# PHARMACY

# FREQUENTLY ASKED QUESTIONS

#### FREQUENTLY ASKED QUESTIONS FOR PHARMACY

- > FAQs concerning Applications
  - Original Registration, Transfer of Ownership, and Re-Registration
- FAQs concerning accessing, reviewing, and updating information for existing permits



## **OUTLINE**

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Q:What types of applications are filed with the Board?

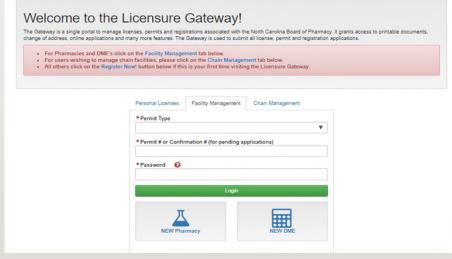
A:There are three types of applications

New Original Registration: Application for pharmacies that have never applied for a permit or do not have an active permit with the Board. Transfer of Ownership: Application for a change of ownership that results in the majority of interest change of a new owner owning greater than 50% with an existing active permit.

Re-Registration: Application for a physical relocation of the facility or a change of ownership between existing partners of the business.

- Q: How do I file a new Pharmacy registration application with the Board?
- A: Applications are filed with the Board of Pharmacy through the Board's Licensure Gateway. From the home page, click the second tab to navigate to the Licensure Gateway page. Once here, click on Facility Management, and then click on NEW Pharmacy to start the new pharmacy registration application.
- Transfer of Ownership and Re-Registration applications, require you to log in under the existing permit number.





- Q:What are the fees related to Pharmacy applications and updates?
- A: Click on the link to access the fee schedule: <a href="http://www.ncbop.org/about/FeeSchedule.pdf">http://www.ncbop.org/about/FeeSchedule.pdf</a>
- Q:Are application fees refundable?
- A: No, it is Board Policy that all fees are nonrefundable as indicated at the start of each application.

reneral	950.00
PHARMACY	FEE
Original Permit Application (In and Out of state)	\$500.00
Transfer of Ownership	\$500.00
Re-Registration	\$500.00
Duplicate Original Certificate	\$25.00
Pharmacist-Manager Change	\$35.00
Renewal	\$200.00
Reinstatement / Late Renewal	\$400.00
DME	CEE

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.

- Q: Once I start the application, may I save it and go back to it later to complete?
- A: No, a new pharmacy registration application may not be saved. Please have your documents ready to upload.
   After 20 minutes of non-activity the application will time out.

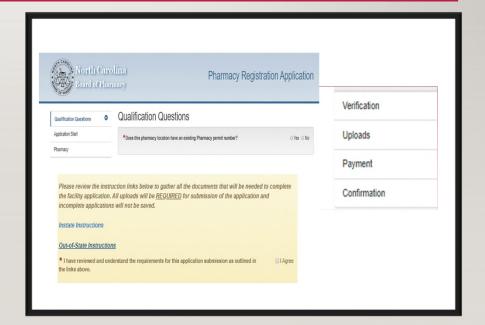
  Application Start

NOTICE: All fees are due at application submission and are NON-REFUNDABLE. The fee for this application is \$500.00.

As a security precaution, sessions end after 20 minutes of inactivity which will result in the application being lost.

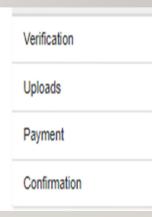


- Q: Are there instructions for filing an application with the Board?
- A:Yes, the links below provide instructions:
- https://portal.ncbop.org/Documents/Instructions/Pharmacy\_Instate\_Instructions.pdf
- https://portal.ncbop.org/Documents/Instructions/Pharmacy\_Out\_of\_State\_Instructions.pdf



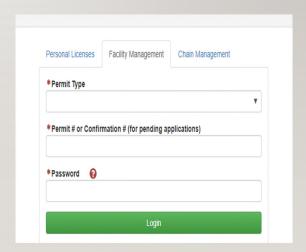
#### --ORIGINAL APPLICATION--

- Q: What are the additional items required with the application?
- A: Required items are explained on the procedure instruction sheet in more detail. See below for a general idea:
- Required items may vary depending on the answer to some of the questions on the application. To the left side of the start application page is an application section index.
- Pictures of the Exterior, Interior and Equipment are required, explanation of that is located on the instruction sheet
- Proof of Occupancy for Instate in addition to pictures.
- Certificates A and B are required for all, C and PM Attestation is required in addition for out of state.
- Copy of your Prescription Label and Verification of Reference Material.
- Operational Inspection and Verification of License or Copy of Permit for out of state.
- Additional documentation depending may also be required if requested by the Board.
- For Transfer and Registrations required uploads will be slightly different depending on application submitted.

