# AGENDA

## Florida Board of Pharmacy
## Compounding Committee Meeting

## April 2, 2018 – 10:00 a.m.

*Residence Inn Tallahassee Universities at the Capitol*
*600 West Gaines Street, Tallahassee, Florida 32304, 850-329-9080*

**Committee Members:**
Mark Mikhael, PharmD
Richard Montgomery, BPharm, MBA
Blanca Rivera, BPharm, MBA
David Wright, BPharm

**Board Staff**
C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor

**Board Counsel:**
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

*Note: Participants in this public meeting should be aware that these proceedings are being recorded.*

1. **Rule 64B16-27.797 - Standards of Practice for Compounding Sterile Products** (pg. 3)

2. **Sterile Compounding Pharmacy Permit applications – discussion and review**
   - Special Pharmacy Permit – DH MQA 1220 (pg. 6)
   - Special Sterile Compounding Pharmacy Permit – DH MQA 1270 (pg. 26)

3. **Stability and chemo attached devices - discussion**

4. **Old Business**

5. **New Business**

6. **Public Comment**

7. **Adjourn**

# TAB #1

**64B16-27.797 The Standards of Practice for Compounding Sterile Products.**

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order; and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office, or ambulatory infusion center).

(1) Adoption of the United States Pharmacopeia: Beginning on October 1, 2014, all sterile compounding shall be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

(a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;

(b) Chapter 71, Sterility Tests;

(c) Chapter 85, Bacterial Endotoxins Test;

(d) Chapter 731, Loss on Drying.

All referenced chapters of the USP, in subsection (1), are specifically referring to the United States Pharmacopeia, 36th revision, Second Supplement, which is hereby incorporated and adopted by reference with the effective chapter dates of December 1, 2013. A subscription to all relevant chapters is available for purchase at www.uspnf.com. The Board has determined that posting the incorporated material on the Internet would constitute a violation of federal copyright law. At the time of adoption, the copyrighted incorporated material will be available for public inspection and examination, but may not be copied, at the Department of Health, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3254, and at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250.

(2) Minimum Standards: The minimum practice and quality standards of the USP are adopted as the minimum standards to be followed when sterile products are compounded. However, nothing in this rule shall be construed to prevent the compounding of sterile products in accordance with standards that exceed the USP.

(3) Current Good Manufacturing Practices: The Board deems that this rule is complied with for any sterile products that are compounded in strict accordance with Current Good Manufacturing Practices per 21 U.S.C. §351 (2012), adopted and incorporated herein by reference, available at https://www.flrules.org/Gateway/reference.asp?No=Ref-04436 and 21 C.F.R. Parts 210 and 211 (2013), adopted and incorporated herein by reference, available at http://www.flrules.org/Gateway/reference.asp?No=Ref-04437.

(4) Registered Outsourcing facilities: For any pharmacy registered as an outsourcing facility, the minimum standards of practice for sterile compounding shall be the current good manufacturing practices as adopted in subsection (3).

(5) Clarifications, Variances, or Exceptions to the United States Pharmacopeia:

(a) Although the USP requires the donning of gloves prior to entry into the clean-room, all required donning of gloves can be performed after entry into the clean-room to avoid contamination of the gloves from the door handle or access device leading into the clean-room.

(b) USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 (see Table 1) environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month.

(c) USP Chapter 797 provides as follows in the "Facility Design and Environmental Controls" section: "An ISO Class 7 (see Table 1) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see Table 1) recirculating devise, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended." Notwithstanding the quoted provision, pharmacies that meet the standards set forth in the section quotes as of the effective date of this rule are not required to change the location of supply air or return filters or ducts so long as the ISO standards are maintained.

(d) USP Chapter 797 provides in part that the compounding facility's ceiling tiles located in the ante-area, buffer area, and clean room that consist of inlaid panels "shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall

be caulked around each perimeter to seal them to the support frame." A pharmacy shall not be required to caulk the inlaid ceiling tiles to the perimeter of the support frame if the following are met:

1. The ceiling tiles are specifically manufactured to be utilized in a facility that must meet and maintain an airborne particulate cleanliness of ISO Class 7 or better.

2. The core of the ceiling tiles are sealed on the front, back, and all edges to render them impervious and hydrophobic, so they can be properly maintained and cleaned as required by this rule.

3. The ceiling tiles are inlaid or installed using a gasket grid sealing system, which is manufactured for use in facilities that must meet and maintain an airborne particulate cleanliness of ISO Class 7 or better. The sealing system must create and maintain a positive seal between the ceiling tiles and the support frame and the seal between the ceiling tiles and support frame shall be secured with retention clips.

*Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10, 10-1-14, 12-18-16.*

# TAB #2

**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

**January 2018**

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 processing delays caused by large volumes 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 your 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 info@floridaspharmacy.gov, or you may at 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 (COR). If compounding sterile preparations, the applicant must submit an additional application on Form DH-MQA 1270, "Special Sterile Compounding Permit" and pay the additional permitting fee.

Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. There are six (6) 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 Permits** may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

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** are not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALF's), Intermediate Care Facility/Developmentally Delayed (ICF-IID's) or other custodial care facilities when defined by Agency for Health Care Administration (AHCA) rules. This permit may not provide medications to in-patients in a hospital.

4. **Special End Stage Renal Dialysis (ESRD) Pharmacy Permits** provides dialysis products and supplies to persons with chronic kidney disease. This permit may not provide medications to in-patients in a hospital.

5. **Special Parenteral/Enteral Extended Scope Pharmacy Permits** is required to compound patient specific enteral/parenteral preparations in conjunction with Institutional Pharmacy permits. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C.

6. **Special Assisted Living Facility (ALF) Pharmacy Permits** is an optional permit for those ALF's providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

Pursuant to Rule 64B16-28.800, applicants for any special pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual which sets for a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

Pursuant to Rule 64B16-28.100(1)(e), F.A.C., the policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

## 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:

| **Application & Fees:** | **Express Mail ONLY** |
|---|---|
| Department of Health | Department of Health |
| Board of Pharmacy | Board of Pharmacy |
| P.O. Box 6320 | 4052 Bald Cypress Way, Bin C-04 |
| Tallahassee, Florida 32314-6320 | 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 owners, officers, and PDMs or CORs are required to submit a set of fingerprints unless the corporation is exempt under 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 PDM or COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, or PDM/COR has already been fingerprinted at the time you are completing this Special Pharmacy permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may 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.

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 may view the vendor options and contact information at:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

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

- 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.
- You must provide the correct ORI number.

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

- The ORI number for the pharmacy profession is **EDOH4680Z.**

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 affirming 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 a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

(3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

**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 7-10 days. You will receive the actual copy of your license within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your license number on our website at http://www.flhealthsource.com/ under "Verify a License."

**Drug Enforcement Administration (DEA)**
**Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.** More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

**IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:**

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has 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.

(e) Has 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, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

**<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>**

# SPECIAL 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.

## SPECIAL PHARMACY PERMIT

_____All Application Questions Answered, including Policy and Procedure questions located within Item #3?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM or COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures which sets forth a detailed description of the type of pharmacy services to be provided within the special pharmacy submitted?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

**FLORIDA BOARD OF PHARMACY**
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

# SPECIAL PHARMACY PERMIT

## APPLICATION

**Application Type – Please choose one of the following:**

___New Establishment ( $255.00 fee)
**Complete: Section A only, along with Items #1, #2, and #3.**

___Change of Ownership ($255.00 fee)
**Complete: Sections A and C only, along with Items #1 and 2.**

___ Change of Location ( $100.00 fee)
**Complete: Sections A and B only.**

___ Stock Transfer (no fee)
**Complete: Section A, pages 2-3 and Section D only.**

**Pharmacy Permit Type – Please choose permit type(s) (fee is $255 for each permit type)**

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

## SECTION A. Please Complete for all Application Types

**Please list your Federal Employer Identification Number:**

| **1. Corporate Name** | | **Telephone Number** |
|---|---|---|
| | | |
| **2. Doing Business As (d/b/a)** | | **E-Mail Address**** (see note below) |
| | | |
| **3. Mailing Address** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **4. Physical Address** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR)** | | |
| **Name** | | **License Number (PS or PU)** |
| | | |
| **E-Mail Address**** (see note below) | | **Telephone Number** |
| | | |
| **6. Contact Person** | | **Title** |
| | | |
| **E-Mail Address**** (see note below) | | **Telephone Number** |
| | | |

***NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.***

**7. Special- Parenteral & Enteral Permits - ONLY**
**Provide 24-Hour Accessible Telephone Number Below:**

(_____) _____- _____

**8. Ownership Information**

**a.** Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

**NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE**

**b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?**

Yes _____ No _____

**c. Does the corporation have more than $100 million of business taxable assets in this state?** *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

**d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 8c. If 8c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 8c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation.** *Attach a separate sheet if necessary.*

| Owner/Officer-Title | Date of Birth | Mailing Address, City State, Zip Code | % of Ownership |
|---|---|---|---|
| | / / | | % |
| | / / | | % |
| | / / | | % |
| | / / | | % |
| | / / | | % |

**9. Has anyone listed in 8d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?** *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

**9a. Has anyone listed in 8d. 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?** *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

| |
|---|
| **Pursuant to Section 465.022(5), Florida Statutes, questions 10 – 19 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.** |
| **10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?** |
| Yes _____ No_____ |
| **11. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?** |
| Yes _____ No _____ |
| **12. 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 crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?** |
| Yes _____ No_____ |
| **13. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever 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_____ |
| **14. 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, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?** |
| Yes _____ No_____ |
| **15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?** |
| Yes _____ No _____ |
| **16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?** |
| Yes _____ No _____ |
| **17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?** |
| Yes _____ No _____ |

