

**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

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.
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:



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 _____



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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**