AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

October 6, 2014

Embassy Suites South - LBV
4955 Kyngs Heath Road
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Committee Members:
Michele Weizer, PharmD, Boca Raton, Chair
Leo "Lee" Fallon, BPharm, PhD The Villages
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

Board Staff:
Patrick Kennedy, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

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

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

Monday, October 6, 2014 – 2:00p.m.

1. Rule 64B16-28.820 – Sterile Products and Special Parenteral/Enteral Compounding

2. Rule 64B16-28.100 – Pharmacy Permits – Applications and Permitting

3. Non-Resident Sterile Compounding Permit Application

4. House Bill 7077

**64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.**

(1) Sterile Products and Parenteral/Enteral Compounding.

(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:

1. Sterile preparations for parenteral therapy, parenteral nutrition, and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions, and/or
3. Sterile preparations of cytotoxic or antineo-plastic agents, and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

(b) Prior to engaging in a sterile products and parenteral/enteral compounding pharmacy practice an entity shall obtain a special sterile products and parenteral/enteral compounding pharmacy permit as provided herein.

(2) Pharmacy Environment. The compounding and dispensing of sterile products and parenteral/enteral prescription preparations within a special sterile products and parenteral/enteral compounding pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General Requirements.

(a) A special sterile products and parenteral/enteral compounding pharmacy shall be under the control and supervision of a licensed pharmacist, who shall be designated prescription department manager on the application for a special sterile products and parenteral/enteral compounding pharmacy. The prescription department manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of operation of said pharmacy. Changes in prescription department manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and prescription department manager of record. A prescription department manager of a special sterile products and parenteral/enteral compounding pharmacy shall not be designated prescription department manager of record of more than one special sterile products and parenteral/enteral compounding pharmacy, unless otherwise approved by the Board. The Board will consider the proximity of the facility as well as the administrative workload created by the two permits, in determining whether or not it will approve the designation of someone as a prescription department manager of more than one special sterile products and parenteral/enteral compounding pharmacy.

(b) A special sterile products and parenteral/enteral compounding pharmacy shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include the time and/or date of expiration on the label. Delivery from the pharmacy to the patient shall be made within a reasonable time. A special sterile products and parenteral/enteral compounding pharmacy shall provide telephone accessibility to its pharmacist(s) for its patients at all hours.

(c) A patient profile shall be maintained for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards which shall be confidential.

(d) A Policy and Procedure Manual shall be prepared and maintained at each special sterile products and parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random production sampling consistent with recommended standards for compounding and dispensing intravenous admixtures as set forth by the Joint Commission on Accreditation of Health Organizations, the National Coordinating Committee and Large Volume Parenteral, and as provided by the Florida Board of Pharmacy.

(e) Compounding shall be conducted within an annually certified laminar air flow (LAF) hood, except in the existence of a Class 100 certified compounding environment, or certified mobile isolation chamber, in which case compounding may be conducted without the use of a certified laminar air flow hood. All cytotoxins must be compounded in a certified vertical laminar air flow hood or certified mobile isolation chamber. The use of a Type A or Type B LAF hood used shall be dependent upon the volume of work anticipated. All certifications shall be performed following manufacturer specification.

(f) Protective garb: gloves, face and eye, and gowns should be provided and used.

(g) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(h) All unused cytotoxic agents and material must be disposed of properly in accordance with accepted professional standards and applicable law.

(i) In conformity with existing and past practices and notwithstanding 3(a) above, there is no minimum hour requirement for the pharmacist to be present and on duty at the facility and no requirement that a pharmacist be present and on duty whenever the facility is operational and open to the public through support staff and pharmacy technicians. However, a pharmacist must be present and on duty (a) whenever drugs are being prepared, compounded, or dispensed, (b) when the part of the facility in which drugs are stored, prepared, compounded or dispensed is not locked or secured or is accessible to the facility staff, or (c) when those acts in which a pharmacist must be present pursuant to applicable Florida Statutes and regulations are performed.

(4) An applicant for a special sterile products and parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) Completed Board of Pharmacy permit application form (Form DPR/PH/107/9-88).

(b) Copy of Policy and Procedure Manual.

(c) Permit fee as provided in Rule 64B16-28.121, F.A.C.

(5) Minimum Requirements for Space, Equipment, Supplies and Publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a sterile products and parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for by this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or shall be under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(c) Equipment:

1. Laminar Air Flow Hood(s):

a. Horizontal and/or.

b. Vertical.

