CANNON BUILDING
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DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
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APPLICATION FOR IN-STATE PHARMACY PERMIT
INSTRUCTION SHEET

When to File Application

This is the application for licensure of Retail and Hospital Pharmacies located in Delaware – that is, In-State Pharmacies.

- A Pharmacy–Hospital license is for the in-house pharmacy that dispenses to hospital in-patients.
- A Pharmacy–Retail license is for any of these types of outlets:
  - Community Pharmacy – A retail pharmacy that dispenses directly to patients and is not a nuclear or specialty institutional pharmacy.
  - Nuclear Pharmacy – A pharmacy that provides radiopharmaceutical services or an appropriate area set aside in institutional facility (Section 13.2 of the Board's Rules and Regulations).
  - Specialty Institutional Pharmacy – Institutional pharmacies which provide specialized pharmacy services not generally obtainable from other pharmacies. Examples are short term or primary care treatment facilities that have onsite pharmacies on site such as outpatient chemotherapy centers, primary treatment centers, free standing emergency rooms, rapid in/out surgical centers and certain county health programs (Section 20.0 of the Board's Rules and Regulations).

File this application when applying for an initial license for any of the above types of in-state pharmacy licenses OR re-applying when a previous Delaware pharmacy license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when an in-state pharmacy already licensed in Delaware:
- Changes ownership (controlling interest), or
- Relocates

Requirements for *All* Applicants

Please read and follow instructions carefully. Failing to follow instructions will delay processing of your application.

☐ Submit completed, signed and notarized *Application for In-State Pharmacy Licensing*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Arrange for the pharmacist-in-charge to sign the **PHARMACIST-IN-CHARGE ACKNOWLEDGMENT** section.
- A pharmacist-in-charge must hold a Delaware Pharmacist license.
- A pharmacist-in-charge properly can only serve in that position for one pharmacy.
- The pharmacist-in-charge of a Nuclear Pharmacy must be a Qualified Nuclear Pharmacist. He or she is responsible for all operations of the Pharmacy and must be personally on the premises at all times that the Pharmacy is open for business.
- If the pharmacist-in-charge has not previously served as a pharmacist-in-charge in Delaware, he or she must appear personally at a regularly scheduled Board meeting within 90 days of assuming the position.

☐ Enclose non-refundable processing fee by check or money order made payable to the "State of Delaware."
- Applications submitted without the required fee will be rejected.

☐ Enclose a separate sheet showing the following information for *each* owner, corporate officer, pharmacist and pharmacy employee listed on the application:
- Name
- Data of Birth
- Social Security Number
- Mailing Address

- [ ] Enclose three sets (copies) of the plans for the pharmacy department.
    - Plans must be drawn to scale and should include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe, security systems, and counters. For specific requirements, refer to 24 *Del.C.* §2533 and Section 3.0 of the Board's Rules and Regulations, both available at www.dpr.delaware.gov.
    - Plans must also show the type of alarm system installed and the name, address, and phone of the provider.
    - If the plans are for a nuclear pharmacy, the plans must show the radioactive storage and product decay area.

- [ ] Enclose sample patient profile that meets the requirements of Section 5.0 of the Board's Rules and Regulations.
  ***Label* each of the following required items on the sample profile:**
    - [ ] Patient's family name and first name
    - [ ] Patient's address and phone number (or location in institution)
    - [ ] Patient's gender and age or date of birth
    - [ ] Original date the medication is dispensed following receipt of the prescription
    - [ ] Number or designation for prescription
    - [ ] Prescriber's name
    - [ ] Name, strength, quantity, directions and refill information of drug dispensed
        - Appropriate directions must also be present if medication is for patients in institutions.
    - [ ] Initials of dispensing pharmacist and date of dispensing medication as a refill if those initials and date are not recorded on original prescription
    - [ ] If patient refuses to give all or part of the required information, the pharmacist shall indicate and initial in the appropriate area
    - [ ] Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug
    - [ ] Annotate the patient's
        - allergies, idiosyncrasies, chronic diseases
        - frequently used over-the-counter medications

      If the answer is none, this must also be shown on the profile.

