



**DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4292**



**SPECIAL PHARMACY PERMIT APPLICATION AND
INFORMATION**

DECEMBER 2010



Dear Florida Pharmacy Permit Applicant,

Thank you for applying for a pharmacy permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you within 30 days if any materials are incomplete.

If you need to communicate with the board staff, you are encouraged to email the board staff at mqa_pharmacy@doh.state.fl.us, or you may call us at (850) 245-4292. Phone calls are returned within 24 hours and emails are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

Special Pharmacy Permit Application Information

Whether opening a new establishment, changing locations, or changing owners, a pharmacy permit is required prior to operating in the State of Florida. The permit application must be completed and returned to the Florida Board of Pharmacy with the required fee of \$255.00. The application must have the original signatures of the owner or officer of the establishment and the Prescription Department Manager (PDM) or Consultant Pharmacist of Record.

Chapter 465, F.S., requires Special Pharmacies to be under the professional supervision of the PDM or Consultant Pharmacist of Record licensed in the State of Florida. A Florida licensed pharmacist shall perform compounding and dispensing of medicinal drugs.

There are eight (8) types of Special Pharmacy Permit applicants. Please read the descriptions below. Check which permit type you are applying on the application.

- 1. Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.
- 2. Special- Parenteral and Enteral Pharmacy Permits** provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special-Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special- Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.
- 3. Special- Closed System Pharmacy Permits** provide medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. A Special- Closed System Pharmacy may share locations with an establishment that holds a Community Pharmacy Permit; however, recordkeeping and inventory for each permittee must be maintained separately and distinct.
- 4. Special- Non-Resident Registration** is required for those pharmacies located outside the state and ships, mails, or delivers a dispensed medicinal drug into this state.
- 5. Special- End Stage Renal Dialysis (ESRD) Pharmacy** provides dialysis products and supplies to persons with chronic kidney failure and requires the services of a Consultant Pharmacist.
- 6. Special- Parenteral/Enteral Extended Scope** is required to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.
- 7. Special- Assisted Living Facility (ALF)** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.
- 8. Community/Special Parenteral/Enteral Pharmacy** – A community/special parenteral/enteral pharmacy provides outpatient parenteral, enteral and cytotoxic pharmacy services. The pharmacy must meet all requirements of both the community AND parenteral/enteral permits, but does not require two separate permits.

Application Processing

Please read all application instructions before completing your application.

- 1) Please mail the application and the \$255.00 application fee and fingerprint fees (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

OR, use the following address if you are using express mail:

Department of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399-3254

Within 30 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If the application is complete, you will be notified that an inspector will contact you to setup an inspection appointment. Please do not contact the board office concerning your inspection date, and allow 30 days for the inspector to contact you. If the inspector has not contacted you within 30 days, then notify the board. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

- 2) Submit fingerprint results

Failure to submit fingerprints will delay your application. All officers, officers and prescription department managers are required to submit a set of fingerprints unless the corporation is exempt under the Section 465.022, Florida Statutes for corporations having more than \$100 million of business taxable assets in this state. These corporations are only required to have the prescription department manager or consultant of record to submit fingerprints. The statute allows the prescription department manager or consultant pharmacist of record for a corporation having more than \$100 million of business taxable assets in this state to submit results on file with DOH or AHCA and area available to the department. If the manager prints were submitted to DOH within one year of the date of the application, they are not required to submit them over.

Applicants can use any Livescan vendor that has been approved by the Florida Department of Law Enforcement to submit their fingerprints to the department. Please ensure that the Originating Agency Identification (ORI) number is provided to the vendor when you submit your fingerprints. If you do not provide an ORI number or if you provide an incorrect ORI number to the vendor, the Board of Pharmacy will not receive your fingerprint results. The applicant is fully responsible for selecting the vendor and ensuring submission of the prints to the Department.

1. **How do I find a Livescan vendor in order to submit my fingerprints to the department?**

The Department of Health accepts electronic fingerprinting service offered by Livescan device vendors that are approved by the Florida Department of Law Enforcement and listed at their site. You can view the vendor options and contact

information at www.doh.state.fl.us/mqa/pharmacy, select Apply for a License, select Pharmacy Permit Information, select Livescan vendor list.

2. What information must I provide to the Livescan vendor I choose?

a) If you are an applicant seeking a license for any profession regulated by the Department of Health, which requires a criminal background search as a condition of licensure, you must provide accurate demographic information at the time your fingerprints are taken, **including your Social Security number**. The Department will not be able to process a submission that does not include your Social Security number

b) You must provide the correct ORI number.