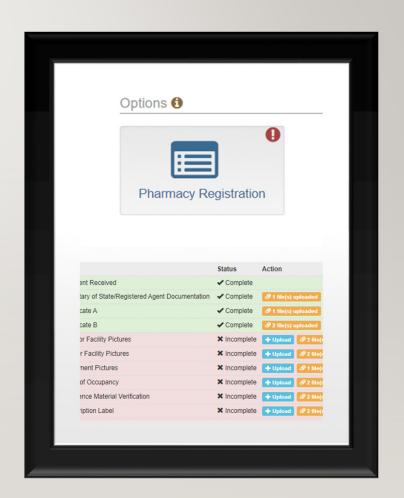


- Q: How do I receive updates or communication concerning my pending application?
- A: Notifications will be sent by email to the email addresses provided on the application.
- Make sure that you provided a valid email address on the application for the Pharmacist Manager and the Pharmacy.
- Email is the primary source of communication (vital).

- Q. How do I log in and review the Pharmacy application that was submitted?
- A: The applicant received an email, upon submission of the application, with a confirmation number. To log in, navigate to the Licensure Gateway page, select Facility Management, choose Pharmacy in the drop-down box under Permit Type, enter in the confirmation number, and the password. Please note, the password is the last four characters of the confirmation number. Once logged in, click on the icon box for the Pending Application to access the checklist and application viewer.
- For Transfer of Ownership applications and Re-Registration applications, log in with the permit number.



- Q: How do I upload additional requested documentation?
- A: Once logged in (slide #10 has log-in instructions), click on the icon box for the pending *Pharmacy Registration* application. This will bring you to your checklist, click on the blue *Upload* button to upload additional documents.



- Q. How do I the access Certificate A for pharmacy application that was submitted?
- A: Go to the Licensure Gateway page, select Facility Management, login in with the confirmation number and the password
  - Click on the icon box for the pending *Pharmacy Registration* application. Once that is opened, click on the tab at the top entitled *Important Files, you will see Certificate A.*

Application Checklist Application Viewer Payment Information Important Files

ORIGINAL
APPLICATIONS
--PERMIT MEETING--

## SEE THE NOTICE ABOVE IN RED

Does the meeting apply to out of state applicants?

A:Yes, Out of State applicants are required to attend too.

#### !! IMPORTANT NOTICE- At the current time, permit meetings are not being held:

- •Due to the current state-wide state of emergency issued by Governor Cooper on March 10, 2020, permit meetings are not being held for the foreseeable future. Keep in mind that the situation could change.
- •The Governor's emergency declaration discourages unnecessary travel and meetings as a means of containing the spread of COVID-19. Accordingly, the Board's Executive Director waives 21 NCAC 46.1606, which requires that the pharmacist-manager of an applicant pharmacy or the person in charge of a facility applying for a device and medical equipment permit to appear personally at the Board office prior to issuing a permit.
- •Approved pending applications will be processed on the date of the next permit meeting.

September 2020

#### \*\*PLEASE SEE THE NOTICE ABOVE IN RED\*\*

- Q:The instructions mentioned a Permit Meeting, is that meeting required?
- A:Yes, it is required of <u>all facility original applicants (applications)</u>, a personal appearance <u>by the Pharmacist Manager (PM) or the Person in Charge (PIC) listed on the Application that was submitted and approved.</u>
- See additional FAQ concerning permit meeting next slide.
- Transfers and Reregistration's' are not required to attend a meeting.

IMPORTANT NOTICE REGARDING PHARMACY & DME PERMIT MEETINGS: 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 - see calendar). Check-in time for the meeting is at 9:45 am. 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.

### DUE THE COVID-19 PANDEMIC, PERMIT MEETINGS ARE NOT CURRENTLY BEING HELD



GENERAL APPLICATION QUESTIONS-ORIGINAL APPLICATIONS-PERMIT MEETINGS

Q: Can you tell me more about the permit meeting?