**18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?** *(If yes, please submit proof.)*

Yes _____ No _____

**19. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466?**

Yes _____ No _____

**20. 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 |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

**21. Has the applicant, affiliated person, partner, officer, directors, Prescription Department Manager 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 _____

| Individual's Name | Pharmacy Name | State | Status |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

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

Yes _____ No _____

**23. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? 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.**

Yes _____ No _____

**24. 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 24a.**

Yes _____ No _____

| **24a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?** |
|---|
| Yes _____ No_____ |
| **25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?** |
| Yes _____ No_____ |
| **26. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?** |
| Yes _____ No_____ |

## SECTION B. Please complete for Change of Location only.

| **1. Current Practice Location Address** | | |
|---|---|---|
| | | |
| **City** | **State** | **Zip** |
| | | |

| **E-Mail Address**** (see note below) | **Telephone Number** |
|---|---|
| | |

| **2. New Practice Location Address** | | |
|---|---|---|
| | | |
| **City** | **State** | **Zip** |
| | | |

| **E-Mail Address**** (see note below) | **Telephone Number** |
|---|---|
| | |

| **Please provide your existing Pharmacy Permit Number(s):** |
|---|
| **Please provide your existing Federal DEA Number:** |
| ***NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.*** |

## SECTION C. Please complete for a Change of Ownership only.

| **1. Are you changing physical locations with this change of ownership?** |
|---|
| Yes _____ No _____ *NOTE: If yes, please complete Section B above.* |
| **2. Please provide date when business transaction for the change of ownership will be completed?** |
| Date: _____ |
| **3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred?** *Note: A copy of the signed letter should be provided with your application.* |
| Yes _____ No _____ |

| SECTION D. Please complete for a Stock Transfer of Ownership Interests only. |
|---|
| **1. Please provide the date the transfer of ownership interest took place?** |
| Date: _____ |
| **2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, question 1 above?** |
| Yes _____ No _____ *NOTE: If yes, please complete Section C above and include the necessary fee.* |

**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 swear or affirm 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 item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

# FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

**NOTICE OF:**

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

**US Department of Justice, Federal Bureau of Investigation,**
**Criminal Justice Information Services Division**

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI( may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

# Electronic Fingerprinting

**Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.**

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases: _____

Address: _____Apt. Number: _____

City:_____ State_____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown)

Sex: _____
(M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Livescan Service provider*.)

## Keep this form for your records.

# Item #1- Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Privacy Statement Acknowledgement

| **File #** (if known)**:** | **License #** (if applicable)**:** |
|---|---|
| | |

**To: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
**(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov**

## Section A. Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Designation

| **Applicant/Pharmacy Name:** | | |
|---|---|---|
| | | |
| **Applicant/Pharmacy Mailing Address:** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **Incoming PDM / COR Name:** | | **License#:** |
| | | |
| **Date Beginning as PDM / COR:** | **Incoming PDM / COR Signature** | |
| | | |
| **PDM / COR Transaction Control Number (TCN) – related to Livescan Fingerprints** *(optional, if known)***:**<br>** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs** | | |
| | | |
| *****Only provide following information if there is an Outgoing PDM or COR at current pharmacy location.***** | | |
| **Outgoing PDM / COR Name:** | | **License#:** |
| | | |
| **Date Ending as PDM / COR:** | **Outgoing PDM/COR Signature** *(optional)* | |
| | | |

## Section B. Incoming PDM / COR Privacy Statement Acknowledgement

***Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM or COR.***

**I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."**

| **Date:** | **Incoming PDM / COR Signature** |
|---|---|
| | |

## Item #2- Affiliate/Owner Privacy Statement Acknowledgement

**To be completed by EACH Affiliate/Owner listed in the application.**

**To:** **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
**(850) 245-4292- phone * (850) 413-6982 – fax *** MQAPharmPDMAffiliate@flhealth.gov

**From:**

| **Affiliate / Owner Name:** | | **File # (required):** |
|---|---|---|
| | | |
| **Applicant Name:** | | |
| | | |
| **Affiliate/Owner Mailing Address:** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **Affiliate/Owner Email **** (see note below) | **Affiliate/Owner Telephone Number** | |
| | | |
| **Affiliate/Owner Transaction Control Number (TCN)** *(optional, if known)***:**<br>** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs** | | |
| | | |
| *NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.* | | |

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

**Affiliate/Owner Signature (Required)** **Date (of signature)**

# Item #3 - Policy and Procedure Questions

**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. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the pharmacy and shall be available for inspection by the Department of Health. 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 Title 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.