3. Where do I get the ORI number to submit to the vendor?

The ORI number for the pharmacy profession is FL924190Z

3) Attestation for Business Taxable Assets

If the applicant has more than \$100 million dollars of business taxable assets in this state, please submit a formal opinion letter from a Certified Public Accountant duly licensed in the state of your principal place of business attesting the corporation has more than \$100 million of business taxable assets in this state for the previous tax year. In lieu of submitting a formal opinion letter from a Certified Public Accountant, the applicant may submit its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

4) Special- Parenteral and Enteral, and Special- Parenteral/Enteral Extended Scope Pharmacy Applicants must complete and submit answers to questions below with the application.

Special- Parenteral and Enteral and Special- Parenteral/Enteral Extended Scope Applicants Complete the Following Questions.

The Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection. Do not send the policy and procedure manual to the board office. The board office will approve the policy and procedure manual based upon answers submitted for the following questions, where applicable, by using excerpts or summaries from the policy and procedure manual.

- 1) List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number (if already licensed as an institutional pharmacy):
- 2) Explain the practice setting of the proposed facility.
- 3) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.
- 4) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

- 5) Address the ratio of supportive personnel to each pharmacist. How will the supportive personnel be utilized? Include a job description for any such supportive personnel.
- 6) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.
- 7) What is the policy regarding the delivery of parenteral/enteral products to the patient? Describe methods used and trace the path the product takes from the time it leaves the permittee until it reaches the patient. Describe how products are protected from extreme temperature conditions.
- 8) Address the policy and procedure, special equipment and special techniques to dispense sterile preparations for parenteral therapy/nutrition. If this type of dispensing will not be performed, please state so accordingly.
- 9) Address the policy and procedure, special equipment and special techniques to dispense sterile jejunostomy feeding/sterile irrigation solutions. If this type of dispensing will not be performed, please state so accordingly.
- 10) Address the policy and procedure, special equipment and special techniques to dispense cytotoxic or anti-neoplastic agents. If this type of dispensing will not be performed, please state so accordingly.
- 11) What is the procedure for the annual review and updating of the policy and procedure manual?
- 12) Include the layout/floor plan of the pharmacy. The drawing must include the dimensions of the clean room and the pharmacy, location of the hood, sink, and other equipment. The drawing must also show the location of the clean room relative to other pharmacy and storage areas.
- 13) Include a sample copy of a patient profile.
- 14) Address the use of aseptic techniques.
- 15) Describe the Quality Assurance Program.
- 16) Describe with detail the policy and procedure for patient education, including the personnel involved.
- 17) Address the policy and procedure for handling waste and returns.
- 18) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.
- 19) Describe the refrigerator/freezer to be used.
- 20) Describe appropriate waste containers for:
 - a. Used needles and syringes.
 - b. Cytotoxic waste including disposable apparel used in preparation.
- 21) Address the following supplies to be used: gloves, mask, gowns, needles, syringes, disinfectant cleaning agents, clean towels, hand-washing materials with bactericidal properties, vacuum containers/transfer sets, and spill kits for cytotoxic agent spills.
- 22) Address the following references to be used:
 - a. Chapters 465 and 893, F.S., and Rule 64B16, F.A.C.
 - b. Authoritative Therapeutic Reference.

- c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.
- 23) Occupational Safety and Health Administration guidelines for safe handling of cytotoxic drugs.

If applying for a Special- Parenteral/Enteral Extended Scope Permit, answer the additional questions below:

- 24) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.
- 25) Address the maintenance of patient profiles and the offer to counsel if dispensing to outpatients.
- 26) Describe the system for the maintenance of compounding records.

Licensure Process

Once the application is deemed complete, the board staff authorizes an inspection. Upon completion of the inspection, the inspector notifies the board office as to whether the inspection was satisfactory or unsatisfactory. If the inspection is satisfactory, a permit number is issued within 10 days. **Please wait 15 days from your satisfactory inspection before checking on the status of your permit.** You may lookup your license number on our website at <http://www.doh.state.fl.us/mqa> under “Lookup Licensee.”

Drug Enforcement Administration (DEA)

The DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit. The Board is responsible for notifying the DEA when the pharmacy permit is issued.

If controlled substances will be involved in your pharmacy practice, you must make an Application for Registration under the Controlled Substance Act of 1970 with the DEA. If possible, you are encouraged to use the on-line form system provided by the DEA. Information is available by visiting their website at <http://www.DEAdiversion.usdoj.gov>. DEA Form 224 may be obtained in paper form by writing to:

Drug Enforcement Administration
Attn: ODR
PO Box 2639
Springfield, VA 22152-2639

Form 224 should be completed and mailed via U.S. Postal service to the address listed on the form.

DEA applications are not required for a change of location or change of name. However, if your pharmacy does change locations, you are required to have a pharmacy inspection prior to operating in the new location and the inspector will contact the board office and the DEA to notify them of the change.