2. Refrigerator/freezer convenient to the clean room.

3. Sink and wash area convenient to the clean room.

4. Appropriate waste containers for:

a. Used needles and syringes.

b. All cytotoxic waste including apparel.

(d) Supplies:

1. Gloves, masks and gowns.

2. Needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. “Spill kits” for cytotoxic agent spills.

(e) Current References:

1. Chapter 465, F.S.

2. Chapter 499, F.S.

3. Chapter 893, F.S.

4. Title 64B16, F.A.C., Rules of the Florida Board of Pharmacy.

5. United States Pharmacopeia and National Formulary, or Remington Pharmaceutical Sciences, or the United States Dispensatory (along with the latest supplements), or an equivalent thereof sufficient in scope to meet the professional practice needs of the pharmacy, and a current authoritative therapeutic reference.

6. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

7. “Practice Guidelines For Personnel Dealing With Cytotoxic Drugs.”

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 456.0196 FS. History–New 4-26-84, Formerly 21S-1.40, Amended 7-27-86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03, 6-4-14.*

# FISCAL YEAR 2014 DEPARTMENT OF HEALTH
# Board of Pharmacy Proposal for Addition of Interpretive Language

RULE NO.: 64B16-28.820

RULE TITLE: Sterile Products and Special Parenteral/Enteral Compounding.

SUBJECT AREA TO BE ADDRESSED: Pharmacist Presence at Special Parenteral/Enteral Facilities.

PURPOSE AND EFFECT: In order to prevent injustice and the decimation of the Special P/E and Sterile Compounding pharmacies that the Board created and in order to meet a real need and demand for healthcare in Florida, the Board must add additional interpretive language regarding when these facilities are operational in accordance with existing and past practices. Generally, these are small businesses that, although they are open to the public, rarely receive or fill orders for customers in person due to the nature of the P/E products and services, do not require a full time on duty pharmacist to service their customers and find it cost prohibitive and unnecessary to employ a full time pharmacist. However, CMS is now attempting to shut down these pharmacies by interpreting Florida law to require a full time pharmacist present and on duty at the facility at all times if it is to be considered operational. The interpretive language that would be added as part (3)(i) would clarify the existing laws, regulations, and past practices of these pharmacies. Mainly, the proposed language clearly states that a pharmacist is only necessary to be present and on duty (a) when drugs are being prepared, compounded or dispensed, (b) when the part of the facility in which drugs are stored, prepared, compounded or dispensed is not locked or secured or is accessible to the facility staff, and (c) when otherwise necessary to perform those specific duties enumerated in the Florida Statutes and various regulations; however, except as stated herein, the performance of support staff and pharmacy technicians allows the facility as a whole to remain operational and open to the public during business hours even when a pharmacist is not present and on duty. Such additional language will seek to correct CMS' misinterpretations of already existing Florida law and past practices and allow the Special P/E and sterile compounding pharmacies to provide the services they were created for and meet the real need for healthcare in Florida.

PROPOSAL: Adding part (i) to 64B16-28.820(3) as follows: (i) In conformity with existing and past practices and notwithstanding 3(a) above, there is no minimum hour requirement for the pharmacist to be present and on duty at the facility and no requirement that a pharmacist be present and on duty whenever the facility is operational and open to the public through support staff and pharmacy technicians. However, a pharmacist must be present and on duty (a) whenever drugs are being prepared, compounded, or dispensed, (b) when the part of the facility in which drugs are stored, prepared, compounded or dispensed is not locked or secured or is accessible to the facility staff, or (c) when those acts in which a pharmacist must be present pursuant to applicable Florida Statutes and regulations are performed.

**64B16-28.100 Pharmacy Permits – Applications and Permitting.**

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://www.doh.state.fl.us/mqa/pharmacy or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.com. The application must be accompanied with a $250 initial permit fee, payable to the Board.

(1) All Permits: A permit is valid only for the name and address to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

(a) A permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

1. A contiguous area under the control of the permit holder. For purposes of this rule, a public thoroughfare will be considered to have not broken the area of contiguity, and

2. An area not more than one half (1/2) mile from the central location of the permit.

(b) The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 “Pharmacy Permit Name Change Form” effective December 2010, which is incorporated by reference herein, and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://www.doh.state.fl.us/mqa/pharmacy.