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

# SPECIAL STERILE COMPOUNDING PERMIT APPLICATION AND INFORMATION

**January 2018**

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 processing delays caused by large volumes 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 your 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 info@floridaspharmacy.gov, or you may at 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 STERILE COMPOUNDING PHARMACY PERMIT APPLICATION INFORMATION

A Special Sterile Compounding Pharmacy (SSCP) Permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounded sterile products. An Outsourcing Facility is considered a pharmacy. An SSCP is not a stand-alone pharmacy permit, and can only be issued to an Outsourcing Facility or a pharmacy in this state that holds an active pharmacy permit. However, the SSCP permit is not required for the following permittees:

- A Special Parenteral/Enteral or Special Parenteral / Enteral Extended Scope pharmacy if the pharmacy holds no other pharmacy permit and is not registered as an Outsourcing Facility; or
- A Type B Modified Class II Institutional Pharmacy that compounds low risk level sterile products for immediate-use in full compliance with Rule 64B16 - 28.802, F.A.C.

The compounding of sterile products must be in strict compliance with the standards set forth in Rules 64B16-27.797 and 64B16-27.700, F.A.C. Passing an on-site inspection is a prerequisite for obtaining a SSCP.

Section 465.022(4), Florida Statutes, also provides that an application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. Pursuant to Rule 64B16-28.100(1)(e), F.A.C., the policy and procedure manual shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations as follows:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

In addition to the written policies and procedures for preventing controlled substance dispensing based on fraudulent prescriptions, the applicant for an SSCP must have and submit written policies and procedures that demonstrate the applicant is in full compliance with the compounding standards set forth by statue and rule.

### Application Processing

**Please read all application instructions before completing your application.**

1) Please mail the application and the $255.00 application fee (cashier's check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

**Application & Fees:**
Department of Health
Board of Pharmacy
P.O. Box 6320
Tallahassee, Florida 32314-6320

**Express Mail ONLY**
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. 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 owners, officers, and Prescription Department Managers (PDMs) or Consultant Pharmacists of Record (CORs) are required to submit a set of fingerprints unless the corporation is exempt under 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 PDM or COR to submit fingerprints.

Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications. **Note: If your officer, owner, PDM or COR has already been fingerprinted at the time you are completing this SSCP permit application, please ensure to provide the Transaction Control Number (TCN), if known, with the requested information in the application.**

Applicants may 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.

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:

http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html

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

- 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.
- You must provide the correct ORI number.

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

- The ORI number for the pharmacy profession is **EDOH4680Z.**

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 affirming 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 a copy of its Florida Corporate Income/Franchise and Emergency Excise Tax Return (Form F-1120, Effective 01/09).

3) Privacy Statement and Attestation

In order for the Board of Pharmacy Office to receive your Livescan electronic fingerprinting results, you must affirm that you have been provided with and read the attached statement from the Florida Department of Law Enforcement regarding the sharing, retention, and right to challenge incorrect criminal history records, and the "Privacy Statement" document from the Federal Bureau of Investigation. The appropriate form(s) to provide this affirmation are included within Items #1 and #2 of the application.

## 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 7-10 days. You will receive the actual copy of your permit within 7 days. **Please wait 7-14 days from your satisfactory inspection before checking on the status of your permit with the Board office**.

You may look up your permit number on our website at http://www.flhealthsource.com/ under "Verify a License."

## Drug Enforcement Administration (DEA)

**Please note that the DEA will not issue a registration until the Florida Board of Pharmacy has issued a pharmacy permit.** More information is available by visiting the DEA website at http://www.DEAdiversion.usdoj.gov, or by contacting them at (800)667-9752.

**IMPORTANT NOTICE: Pursuant to Section 465.022(5), F.S., the Department or Board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:**

(a) Has obtained a permit by misrepresentation or fraud.

(b) Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d) Has 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.

(e) Has 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, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f) Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

**<u>If applicable to you, please provide the documentation to the Florida Board of Pharmacy.</u>**

# 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.

## SPECIAL STERILE COMPOUNDING PHARMACY PERMIT

_____All Application Questions Answered?

_____$255.00 Fee Attached (Permit fee includes $250 application fee and $5.00 unlicensed activity fee)

_____Articles of Incorporation paperwork from the Secretary of State provided?

_____PDM or COR Designation and Privacy Statement Acknowledgement provided (Application Item #1)?

_____Affiliate/Owner Privacy Statement Acknowledgement provided for each affiliate/owner (Application Item #2)?

_____Applicant/Affiliate/Owner supplemental documents provided for explaining any previous ownership, disciplinary actions, voluntary relinquishments and/or criminal activity?