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A: Informative meeting on NC Laws and Rules, Procedures, and for clarification of any matters concerning the application for permit. <a href="http://www.ncbop.org/resourcesfornewpermitholders.htm">http://www.ncbop.org/resourcesfornewpermitholders.htm</a>

Q:What do I need to bring?

A: The PM/PIC is required to attend the meeting. They must bring a valid photo ID.

Q: How long does the meeting normally last.

A: The permit meeting normally lasts about one and half hours.

Q: Do I need to schedule in advance?

A:You are not required to schedule in advance. Please decide which permit meeting is convenient for you to attend. Check the website for the meeting dates- <a href="http://www.ncbop.org/calendar.htm">http://www.ncbop.org/calendar.htm</a>

ORIGINAL APPLICATION

- Q: Does the PIC or PM need to have a pharmacist license in North Carolina in order for the pharmacy to apply for the facility license?
- A:The Pharmacist Manager does not need a license in NC.The license is required to be a valid active license.
- Unless the pharmacy is providing remote order processing. If this is the case, then all staff that are reviewing prescriptions are required to have a NC license:

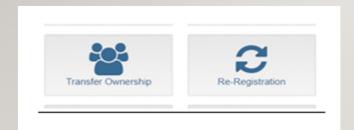
21 NCAC 46 .1417 REMOTE MEDICATION ORDER PROCESSING SERVICES (a) Purpose. The purpose of this Rule is to set out requirements under which health care facility pharmacies may contract for the provision of remote medication order processing services.

http://www.ncbop.org/LawsRules/rules.1400.pdf

WHEN IS A
NEW PERMIT
REQUIRED
FOR AN
EXISTING
PERMIT?

- 21 NCAC 46 .1603 WHEN NEW PERMIT REQUIRED: A new pharmacy, device, or medical equipment permit is required for a new location, 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 most 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.
- See FAQs for Transfer of Ownership or Reregistration

#### \*RE-REGISTRATION



#### **Transfer of Ownership and Reregistration Applications**

There are three types of applications that are considered a Transfer or Re-Registration

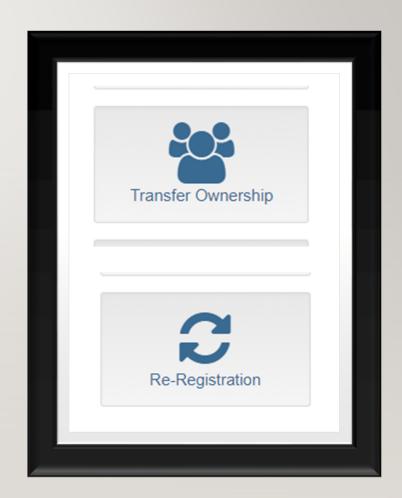
A Transfer of Ownership application is required when a <u>new</u> entity or different person takes over majority interest (greater than 50%) of the business at the permit holder level or above. This results in a new permit number being issued.

A Re-Registration application is required when the majority ownership interest (greater than 50%) changes between <u>existing</u> partners, owners, parties, and/or entities.

A Re-Registration application is required for a new location; when a permit holder physically moves the facility to a new location.

#### \*RE-REGISTRATION

- Q: How far in advance do I need to submit a Transfer of Ownership Application or Reregistration?
- A: <u>Submission of the application is required at least six weeks prior</u> to the effective date
  of the transfer/re-registration. This ensures that the application may be reviewed and
  processed on the transfer/re-registration on the effective date. The Board does not "post
  date" or "pre-date" a transfer of ownership. Keep in mind, no application is guaranteed
  approval.
- Q:What do I put as the opening date? I am not sure of the transfer of relocation date, that has not been confirmed.
- A: Give the anticipated date on the application for the transfer or re-registration and make sure to communicate with the Board in advance if the date changes.
- Q: My transfer or re-registration date has changed; how do I update and notify the Board?
- A: Make sure to communicate with the Board several business dates in advance if the date changes. Please email Wendy Watson the new information, please be sure to include the DBA and the permit number of the pharmacy.