(c) Each applicant must file with the board a legible set of fingerprint cards and a $48 fee for each person who submits an application meeting the requirements in Section 465.022(3), F.S. An applicant may register demographic information and purchase fingerprint cards (FD-258) at http://http://www.fldoh.sofn.net/. If an applicant chooses not to purchase a fingerprint card, the applicant must make sure the police or agency that rolls the fingerprints uses a FD-258 fingerprint card. A Non-Resident Pharmacy Registration applicant is not required to submit a legible set of fingerprints upon application.

(d) Passing an on-site inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the on-site inspection, the board inspector will document the applicant’s compliance with all applicable rules and statutes.

(e) Each applicant must attach to the application the applicant’s written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

(2) Community Pharmacy Permit as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, “Community Pharmacy Permit Application and Information,” effective August 2012 which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02298.

(a) Applicants for a Community Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a prescription department manager as required by Section 465.018, F.S.;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, “Prescription Department Manager Change,” effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02299.

(c) The policy and procedure manual for Community Pharmacies shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations. The policy and procedural manual shall provide the following:

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.

(3) Institutional Pharmacy Permits as authorized by Section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for a Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02300.

(a) Applicants for an Institutional Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a consultant pharmacist of record as required by Section 465.019, F.S.;

(b) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02301.

(4) Nuclear Pharmacy Permit as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02302.

(a) Applicants for a Nuclear Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a nuclear pharmacist of record as required by Section 465.0193, F.S.;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02303.

(a) Applicants for a Special Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.

(d) The Board recognized the following types of Special Pharmacy permits:

1. Special Limited Community Permit 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 Permit is required to 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 Permit is 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, ALF's, Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. Special Pharmacy – End Stage Renal Disease (ESRD) Permit is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for pharmacies to compound patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.

6. Special – Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6) Internet Pharmacy Permit as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012.

(a) Applicants for an Internet Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, F.S.;

(b) As set forth in Section 465.0197, F.S., the permittee shall notify the board within 30 days of any change of location, corporate officers, and the pharmacist serving as the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(7) Non-Resident Pharmacy Registration as authorized by Section 465.0156, F.S., is required for those pharmacies located outside the state and which ships, mails, or delivers a dispensed medicinal drug into this state. Applicants for a Non-Resident Registration must complete an application for a registration using an original Form DH-MQA 1217, "Non-Resident Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02304. Applicants for registration as a non-resident pharmacy must comply with all requirements found in Section 465.0156, F.S.

(8) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, any pharmacy engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," effective May 2013, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-03142.

(a) All applicants that hold an active pharmacy permit that are currently engaged in sterile compounding have 180 days from the effective date of this amendment (eff. 9/23/13) to obtain a Special Sterile Compounding Permit. All pharmacies, which obtain the permit within the 180 days, on or before March 21, 2014, are exempt from paying an additional application or license fee.

(b) Applicants for a Special Sterile Compounding Permit must:

1. Comply with all permitting requirements in subsection (1) of this rule;

2. Designate a prescription department manager or consultant pharmacist of record.

(c) The permittee and the newly designated prescription department manager of record or consultant pharmacist of record shall notify the board within 10 days of any change in the prescription department manager or consultant pharmacists of record on FORM DH-MQA PH10, "Prescription Department Manager Change," effective December 2010 or FORM DH-MQA 1184, "Change of Consultant Pharmacist of Record."

*Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 456.0635, 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13, Amended 9-23-13.*

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

# SPECIAL NONRESIDENT STERILE COMPOUNDING APPLICATION

**&**

**SUPPORTING DOCUMENTATION**

**OCTOBER 2014**

DH5003-MQA-9/14
Rule 64B16-28.100 F.A.C.

Dear Florida Permit Applicant,

Thank you for applying for a permit in the State of Florida. A Nonresident Sterile Compounding Permit as authorized by Section 465.0158, Florida Statute is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

We welcome nonresident compounding pharmacies (currently registered under s. 465.0156, F.S.) and outsourcing facilities seeking mandatory Nonresident Sterile Compounding Permits. Your assistance in providing all required information below will enable the Florida Board of Pharmacy (the board) to process your application as quickly as possible. You are encouraged to apply as early as possible in order to avoid any undue delays.