_____Applicant/Affiliate/Owner pharmacy permit questions answered and supplemental documents provided?

_____Policies and Procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships submitted?

_____Policies and Procedures for the compounding of sterile products?

**FLORIDA BOARD OF PHARMACY**
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.floridaspharmacy.gov

# SPECIAL STERILE COMPOUNDING PERMIT

## APPLICATION

| **Application Type – Please choose one of the following:** | |
|---|---|
| ___New Establishment ( $255.00 fee)<br>**Complete: Section A only, along with Items #1, #2, and #3.** | ___ Change of Location ( $100.00 fee)<br>**Complete: Sections A and B only.** |
| ___Change of Ownership ($255.00 fee)<br>**Complete: Sections A and C only, along with Items #1 and 2.** | ___ Stock Transfer (no fee)<br>**Complete: Section A, pages 2-3 and Section D only.** |

## SECTION A. Please Complete for all Application Types

**Please list your Federal Employer Identification Number:**

**Please provide your current pharmacy permit number(s):**

**Is the applicant an outsourcing facility?** Yes _____ No_____

| **1. Corporate Name** | | **Telephone Number** |
|---|---|---|
| | | |
| **2. Doing Business As (d/b/a)** | | **E-Mail Address**** (see note below) |
| | | |
| **3. Mailing Address** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **4. Physical Address** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR)** | | |
| **Name** | | **License Number (PS or PU)** |
| | | |
| **E-Mail Address**** (see note below) | | **Telephone Number** |
| | | |
| **6. Contact Person** | | **Title** |
| | | |
| **E-Mail Address**** (see note below) | | **Telephone Number** |
| | | |

***NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.***

**7. Ownership Information**

**a.** Type of Ownership: _____Individual _____Corporation _____Partnership

_____Other: _____

**NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE**

**b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?**

Yes _____ No _____

**c. Does the corporation have more than $100 million of business taxable assets in this state?** *If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income /Franchise and Emergency Excise Tax Return (F-1120).*

Yes _____ No _____

**d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5% or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 7c. If 7c is "Yes", please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 7c is "Yes" and the prints are on file with DOH or AHCA and available to the Board of Pharmacy, the requirement to submit the prints for this person is met. Also, if the % of Ownership column does not add to 100%, please provide an explanation.** *Attach a separate sheet if necessary.*

| Owner/Officer-Title | Date of Birth | Mailing Address, City State, Zip Code | % of Ownership |
|---|---|---|---|
| | / / | | % |
| | / / | | % |
| | / / | | % |
| | / / | | % |
| | / / | | % |

**8. Has anyone listed in 7d. had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?** *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

**8a. Has anyone listed in 7d. 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?** *If yes, please provide a signed statement disclosing the reason the entity was closed.*

Yes _____ No _____

| |
|---|
| **Pursuant to Section 465.022(5), Florida Statutes, questions 9 – 18 are being asked. If you answer "Yes" to any of the following questions, explain <u>on a separate sheet</u> providing accurate details and submit copies of supporting documentation.** |
| **9. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant obtained a permit by misrepresentation or fraud?** |
| Yes _____ No_____ |
| **10. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation?** |
| Yes _____ No _____ |
| **11. 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 crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy?** |
| Yes _____ No_____ |
| **12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever 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_____ |
| **13. 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, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009?** |
| Yes _____ No_____ |
| **14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?** |
| Yes _____ No _____ |
| **15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period?** |
| Yes _____ No _____ |
| **16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application?** |
| Yes _____ No _____ |

**17. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?** *(If yes, please submit proof.)*

Yes _____ No _____

**18. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466?**

Yes _____ No _____

**19. 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 |
|---|---|---|
| | | |
| | | |
| | | |

**20. Has the applicant, affiliated person, partner, officer, directors, Prescription Department Manager 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 _____

| Individual's Name | Pharmacy Name | State | Status |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

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

Yes _____ No _____

**22. Has the applicant, affiliated person, partner, officer, or director ever been convicted of a felony or misdemeanor, excluding minor traffic convictions? 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.**

Yes _____ No _____

**23. Does the applicant, affiliated person, partner, officer, or director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes please answer 23a.**

Yes _____ No _____

**23a. Does the applicant, affiliated person, partner, officer, or director have a repayment plan approved by the department?**

Yes _____ No_____

| **24. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or prosecution for a crime in any jurisdiction?** |
|---|
| Yes _____ No_____ |
| **25. Is the applicant, affiliated persons, partners, officers, or directors, under investigation or pending administrative action by the licensing authority of any jurisdiction, including its agencies and subdivisions?** |
| Yes _____ No_____ |
| **26. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 5 years? If yes, please submit the Form 483 or Warning Letter, any corrective action plan, and supporting documentation demonstrating how the corrective action plan was implemented. Supporting documentation may include but is not limited to pictures, facility diagrams and updated policies and procedures.** |
| Yes _____ No_____ |

## SECTION B. Please complete for Change of Location only.

| **1. Current Practice Location Address** | | |
|---|---|---|
| | | |
| **City** | **State** | **Zip** |
| | | |

| **E-Mail Address**** (see note below) | **Telephone Number** |
|---|---|
| | |

| **2. New Practice Location Address** | | |
|---|---|---|
| | | |
| **City** | **State** | **Zip** |
| | | |

| **E-Mail Address**** (see note below) | **Telephone Number** |
|---|---|
| | |

| **Please provide your existing Pharmacy Permit Number(s):** |
|---|
| **Please provide your existing Federal DEA Number:** |
| ***NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.*** |

