of the state the facility is physically located in.

 I answered "Yes" to Item 11 (page 2), provide the Board with appropriate documentation, including but not limited to the charging document, consent order and any disposition of the charge.

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 Item #1 and #2 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 received notification), as well as the status of your application once it has been reviewed (up to 6 weeks, estimated not guaranteed). 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: The **Person-In-Charge (PIC) is the person responsible for the permit** and is required to be physically present at the facility site the majority of the time that the facility is open. The PIC is the contact person for the permit and is responsible for making sure the facility is in compliance. A PIC CAN ONLY BE ASSIGNED TO ONE DME PERMIT. REFER TO RULE 21 NCAC 46 .2605.

I have had a change to my application (address, person in charge, 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 is 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 person in charge who must be present at the time of issuance for clarification of any matters in question.** 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. Receipt and issuance of device 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. If the permit has not been issued within six (6) months of the receipt of the application in the Board office, the application will be deemed void and a new application must be completed. The Board has a no refund of fees policy.

-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 called 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

-Person in Charge Passport-like Photograph on the application* - Colored Photograph (No black/white photograph), printed on matte or glossy paper, 2x2 inches in size, taken in front of a neutral background, front-facing, chest upward within the last 6 months.

-Renewal information: Permits expire 12/31 of each calendar year. Renewals are required to be renewed online through the Board's website, 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 person in charge. <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:

<http://www.ncbop.org/dmetransferofownership.html>

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