Florida Statute requires the board to receive a completed application and all applicable fees before reviewing an application. So please read these instructions carefully and fully before submitting the application. Keep a copy of the completed application and all other materials for your records. When mailing the completed application and fees, use the address noted in the instructions and on the application form.

Upon receipt of your application, you will be notified and your fees will be verified and deposited. Board staff will then notify you in 7-14 days of any deficiencies in your application. If you need to communicate with the board, 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 within 48 hours during normal business hours.

Our staff is committed to providing prompt and reliable information to our customers. Customer service is important to us. And while we strive to process your application as quickly as possible, we welcome your comments on how our services may be improved.

Sincerely,

The Florida Board of Pharmacy

## APPLICATION PROCESSING

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

1) Applications should be mailed along with a $255.00 application fee (check or money order made payable to the FLORIDA DEPARTMENT OF HEALTH) to the following address:

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

Applicants will be notified within 7 to 14 days of the receipt of an application and informed of any deficiencies. In cases of deficient applications, applicants will be notified in writing of what is required to complete the application.

2) Along with their application **Nonresident Pharmacies** must submit a letter of licensure verification for both the facility and the Pharmacy Manager from their local state, territory or district board of pharmacy. The letter must include the original licensure date, the expiration date; and current licensure status. Nonresident Pharmacies must also submit a copy of their most recent inspection by the state, territory, or district board of pharmacy or the entity responsible for conducting inspections in the state where they are physically located. Inspections must display compliance with USP Chapter <797>.

An inspection report is current if the inspection was conducted within 6 months before the date of submitting the application for the initial permit or within 1 year before the date of submitting an application for permit renewal. If you are unable to submit a current inspection report conducted displaying compliance with USP Chapter <797> due to acceptable circumstances as established by rule, or if no current inspection has been performed, the department shall:

A. Conduct or contract with an entity to conduct, an onsite inspection for which all costs shall be borne by the applicant; *or*

B. Accept a current and satisfactory inspection report from an entity approved by the board.

3) Along with their applications **Outsourcing Facilities** must submit proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services; *and* a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act, Pub. L. No. 113-54.

## PERMITTING

Once an application is deemed complete and is approved, board staff will issue the applicant a new permit number. The “hard copy” permit should arrive at the applicant’s listed address within 7 days of the issue date.

## USP <797> OVERVIEW (Pharmacies Only. Outsourcing Facilities may skip.)

**All pharmacies must answer the following questions.** The questions will help our inspectors understand more about your pharmacy's approach to USP Chapter <797>. Please answer the following questions as completely and legibly as possible. Attach additional pages if needed.

**1.** These questions relate to your primary engineering controls.

a. How many primary engineering controls do you have? _____

b. What kind are they? (select all that apply)

- ☐ Laminar Airflow Workbench (LAFW)
- ☐ Compounding Aseptic Isolator (CAI)
- ☐ Biological Safety Cabinet (BSC)
- ☐ Compounding Aseptic Containment Isolator (CACI)
- ☐ Integrated vertical clean bench
- ☐ Other: please describe _____

c. Where are your primary engineering controls located? (select all that apply)

- ☐ Positive Pressure ISO Class 7 buffer room with walls/doors
- ☐ Negative Pressure ISO Class 7 buffer room with walls/doors
- ☐ Positive Pressure ISO Class 7 anteroom
- ☐ Positive Pressure ISO Class 8 anteroom
- ☐ Non-ISO classed segregated compounding area for non-hazardous compounding
- ☐ Non-ISO classed containment segregated compounding room with 12 ACPH/negative pressure
- ☐ Other: please describe _____

d. What was the date of the last certification your primary and secondary engineering controls?

_____

e. Did the certification of the primary and (if applicable) secondary engineering controls include testing of non-viable particle counts and airflow pattern smoke testing ***under dynamic operating conditions*** (while pharmacy staff are working or simulating work in the area being tested)?

☐ Yes ☐ No

**2.** What kind of gloves and alcohol are in use at your pharmacy for sterile compounding activities?

| Describe briefly: |
|---|
| |

**3.** If your pharmacy uses isolators (Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators), describe how gloves are donned before compounding in your isolator/s.