- Q: Is my permit transferrable to another owner?
- A: Permits are non-transferrable as indicated on your Original Certificate; a new owner can apply through an existing valid active permit. The new owner is required to do that in advance by submitting the Transfer of Ownership application, go through the application process and be approved.
- Q:Am I required to file an application for a change of ownership above the permit holder or indirect change of ownership.
- A: Yes, a transfer of ownership application is required if the majority of interest changes (greater than 50%) at the permit holder level or above the permit holder level, as per rule 21 NCAC 46.1603.
- Q:The ownership change did not result in the majority interest changing, how do I update this
  information.
- A:This would be considered a non-controlling owner change which may be updated by logging in under the permit number, scroll down under Options to the box for *Update Non-Controlling Owners*.



- Q: Does the Board give Power of Attorney over the existing permit number?
- A: No, the Board does not grant power of attorney over the existing permit number. That is why it is important for the new owner to apply in advance of the transfer to obtain the new permit number.
- Q: Does the Board consider the permit valid if the ownership has already taken effect before getting the new ownership approved.
- **A:** No, that is why it is important for the new owner to apply in advance for approval of the transfer to obtain the new permit number.





- Q:When will the new permit number go into effect?
- A: On the application it asks for the effective date, that is the date that you
  give the Board as the date of transfer. That date should be a future date, if
  approved the new number will be issued once that date is confirmed by the
  applicant.
- Q:What if I filed the application too close or after the effective date (not allowing the six-week review/processing time)?
- A: If a transfer of ownership requiring a new permit occurs, and the
  pharmacy has not obtained the new permit by the effective date of the
  transfer of ownership, the previous permit becomes void (i.e. no longer
  active) as of the effective date of the transfer of ownership, which could
  result in Board action. It is extremely important to submit the application
  well before the transfer occurs.



- Q: How do I apply for a Transfer of Ownership of a new owner?
- A: Instructions: In order to do a transfer of ownership you need to do the
  following: Submit the completed application to the Board through the Licensure
  Gateway under Facility Management. Log in under the permit number that you are
  transferring from. The existing owner and new owner are both involved in the
  submission.
- I. Scroll down and select the Transfer of Ownership icon box and start the application process.
- 2. The application submitted should include the correct information going forward, the effective date should be the date of the transfer.
- 3. All applicants should upload an explanation of the change, which can include an organizational chart and/or pre/post-closing chart if applicable (uploaded to the Corp. Chart specified upload).
- 4. Out-of-state pharmacy applicants must also include a recent operational inspection and a copy of the license from your state.
- 5. Permit meeting is not required for a Transfer of Ownership application.
- 6. A new permit number will be issued, and the old permit number will go inactive when processed.
- <u>Send in prior to transfer (at least six weeks)</u> so the application can be reviewed and processed on the transfer date. The Board does not post date or pre-date transfer of ownership.

# RE-REGISTRATION BETWEEN EXISTING PARTNERS ONLY



(NOT A NEW PARTNER OR NEW OWNER)

- Q: How do I change ownership between existing partners that is greater than 50% of the majority control of the business?
- A:This type of ownership change requires a Re-Registration Application. This type of application is specifically for majority ownership changes between existing (not a new partner or new owner) partners only. Submit the completed application to the Board through the Licensure Gateway page, under Facility Management. Log in under the permit number that you are re-registering. Instructions:
- I. Scroll down and select the **Re-Registration icon box** and start the application process.
- 2. The application submitted should include the correct information going forward and the effective date should be the date the registration will take place.
- 3. All applicants should upload an explanation of the change, which can include an organizational chart and/or pre/post-closing chart if applicable (uploaded to the Corp. Chart specified upload).
- 4. Out-of-state pharmacy applicants must also include a recent operational inspection and a copy of the license from your state
- 5. A new permit number will remain the same once the Re-Registration is complete.
- <u>Send in prior to transfer (at least six weeks)</u> so the application can be reviewed and processed on the effective date. The Board does not post date or pre-date.

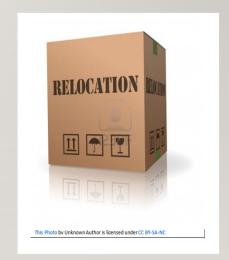
### RE-REGISTRATION FOR CHANGE OF ADDRESS



- Q: I am relocating my facility and physically moving to a new location, how do I update my new address?
- A: CHANGE OF ADDRESS ("RE-REGISTRATION") requires a Re-Registration application, fee, and approval by the Board.