Additional Requirement for Nuclear Pharmacies

- [ ] Submit a copy of your approved Delaware Office of Radiation Control or Nuclear Regulatory Commission license.

Inspection Requirement

In addition to meeting all the requirements above, the pharmacy must be inspected before opening. A pharmacy representative ***must notify the Board office*** when the pharmacy is ready for inspection. When the pharmacy passes the final inspection, the Board office will issue the license.

Reporting Remodeling of an In-State Pharmacy

If an in-state pharmacy will be remodeling but ***there is no change in ownership nor location***, file an *Application for In-State Remodeling Permit* instead of the *Application for In-State Pharmacy Permit.*

Reporting an In-State Pharmacy Name Change

If the in-state pharmacy's name changes but ***there is no change in ownership nor location***, it is not necessary to submit an *Application for In-State Pharmacy Permit*. Instead, submit:

- [ ] Letter notifying the Board of the change that includes the pharmacy's old name, new name, license number and effective date of change.

- [ ] Duplicate license fee by check or money order made payable to the "State of Delaware."
    - The duplicate license will show the new name, but the license number will not change.

Controlled Substances Registration

If the in-state pharmacy stores and/or dispenses controlled substances, a separate *Controlled Substances Application for Facilities* is required.

A pharmacy must have a Delaware Pharmacy permit, Delaware controlled substance registration <u>and</u> federal DEA permit before storing and/or dispensing controlled substances in Delaware.

For Board of Pharmacy Use Only
☐ Verification
☐ Background
☐ Office Approval
☐ Inspection

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APPLICATION FOR IN-STATE PHARMACY PERMIT

TYPE OF APPLICATION

1. Select the items that describe the type of application:

☐ Initial Application –
 ☐ This pharmacy has never held a Delaware Pharmacy license.
 ☐ This pharmacy previously held Delaware Pharmacy license number **A____-** ______________ that has lapsed and is no longer renewable.

☐ Application Due to Change of Ownership – Pharmacy license number **A___-** ______________

☐ Application Due to Relocation – Pharmacy license number **A___-** ________________

2. Select type of pharmacy:

☐ Retail – Select type of retail outlet:
 ☐ Community
 ☐ Nuclear
 ☐ Specialty Institutional

☐ Hospital (In-patient dispensing *only*)

CONTACT AND LOCATION INFORMATION

3. Name of Business (as it should appear on license): ____

4. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: ______________________________ ____________________________ ___________________________

5. ***Location*** **Address**: ____
Street (*No PO Boxes*) Note: If you are reporting relocation, this is the *new* location.

____ ______________________________ _________________
City State Zip

6. Phone: ___________________________________ Email: ____

7. ***Mailing*** **Address** (*if different from physical location*): ____

____ ______________________________ _________________
City State Zip

8. Enter the following information about the contact person in the district/corporate office who will be responsible for receiving and forwarding Delaware Board of Pharmacy alerts:

Name: ____ Email: __________________________________

LICENSURE INFORMATION

9. Will you store and/or dispense controlled substances? Yes ☐ No ☐

> **A pharmacy must have a Delaware Pharmacy permit, Delaware controlled substance registration <u>and</u> federal DEA permit before storing and/or dispensing controlled substances in Delaware.**

10. If applying as a Nuclear Pharmacy, do you have a Delaware Office of Radiation Control and/or Nuclear Regulatory Commission license? Yes ☐ No ☐ **If yes, submit a copy of your Delaware Office of Radiation Control or Nuclear Regulatory Commission license**.

OWNERSHIP INFORMATION

11. Type of Business Owner (check <u>one</u>):

☐ Sole Proprietor – Go to Question 12
☐ Individual with federal employee identification number – Go to Question 12.
☐ Partnership – **Skip to** Question 13.
☐ Corporation – Enter Date of Corporate Charter: ____________________ **Skip to** Question 13.