## SECTION C. Please complete for a Change of Ownership only.

| **1. Are you changing physical locations with this change of ownership?** |
|---|
| Yes _____ No _____ *NOTE: If yes, please complete Section B above.* |
| **2. Please provide date when business transaction for the change of ownership will be completed?** |
| Date: |
| **3. Do you have a signed letter from both the buyer and seller which indicates dates that pharmacy permit license should be transferred?** *Note: A copy of the signed letter should be provided with your application.* |
| Yes _____ No _____ |

| SECTION D. Please complete for a Stock Transfer of Ownership Interests only. |
|---|
| **1. Please provide the date the transfer of ownership interest took place?** |
| Date: |
| **2. Did your company's FEIN change as a result of the transfer of ownership interest referenced in Section D, question 1 above?** |
| Yes _____ No _____ *NOTE: If yes, please complete Section C above and include the necessary fee.* |

**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 swear or affirm 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 item, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ DATE_____
(Owner or officer of establishment)

# FLORIDA DEPARTMENT OF LAW ENFORCEMENT

NOTICE FOR APPLICANTS SUBMITTING FINGERPRINTS WHERE CRIMINAL RECORD RESULTS WILL BECOME PART OF THE CARE PROVIDER BACKGROUND SCREENING CLEARINGHOUSE

**NOTICE OF:**

- **SHARING OF CRIMINAL HISTORY RECORD INFORMATION WITH SPECIFIED AGENCIES,**
- **RETENTION OF FINGERPRINTS,**
- **PRIVACY POLICY, AND**
- **RIGHT TO CHALLENGE AN INCORRECT CRIMINAL HISTORY RECORD**

This notice is to inform you that when you submit a set of fingerprints to the Florida Department of Law Enforcement (FDLE) for the purpose of conducting a search for any Florida and national criminal history records that may pertain to you, the results of that search will be returned to the Care Provider Background Screening Clearinghouse. By submitting fingerprints, you are authorizing the dissemination of any state and national criminal history record that may pertain to you to the Specified Agency or Agencies from which you are seeking approval to be employed, licensed, work under contract, or to serve as a volunteer, pursuant to the National Child Protection Act of 1993, as amended, and Section 943.0542, Florida Statutes. "Specified agency" means the Department of Health, the Department of Children and Family Services, the Division of Vocational Rehabilitation within the Department of Education, the Agency for Health Care Administration, the Department of Elder Affairs, the Department of Juvenile Justice, and the Agency for Persons with Disabilities when these agencies are conducting state and national criminal history background screening on persons who provide care for children or persons who are elderly or disabled. The fingerprints submitted will be retained by FDLE and the Clearinghouse will be notified if FDLE receives Florida arrest information on you.

Your Social Security Number (SSN) is needed to keep records accurate because other people may have the same name and birth date. Disclosure of your SSN is imperative for the performance of the Clearinghouse agencies' duties in distinguishing your identity from that of other persons whose identification information may be the same as or similar to yours.
Licensing and employing agencies are allowed to release a copy of the state and national criminal record information to a person who requests a copy of his or her own record if the identification of the record was based on submission of the person's fingerprints. Therefore, if you wish to review your record, you may request that the agency that is screening the record provide you with a copy. After you have reviewed the criminal history record, if you believe it is incomplete or inaccurate, you may conduct a personal review as provided in s. 943.056, F.S., and Rule 11C8.001, F.A.C. If national information is believed to be in error, the FBI should be contacted at 304-625-2000. You can receive any national criminal history record that may pertain to you directly from the FBI, pursuant to 28 CFR Sections 16.30-16.34. You have the right to obtain a prompt determination as to the validity of your challenge before a final decision is made about your status as an employee, volunteer, contractor, or subcontractor.

Until the criminal history background check is completed, you may be denied unsupervised access to children, the elderly, or persons with disabilities.

The FBI's Privacy Statement follows on a separate page and contains additional information.

**US Department of Justice, Federal Bureau of Investigation,**
**Criminal Justice Information Services Division**

Privacy Statement

Authority: The FBI's acquisition, preservation and exchange of information requested by this form is generally authorized under 28 U.S.C. 534. Depending on the nature of your application, supplemental authorities include numerous Federal statutes, hundreds of State statutes pursuant to Pub.L.92-544, Presidential executive orders, regulations and/or orders of the Attorney General of the United States, or other authorized authorities. Examples include, but are not limited to: 5 U.S.C. 9101; Pub.L.94-29; Pub.L.101-604; and Executive Orders 10450 and 12968. Providing the requested information is voluntary; however, failure to furnish the information may affect timely completion of approval of your application.

Social Security Account Number (SSAN): Your SSAN is needed to keep records accurate because other people may have the same name and birth date. Pursuant to the Federal Privacy Act of 1974 (5 USC 552a), the requesting agency is responsible for informing you whether disclosure is mandatory or voluntary, by what statutory or other authority your SSAN is solicited, and what uses will be made of it. Executive Order 9397 also asks Federal Agencies to use this number to help identify individuals in agency records.