Starting from the Licensure Gateway page, under Facility Management, <u>log in with the permit number</u> information. Then, scroll down and select Re-Reregistration to complete the application. Please note some of the requirements below:

- I. Pictures of the new site, interior/exterior are required.
- 2. Proof of Occupancy (new lease agreement, license, etc.) proof that you occupy the new location.
- 3. Operational Inspection report (for out of state applicants).
- 4. Submit <u>prior to relocation date (at least six weeks)</u> so the application can be reviewed and processed on the effective date of the relocation if approved.
- The permit number will remain the same (i.e. will <u>not</u> change) upon completion of the application process.



# UPDATING AND MAINTAINING VITAL

### INFORMATION ON THE PERMIT

All updates should be updated within 30 days of a change online through the Licensure Gateway. No paper notifications should be sent. This includes, but not limited to:

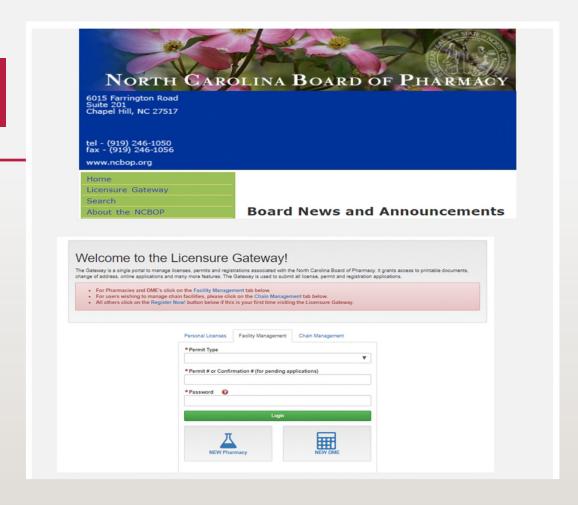
- Email addresses for the PM, the email address for the facility, hours of operation, phone numbers
- Pharmacy Services updates, non-controlling owner changes, name changes, Pharmacist Manager changes, closures, Pharmacist/Technician Ratio changes, employee changes, address corrections (not due to a relocation/physical move)

Please allow 5-7 business days for these types of change requests to be reviewed/updated



- Q. How do I log in and review the Pharmacy's profile information to update?
- A: Go to the Licensure Gateway, select the second tab for Facility Management, login in with the permit number and the password (last four digits of the permit number)

https://portal.ncbop.org/



-- EDITING INFORMATION ON THE FACILITY PROFILE--

- Q:What information can I edit myself on my profile?
- A: Items at the top with "blue gears" are editable information:
  - Email Addresses for the PM and Facility (keep updated, a primary source of communication)
  - Hours of Operation
  - Phone numbers

\*Click on the gear icon beside the information and update\*



--PHARMACIST MANAGER CHANGE--

- Q: How do I submit a change in pharmacist manager for the Pharmacy?
- A: Once logged in under your profile, scroll down to icon boxes under Options select the Update Manger box, submit the new pharmacist manager's information.
- Q: Is there a fee for the pharmacist manager change?
- A:Yes, the fee is \$35.00

Q: I submitted a change in pharmacist manager for the Pharmacy, it's asking for an attestation, how do I upload?

A: Once logged in under the pharmacy profile, scroll down to icon boxes select the *Update Manger* box, open the pending application and upload the attestation to the checklist.

--PHARMACY SERVICE UPDATE--



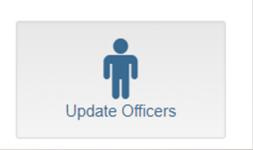
- Q: How do I update the services that the Pharmacy provides?
- A: Once logged in under your profile, scroll down to Icon boxes under Options, select View/Update Services and begin the submission process.
  - Changing/adding, increasing/decreasing the compounding services
  - Adding a website
  - Changes to specializing in certain pharmacy services
  - Changes in offering vaccines
  - Providing or updating DEA and EIN number

Q:The Pharmacy is now participating in donations how do I update this information? (donate or dispense donated prescription drugs, devices, or supplies under 21 NCAC 46.2513)

A:This is part of the services update.