12. Enter the following information about the owner and then skip to Question 14.

Full Name: ____

Date of Birth: _______________ Social Security Number: ________________________

Mailing Address: ____

______________________________ ______________________________ ____________
City State Zip

13. If a partnership, list ***all active partners***. If a corporation, list ***all principal officers***.

FULL NAME	TITLE

Enclose a separate sheet showing name, date of birth, Social Security Number and mailing address for each person you listed above.

14. Do you understand that the Board must be notified within ten days of a change of ownership? Yes ☐ No ☐

PHARMACIST AND EMPLOYEE INFORMATION

15. Enter the following information about the Pharmacist-in-Charge:

Full Name: ___________________________________ Delaware License Number: **A1-**____________________

Date of Birth: _______________ Social Security Number: ________________________

Mailing Address: ____

______________________________ ______________________________ ____________
City State Zip

Arrange for this person to sign the *Pharmacist-in-Charge Acknowledgment* on this application. If this person has not previously served as a Pharmacist-in-Charge in Delaware, he or she must appear personally before the Board within 90 days of assuming the position.

16. List all other registered pharmacists who will be dispensing at the Pharmacy.

FULL NAME	LICENSE NUMBER
	A1-____________________
	A1-____________________
	A1-____________________
	A1-____________________
	A1-____________________

Enclose a separate sheet showing name, date of birth, Social Security Number and mailing address for each person you listed above.

17. List all unregistered employees who will be working in the Pharmacy.

FULL NAME	EMPLOYMENT START DATE

Enclose a separate sheet showing name, date of birth, Social Security Number and mailing address for each person you listed above.

DISCLOSURES

18. Have any of the owners, corporate officers, pharmacists or unregistered employees listed above ever been convicted of or entered a plea of guilty or *nolo contendere* (no contest) to any felony, misdemeanor or any other criminal offense, including any offense for which they have received a pardon, in any jurisdiction? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and arrange for the Board office to receive a state and federal criminal background check for all persons.**

19. Are any of the owners, corporate officers, pharmacists or unregistered employees listed above presently charged with committing a felony? **If yes, explain in detail on a separate sheet**.

20. Have any of the owners, corporate officers or pharmacists listed above ever applied for a pharmacy permit or controlled substances registration in any State and had the application denied? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet.**

21. Has any of the owners, corporate officers or pharmacists listed above ever been the subject of any disciplinary action (formal or informal) by any federal or state agency or any hospital credentials committee including, but not limited to, revocation or suspension of a controlled substance registration or is any such action pending? Yes ☐ No ☐ **If yes, explain in detail on a separate sheet and enclose any relevant documents.**

INFORMATION ABOUT PHARMACY OPERATION

22. Pharmacy Department hours:

Weekdays	__________ A.M. to __________ PM
Saturday	__________ A.M. to __________ PM
Sunday	__________ A.M. to __________ PM
Holidays	__________ A.M. to __________ PM

23. Enter Hours of Business Site:

Weekdays	__________ A.M. to __________ PM
Saturday	__________ A.M. to __________ PM
Sunday	__________ A.M. to __________ PM
Holidays	__________ A.M. to __________ PM

24. The Prescription Department must occupy at least 250 square feet of floor space excluding a storeroom. The prescription counter must be at least 18 inches wide with four linear feet kept clear and free of all merchandise for each pharmacist working concurrently. The aisle behind the counter must be at least 30 inches wide and shall be kept free of obstruction at all times. Are these requirements met? Yes ☐ No ☐

25. Will the pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices? Yes ☐ No ☐

26. Will the pharmacy have a dispensing area of adequate size and space for proper compounding, dispensing, and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel? Yes ☐ No ☐

27. The area in which drugs and devices are stored must be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit. Will the pharmacy have sufficient environmental control, i.e. lighting, ventilation, heating, and cooling, to maintain the integrity of drugs and devices? Yes ☐ No ☐

28. The sink in the pharmacy area must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized. Will the pharmacy contain a sink with hot and cold running water? Yes ☐ No ☐