Principal Purpose: Certain determinations, such as employment, security, licensing and adoption, may be predicated on fingerprint based checks. Your fingerprints and other information contained on (and along with) this form may be submitted to the requesting agency, the agency conducting the application investigation, and/or FBI for the purpose of comparing the submitted information to available records in order to identify other information that may be pertinent to the application. During the processing of this application, and for as long hereafter as my be relevant to the activity for which this application is being submitted, the FBI( may disclose any potentially pertinent information to the requesting agency and/or to the agency conducting the investigation. The FBI may also retain the submitted information in the FBI's permanent collection of fingerprints and related information, where it will be subject to comparisons against other submissions received by the FBI. Depending on the nature of your application, the requesting agency and/or the agency conducting the application investigation may also retain the fingerprints and other submitted information for other authorized purposes of such agency(ies).

Routine Uses: The fingerprints and information reported on this form may be disclosed pursuant to your consent, and may also be disclosed by the FBI without your consent as permitted by the Federal Privacy Act of 1974 (5 USC 552a(b)) and all applicable routine uses as many be published at any time in the Federal Register, including the routine uses for the FBI Fingerprint Identification Records System (Justice, FBI-009) and the FBI's Blanket Routine Uses (Justice/FBI-BRU). Routine uses include, but are not limited to, disclosures to: appropriate governmental authorities responsible for civil or criminal law enforcement counterintelligence, national security or public safety matters to which the information may be relevant; to State and local governmental agencies and nongovernmental entities for application processing as authorized by Federal and State legislation, executive order, or regulation, including employment, security, licensing, and adoption checks; and as otherwise authorized by law , treaty, executive order, regulation, or other lawful authority. If other agencies are involved in processing the application, they may have additional routine uses.

Additional Information: The requesting agency and/or the agency conducting the application investigation will provide you additional information pertinent to the specific circumstances of this application, which may include identification of other authorities, purposes, uses, and consequences of not providing requested information. In addition, any such agency in the Federal Executive Branch has also published notice.

# Electronic Fingerprinting

**Take this form with you to the Live Scan service provider. Please check the service provider's requirements to see if you need to bring any additional items.**

- Background screening results are obtained from the Florida Department of Law Enforcement and the Federal Bureau of Investigation by submitting to a fingerprint scan using the Livescan method;
- You can find a Livescan service provider at: http://www.floridahealth.gov/licensing-and-regulation/background-screening/livescan-service-providers.html
- Failure to submit background screening will delay your application;
- Applicants may use any Livescan service provider approved by the Florida Department of Law Enforcement to submit their background screening to the department;
- If you do not provide the correct Originating Agency Identification (ORI) number to the livescan service provider the Board office will not receive your background screening results;
- You must provide accurate demographic information to the livescan service provider at the time your fingerprints are taken, ***including your Social Security number (SSN)***;
- The ORI number for the Board of Pharmacy is **EDOH4680Z**.
- Typically background screening results submitted through a Livescan service provider are received by the Board within 24-72 hours of being processed.
- If you obtain your Livescan from a service provider who does not capture your photo you may be required to be reprinted by another agency in the future.

Name:_____ SSN#: _____ - ____ - _____

Aliases: _____

Address: _____Apt. Number: _____

City:_____ State_____Zip Code: _____

Date of Birth: _____/_____/_____ Place of Birth: _____
(MM/DD/YYYY)

Weight: _____ Height: _____ Eye Color:_____ Hair Color: _____

Race: _____ Sex: _____
(W-White/Latino(a); B-Black; A-Asian; NA-Native American; U-Unknown) (M=Male; F=Female)

Citizenship: _____

Transaction Control Number (TCN#):_____
(*This will be provided to you by the Livescan Service provider*.)

## Keep this form for your records.

# Item #1- Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Privacy Statement Acknowledgement

| File # (if known): | License # (if applicable): |
|---|---|
| | |

**To: Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
**(850) 245-4292- phone * (850) 413-6982 – fax * MQAPharmPDMAffiliate@flhealth.gov**

## Section A. Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR) Designation

| | | |
|---|---|---|
| **Applicant/Pharmacy Name:** | | |
| | | |
| **Applicant/Pharmacy Mailing Address:** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **Incoming PDM / COR Name:** | | **License#:** |
| | | |
| **Date Beginning as PDM / COR:** | **Incoming PDM / COR Signature** | |
| | | |
| **PDM / COR Transaction Control Number (TCN) – related to Livescan Fingerprints** *(optional, if known)*: ** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs** | | |
| | | |
| *****Only provide following information if there is an Outgoing PDM or COR at current pharmacy location.***** | | |
| **Outgoing PDM / COR Name:** | | **License#:** |
| | | |
| **Date Ending as PDM / COR:** | **Outgoing PDM/COR Signature** *(optional)* | |
| | | |