☐ Not applicable because we do not use isolators for sterile compounding.

| Describe briefly: |
|---|
| |

**4.** Primary engineering controls must be disinfected at frequent intervals with sterile 70% IPA during use but they also must be part of the daily cleaning routine. Briefly describe how the inside of your primary engineering controls are cleaned and disinfected (as well as the agents used) daily during your pharmacy's daily cleaning routine.

| Describe briefly: |
|---|

**5.** Before pharmacy staff or outsourced cleaning staff are allowed to perform daily and monthly cleaning activities, they must receive (at minimum) training and competency verification in which two areas?

| 1.<br>2. |
|---|

**6.** USP <797> requires that each compounding staff member successfully complete some training and testing before they are allowed to make compounded sterile preparations for human use. Briefly describe this type of training and testing at your facility.

| Describe briefly: |
|---|

**7.** These questions relate to viable air sampling. Please provide a short answer to each.

a. How often does your pharmacy perform viable air sampling? _____

b. Where is viable air sampling performed?_____

_____

c. How large are the samples of air you are sampling?_____

d. What are your action levels?_____

**8.** Surface sampling is a personnel metric that is required "periodically" by USP Chapter <797>. How is it performed at your pharmacy? Briefly describe under what conditions it is performed, how often, with what and where it is performed.

| Describe briefly: |
|---|

**9.** USP Chapter <797> requires Gloved fingertip sampling. Briefly describe how and when your pharmacy performs gloved fingertip sampling.

| Describe briefly: |
|---|

**10.** What activities would occur at your pharmacy if the results (number of colony forming units) of one of your Environmental Sampling samples exceeded the preselected Action Levels for that area.

| Describe briefly: |
|---|

**11.** Please explain how the concept of “first air” is critical to executing sterile compounding with proper aseptic technique.

| Describe briefly: |
|---|
| |

**12.** If a pharmacy uses a 0.22 micron filter for the purposes of sterilization, what test is required before that batch may be released?

_____

**13.** According to USP Chapter <797>, is sterility testing required if a beyond-use date of 30 days refrigerated is assigned to a medium risk level batch?

| Answer Yes or No and then briefly explain your rationale: |
|---|
| |

**14.** During a compounding process, the pharmacy removes the vial stopper from a product purchased from an FDA registered manufacturer. Does this change the risk level that should be assigned to the final CSP made from that product and what risk level would you assign it?

| Answer: Yes or No then indicate the risk level you would assign this CSP and your rationale: |
|---|
| |

**15.** Please provide us with your opinion about the practice of Lyophilization by pharmacies that perform sterile compounding (“freeze drying” solutions to make lyophilized powder).

| Describe your opinion of Lyophilization below including its use in pharmacy: |
|---|
| |

**16.** If a pharmacy has performed sterility testing on a batch (or outsourced it to a vendor who performs sterility testing in compliance with USP Chapter <71> on their behalf) and the batch fails, is it acceptable practice to retest that batch?

| Answer Yes or No and then briefly describe your rationale: |
|---|
| |

## POLICIES & PROCEDURES

***Applicants must submit their existing policies and procedures for sterile compounding with this application.*** The policies and procedures must comply with pharmaceutical standards in chapter 797 of the United States Pharmacopoeia and any standards for sterile compounding required by board rule or current good manufacturing practices for an outsourcing facility.

The Prescription Department Manager or Pharmacist in Charge is responsible for developing and maintaining a current policy and procedure manual. The permittee must make available the policy and procedure manual to the appropriate state or federal agencies upon inspection.

**List the following:**

Firm Name:

Doing business as (d/b/a):

Telephone number:

Address:

Permit number:

## IMPORTANT NOTICE

**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 pharmacist in charge of the applicant:**

**(a) 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.**

**(b) 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.**

**(c) 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.**

**(d) 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.**

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

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

**(g) 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.**

**(h) 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.**

**(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.**

**If this is applicable to you, please provide documentation to the Florida Board of Pharmacy.**

**FLORIDA BOARD OF PHARMACY**
P.O. Box 6320 | Tallahassee, FL 32314
(850) 245-4292 | www.floridaspharmacy.gov

# NONRESIDENT STERILE COMPOUNDING APPLICATION

**Application Type:**

☐ **New Establishment $255 fee (1020)** ***(New applicants must also apply for the Special Nonresident Pharmacy Permit)***

☐ **Change of Location $100 fee (3012)** _____ **Existing Sterile Compounding Permit Number**

☐ **Change of Ownership* $255 fee (1023 create new file)** _____**Existing Nonresident Permit Number**