--NON-CONTROLLING OFFICER OR OWNER UPDATE--

- Q:The Officers and/or the Owners of the business have changed, is this required to be updated?
- A:Yes, 21 NCAC 46.1607 number (6) Disclose the location, names, and titles, of all principal corporate officers, if incorporated, and if unincorporated, partners, or owners of the pharmacy. A report containing this information shall be made on an annual basis and within 30 days of each change of any principal office, pharmacist manager of any location dispensing prescription legend drugs to an ultimate user in this State, principal corporate officer if incorporated, and if unincorporated, partner or owner of the pharmacy.



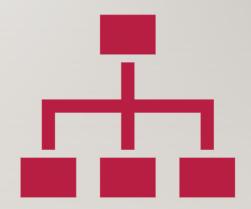






#### --NON-CONTROLLING OFFICER--

- Q: How do I update the officers of the business, with the Board?
- A: Once logged in under the facility profile, scroll down to icon boxes under *Options*, select *Update Officers*. If you need to upload any documentation you can do when you submit the officer change.

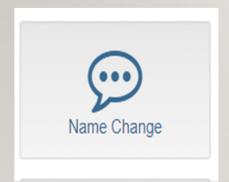


#### NON-CONTROLLING OWNER UPDATE



- Q: How do I update the Non-Controlling Owners of the business with the Board?
- A: Once logged in under the facility profile, scroll down to icon boxes under *Options*, select *Update Non-Controlling Owners*.
  - If you need to upload any documentation you can do so when you submit the change. If you are listing a LLC or Corporation as 100%, you are required to list owners that make up the entity, with percentages.
- Q:This was an indirect change in ownership that requires an update and did not affect the direct ownership listed as the current owner on the profile, how do I update this?
- A: If the direct ownership at the permit holder level stays the same, you can log in and update that to remain the same, then upload your corporate chart of the new tiers of ownership with an explanation of what changed, at what level. That still needs to be submitted.
  - Example: profile shows ABC Pharmacy, LLC as 100%, with tiers of ownership above. Tier two, had a change that resulted in 25% change. You would list ABC, LLC still at 100% but upload your updated chart to show the change with an explanation to include the percentage of change.

-- UPDATING A BUSINESS NAME--



- Q: How do I submit a Name change of the facility to the Board?
- A: Once logged in under the pharmacy profile, scroll down to the icon boxes under Options and select the Name Change box. This is to update minor changes that do not result in a transfer of ownership.
  - Name changes to add, change or update DBA (doing business as) or rebranding, adding Corporate name should be submitted here. If the name is changing due to a new owner or ownership change that results in more than 50% of the controlling interest of the business changing that should be updated on the Transfer of Ownership application.

#### -- CORRECTING THE FACILITY ADDRESS--

- Q:The pharmacy has physically moved; how do I update that information?
- A: Relocations require the submission of the Re-Registration application. Please see previous slides for instructions concerning the Re-Registration Application process.
- Q:How do I notify the Board if the pharmacy did not move or relocate, but my address has changed or needs correcting?
- A: Address Updates are done when EMS/County/Post Office changed the address, or you need to submit a correction, but you did not physically move. See instructions below.
- Q: How do I submit a correction or update to the Pharmacy's physical address or changing/adding a mailing address?
- A: Once logged in under your profile, scroll down to icon boxes under Options, select the Address Update
  box to make corrections, or minor changes that do not result in a relocation of the facility. Physical
  addresses are for the actual permitted site. Updates are done when you are adding a PO Box or simply
  correcting a typo. Relocations require the submission of the Re-Registration application.



# UPDATING VITAL INFORMATION --CLOSING OF A FACILITY--



- Q:What do I need to do if the pharmacy is closing?
- A: As per the rule, noted below, submission of the closing documents should be within 10 days of the effective closing date. Disclosure of where files and records are going to be kept, or transferred to, is required on the application as well. See rule: 21 NCAC 46 .2502 (h) and (i) SECTION .2500 MISCELLANEOUS PROVISIONS
  - Instructions: Once logged in under your profile, scroll down to icon boxes under *Options*, select *Close Facility* and begin the submission process.
  - Paper notifications should not be sent, closings are required to be submitted online.
  - Q: Do we still need to submit the closing if the out of state location is not closing?
  - A: Yes, you are required to close out the NC permit for the facility.