29. Refrigerators and freezers (where required) will be maintained at the USP/NF range: Refrigerator – 36 ° to 46 ° Fahrenheit; Freezer – minus 4 ° to plus 14 ° Fahrenheit. Will the pharmacy have suitable refrigeration with appropriate monitoring device? Yes ☐ No ☐

30. An area must be provided to afford the patient privacy from auditory detection by any unauthorized person(s. In most settings, an area partitioned by a 5 foot divider on 2 sides with a minimum of 9 square feet will satisfy this requirement. Will the pharmacy have an area which assures patient privacy to facilitate counseling? Yes ☐ No ☐

31. A sign, with letters not less than 3/4" in height, in the vicinity of the prescription department and visible to the public must list the names of the pharmacists employed at that pharmacy or the name of the pharmacist on duty. Will the pharmacy meet this requirement? Yes ☐ No ☐

32. Do the floor plans for the pharmacy include the type of alarm system installed and the name, address, and phone number of the provider? Yes ☐ No ☐

33. When a pharmacist is not physically present but the operation is open for business, the pharmacy department must be physically or electronically secured form floor to ceiling. The partitioned off section must be not less than five fee high measured from the floor. Will the pharmacy meet this requirement? Yes ☐ No ☐

34. No one but a pharmacist is allowed to unlock and lock the prescription department. Will the pharmacy meet this requirement? Yes ☐ No ☐

35. Each pharmacy is required to maintain a library of the latest edition and supplements of current reference sources (either hard copy or electronic) appropriate to the practice and to the care of the patient served. Will the pharmacy meet this requirement? Yes ☐ No ☐ If yes, explain how you will assure that current information is readily available (e.g., FDA website): ____

36. The pharmacy must maintain the following records:
    - the original of every prescription compounded or dispensed at the pharmacy for a period of at least three years
    - patient profile record for a period at least one year from the date of the last entry in the profile record unless it is also used as a dispensing record.
    - *(Nuclear Pharmacies only)* records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with NRC statute(s) and regulation(s)

    Will the pharmacy meet these recordkeeping requirements? Yes ☐ No ☐

37. When receiving a new prescription, a pharmacist (or pharmacy intern under the direct supervision of a pharmacist) must examine the patient profile before dispensing the medication to determine the possibility of a harmful drug interaction or reaction. If a potential harmful reaction or interaction is recognized, the pharmacist must take appropriate action to avoid or minimize the problem, including consultation with the physician as necessary. Will the pharmacy meet this requirement? Yes ☐ No ☐

- **Enclose three sets (copies) of the plans for the pharmacy department. Plans must be drawn to scale and should include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe, security systems, and counters. If applying as a Nuclear Pharmacy, the plans must show a radioactive storage and product decay area.**
- **Enclose a sample patient profile. See the Instruction Sheet for checklist of items that must appear on the sample.**

PHARMACIST-IN-CHARGE ACKNOWLEDGMENT

I understand that I am responsible for conducting and managing the prescription department in compliance with all applicable state and federal laws.

Have you read and understood your responsibilities in Section 3.1 of the Board's Rules and Regulations?
Yes ☐ No ☐

Do you agree to notify the Board of Pharmacy in writing within 10 days of your termination as pharmacist-in-charge? Yes ☐ No ☐

Pharmacist-in-Charge Signature: ________________________________ Delaware License **A1 -** _______________

When your application is complete, please allow 4-8 weeks to receive your permit. A complete application is one that includes all required documentation and correct payment.

Applications that are not complete within six (6) months of filing may be considered abandoned and discarded.

AFFIDAVIT

I hereby swear or affirm that the foregoing statements are correct and do hereby agree to abide by the pharmacy laws of the State of Delaware and to all rules and regulations of the Delaware State Board of Pharmacy.

Signature:____ Date: __________________

Print Name:____ Position: ___________________________________

State: _____________________________ County: _______________________

Sworn or affirmed before me a Notary Public this___________________ day of ____________________ 2_____

Notary Public: ____

SEAL

My commission expires on ______________________

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED FEE WILL BE REJECTED.