## Section B. Incoming PDM / COR Privacy Statement Acknowledgement

***Note: Acknowledgment should be completed by same person listed in Section A above as Incoming PDM or COR.***

**I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."**

| Date: | Incoming PDM / COR Signature |
|---|---|
| | |

## Item #2- Affiliate/Owner Privacy Statement Acknowledgement

**To be completed by EACH Affiliate/Owner listed in the application.**

**To:** **Florida Board of Pharmacy, Post Office Box 6320, Tallahassee, FL 32314-6320**
**(850) 245-4292- phone * (850) 413-6982 – fax *** MQAPharmPDMAffiliate@flhealth.gov

**From:**

| **Affiliate / Owner Name:** | | **File # (required):** |
|---|---|---|
| | | |
| **Applicant Name:** | | |
| | | |
| **Affiliate/Owner Mailing Address:** | | |
| | | |
| **City** | **State** | **Zip** |
| | | |
| **Affiliate/Owner Email **** (see note below) | **Affiliate/Owner Telephone Number** | |
| | | |
| **Affiliate/Owner Transaction Control Number (TCN)** *(optional, if known)***:**<br>** For more information regarding Livescan Fingerprints to: http://flhealthsource.gov/bgs-faqs** | | |
| | | |
| *NOTE: Under Florida law, email addresses are public records. If you do not want your e-mail address released in response to a public records request, do not provide an email address or send electronic mail to our office. Instead contact the office by phone or in writing.* | | |

I have been provided and read the statement from the Florida Department of Law Enforcement regarding the sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation."

_____ _____

**Affiliate/Owner Signature (Required)** **Date (of signature)**

# Item #3 - Policy and Procedure Questions

**All Applicants Must Complete the Following Questions.**

The Prescription Department Manager or Consultant Pharmacist of Record is responsible for developing and maintaining a current policy and procedure manual. A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the pharmacy and shall be available for inspection by the Department of Health. 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.

List the following:
Firm Name:
Doing business as (d/b/a):
Telephone number:
Address:
Permit number:

1) Explain the practice setting of the proposed facility.

2) What are the objectives and purpose of the permittee? Give detailed explanation of the services of the facility scope and practice.

3) What are the experience, qualifications, special education, and/or training of the compounding pharmacist? Please provide a resume.

4) What is the ratio of supportive personnel to each pharmacist? How will the supportive personnel be utilized? Include a job description for any such supportive personnel.

5) What categories of parenteral/enteral products will be prepared (i.e. IV, enteral, irrigating, and oncology products)? Include sample labels.

6) 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.

7) 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.

8) What are 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.

9) What is 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.

10) What is the procedure for the annual review and updating of the policy and procedure manual?

11) 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.

12) Include a sample copy of a patient profile.

13) What aseptic techniques are utilized?

14) Describe the Quality Assurance Program.

15) Describe with detail the policy and procedure for patient education, including the personnel involved.

16) What are the policy and procedures for handling waste and returns?

17) Describe the type of certified laminar flow hood(s) to be used and the frequency of certification.

18) Describe the refrigerator/freezer to be used.

19) Describe appropriate waste containers for:

    a. Used needles and syringes.

    b. Cytotoxic waste including disposable apparel used in preparation.

20) 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.

21) How will you utilize the following reference material to ensure patient safety?

    a. Chapters 465 and 893, F.S., and Rule Title 64B16, F.A.C.

    b. Authoritative Therapeutic Reference.

    c. Handbook of Injectable Drugs by American Society of Health-System Pharmacists.

22) What steps will be taken to ensure safe handling of cytotoxic drugs related to the Occupational Safety and Health Administration guidelines.

23) Describe the individual responsibilities of the Special- Parenteral/Enteral Extended Scope Permit and the supplied institutional pharmacy permits, if applicable.

24) What are the protocols for the maintenance of patient profiles and the offer to counsel if dispensing to outpatients?

25) Describe the system for the maintenance of compounding records.

26) What percentage of your business is related to sterile compounding?

27) Describe the types of sterile products you will compound.

28) Are the products you will be compounding:

    a. be pursuant to a patient-specific prescription

b. be prepared in bulk (compounding multiple doses from a single source or batch)

c. be prepared in bulk for office use.

30) Will your pharmacy ship sterile compounded products to other states?

If yes, provide a list of states to which your pharmacy will ship.

31) Provide the total number of pharmacy staff and indicate how many will be preparing sterile products;

a. Pharmacists

b. Pharmacy Interns

c. Pharmacy Technicians

32) Provide the number of clean rooms in your pharmacy.

33) Provide the number of laminar flow hoods in your pharmacy.

34) When was the last time your clean room was certified by an independent contractor for Controlled Environment Testing Association CAG 003-2006? Provide a copy of the most recent inspection and the name and address of the independent contractor.

35) When was the last time your laminar flow hood was certified by an independent contractor for National Sanitation Foundation Standard 49? Provide a copy of the most recent inspection and the name and address of the independent contractor.

36) Has your company ever recalled a sterile compounded product due to a compounding error? If yes, list the name (s) of the drug and the reason for the recall.