PRE-INSPECTION CHECKLIST

- _____ Is there an adequate sink in workable condition that is easily accessible to the prescription counter that will be available during the hours when the prescription department is normally open for business pursuant to Rule 64B16-28.102, F.A.C.?
- _____ Is the pharmacy department equipped an area suitable for private patient counseling if applying for a community pharmacy permit pursuant to Rule 64B16-28.1035, F.A.C.?
- _____ Are all required signs displayed?
- Daily operating hours pursuant to Rule 64B16-28.1081, F.A.C.
 - “Consult your pharmacist regarding the availability of a less expensive generically equivalent drug and the requirements of Florida law” pursuant to Section 465.025(7), F.S.
 - Prescription Department Closed pursuant to Rule 64B16-28.109, F.A.C.
 - Pharmacist meal breaks pursuant to Rule 64B16-27.400(6), F.A.C.
 - Patient Consultation Area pursuant to Rule 64B16-28.1035, F.A.C.
- _____ If compounding sterile preparations, is your pharmacy compliant with Standards for Compounding Sterile Preparations pursuant to Rule 64B16-27.797, F.A.C.?

You may download a copy of the inspection form from the website at http://doh.state.fl.us/mqa/enforcement/enforce_forms.html



FLORIDA BOARD OF PHARMACY
 P.O. Box 6320
 Tallahassee, FL 32314-6320
 Telephone (850) 488-0595
<http://www.doh.state.fl.us/mqa/pharmacy>

SPECIAL PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following:

- New Establishment \$255 fee**
- Change of Location \$100 fee** _____ (existing permit number)
- Change of Ownership (a new permit number will be issued) \$255** _____ (existing permit number)
- Additional Permit Type \$255 fee** _____ (existing permit number)

Type of Special Pharmacy Permit - Please choose one of the following:

- Special- Limited Community
- Special- Parenteral and Enteral
- Special- Closed System Pharmacy
- Special- ESRD
- Special- Parenteral/Enteral Extended Scope
- Special- ALF
- Community/Special Parenteral and Enteral
- Special- Closed System Pharmacy/Parenteral and Enteral

Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? **Yes** **No**

Please list your Federal Employer Identification Number _____

1. Corporate Name	Telephone Number

2. Doing Business As (d/b/a)	E-Mail Address

3. Mailing Address

City	State	Zip

4. Physical Address

City	State	Zip

5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record

Name	License No.	Start Date	Signature

6. Contact Person	Telephone Number

7. DEA Registration Number	8. Date ready for inspection (must be within 90 days of the date of the application) _____
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9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. If not available you may write in pending.

Name	Telephone Number	Permit Number	
Street Address	City	State	Zip

10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)

13a Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?

Yes _____ No _____ If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No _____ If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2), Florida Statutes, questions 15 through 21 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)

Yes _____ No _____

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 18.)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

18. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

19. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 20 and 21)

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

20. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

21. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details)

22. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes _____ No _____ (If yes, submit proof)

23. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. Attach a separate sheet if necessary.

Yes _____ No _____

State	Permit Type	Permit Number

24. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. Attach a separate sheet if necessary.

Yes _____ No _____ (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

25. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

26. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

27. Is there any other permit issued by the Department Health located at the physical location address on this application?

No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details)

28. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 28d.

No _____ Yes _____ (If yes, explain on a separate sheet providing accurate details)

29. Is the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?

No _____ Yes _____

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

I hereby attest that these statements are true and correct and recognize that providing false information may result in disciplinary action against my license or criminal penalties pursuant to sections 465.016, 775.082, 775.083, and 775.084, F.S.

SIGNATURE _____ TITLE _____ DATE _____

Owner/Officer

PHARMACY PERMIT APPLICATION CHECKLIST

Keep a copy of the completed application for your records.

It is recommended that you use the following checklist to help ensure that your application is complete. Failure to attach any required document, or to have required documentation sent to the Board, will result in an incomplete application. Final approval for inspection cannot be granted until the application is complete. Faxed applications will not be accepted.

COMMUNITY/SPECIAL- PARENTERAL & ENTERAL OR SPECIAL PARENTERAL &ENTERAL

- _____ **Application completed (all questions answered)**
- _____ **Application signed**
- _____ **Consultant Pharmacist of Record/Prescription Department
Manager Listed with Signature**
- _____ **\$255.00 Fee Attached (Permit fee includes \$250 application fee
and \$5.00 unlicensed activity fee)**
- _____ **Copy of Articles of Incorporation from the Secretary of
State's Office**
- _____ **Fingerprints have been submitted via livescan for all officers and
owners and the prescription department manager or consultant
pharmacist of record.**
- _____ **Attach proof from AHCA of fingerprint results if applicable for
prescription department manager or consultant
pharmacist of record. Fingerprint results must be
within one year of the application date.**
- _____ **Attestation for Business Taxable Assets of \$100 million
if applicable**
- _____ **Bill of Sale is required for Change of Ownership**