***New permit number will be issued**

**Federal Employer Identification Number (FEIN)**

**1. Corporate Name** | **Telephone Number**

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

**3. Mailing Address**

City | State | Zip

**4. Physical Address**

City | State | Zip

**5. Prescription Department Manager (PDM) or Pharmacist In Charge (PIC)**

Name | License No. | Start Date | Signature

**6. Contact Person** | **Telephone Number**

**7. DEA Registration Number (If applicable)**

**8. Do you have 24-hr access to patient records?**
___ Yes ___ No (If no explain on separate sheet)

**9. Date of last inspection** _____

**10. If your facility is a pharmacy, has the facility received an inspection within the last 6 months that ensures compliance with USP 797 standards; or if your facility is an outsourcing facility, has an inspection been conducted in the last 6 months that ensures compliance with current good manufacturing practices? (Attach a copy of the inspection report, a copy of the floor plan and a copy of your policies and procedures manual**).

_____Yes _____No

**11. Prescription Department Operating Hours**

Monday-Friday: Open _____Close: _____

Saturday: Open _____Close: _____

Sunday: Open _____Close: _____

**11a. Toll-Free Telephone Number**
(available 6 days a week for 40 hours)

(_____) _____- _____

**12. 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 SECRETARY OF STATE'S OFFICE WHERE THE FACILITY IS LOCATED.**

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

Yes _____ No _____

**c. Persons having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant.** ***Attach a separate sheet if necessary.***

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

**Questions 13 through 21 are required pursuant to Section 456.0635(2) *Florida Statutes*. Please explain any "yes" answered to the following questions on a separate sheet, providing as much detail as possible. Please also provide copies of any relevant supporting documentation.**

**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, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)**

Yes_____ No _____

**13a. If "yes" to 13, for the felonies of the third degree, is the date of application more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).**

Yes_____ No_____

**13b. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?**

Yes_____ No_____

**13c. If "yes" to 13, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).**

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 to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?**

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

**14a. If "yes" to 14, is the date of application more than 15 years after the sentence and any subsequent period of probation ended?**

Yes_____ No_____

**15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 16.)**

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

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

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

**17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 18 and 19)**

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

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

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

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

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

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

Yes_____ No_____ (If yes, explain on a separate sheet providing accurate details)

**21. 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 |
|---|---|---|
| | | |
| | | |

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

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

| Pharmacy Name | State | Status |
|---|---|---|
| | | |
| | | |

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

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

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

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

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

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

**26. Does the applicant, affiliated person, partner, officer, director or Pharmacist in Charge have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes, please answer 26a.**

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

**26a. Does the applicant, affiliated person, partner, officer, director or Pharmacist in Charge have a repayment plan approved by the department?**

Yes _____ No _____

## ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

**********

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

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

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 and/or criminal penalties.

SIGNATURE _____ TITLE _____DATE_____
Owner/Officer

**********

**FLORIDA BOARD OF PHARMACY**
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.floridaspharmacy.gov

# ATTESTATION FORM

Section 465.0156(3) (c), F.S., requires that applicants submit a written attestation by an owner or officer of the applicant and by the applicant's Prescription Department Manager, (PDM) or Pharmacist In Charge (PIC).

*I certify as the attestor that I have read and understand the laws and rules governing sterile compounding in the State of Florida, and that any sterile compounded product shipped, mailed, delivered, or dispensed into the State of Florida from our facility meets or exceeds the standards for sterile compounding set by the State of Florida and has not been compounded in violation of the laws and rules of the state, territory, or district in which our facility is located.*

SIGNATURE _____ TITLE _____DATE_____
**(Owner/Officer)**

SIGNATURE _____ TITLE _____DATE_____
**(PDM/PIC)**

# PHARMACY PERMIT APPLICATION CHECKLIST

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

_____ **Application completed (all questions answered)**

_____ **Application signed**

_____ **Attestation form signed by an owner/officer and the PDM/PIC**

_____ **Consultant Pharmacist of Record/Prescription Department Manager Listed with Signature**

_____ **$255.00 Fee Attached (Fee required for new establishments only)**

_____ **Copy of Articles of Incorporation from the Secretary of State's Office (Required for new establishments)**

_____ **Bill of Sale is required for Change of Ownership**

_____ **Policy & Procedure Questions Answered**

## KEEP A COPY OF THE COMPLETED APPLICATION FOR YOUR RECORDS