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

# NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FORNONRESIDENT PHARMACIES

## JULY 2016

DH5003-MQA, 07/16
Rule 64B16-32.007, F.A.C.

## Nonresident Sterile Compounding Permit for Nonresident Pharmacies Information

A Nonresident Sterile Compounding Permit as authorized by Section 465.0158, *Florida Statutes* is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

## Definition:

For purposes of this application, when the term "affiliated person" is used, the term shall mean any person who has an ownership interest of 5% or greater in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy.

## Application Processing

1. Please mail the application and the $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 6330
   Tallahassee, Florida 32314-6320

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

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

2. Along with the application, Nonresident Pharmacies must submit the following:

   **a.** A letter of licensure verification for both the facility and the Prescription Department Manager or Pharmacist in Charge or equivalent from the state, territory or district regulatory or licensing agency. The letter must include the original licensure date, the expiration date, and current licensure status.

   **b.** A copy of a current inspection report from an inspection conducted by the regulatory or licensing agency of the state, territory, or district in which the applicant is located. The inspection report is current if the inspection was conducted within six months before the date of submission of this application. The current inspection report must demonstrate that the applicant is fully compliant with chapters 797, 71, 85, and 731 of the United States Pharmacopeia that are adopted in Rule 64B16-27.797(1), Florida Administrative Code.

   If you are unable to submit a current inspection report demonstrating compliance with the applicable chapters of the pharmacopeia, due to acceptable circumstances as established by Rule 64B16-28.905, F.A.C. or if no current inspection has been performed, the applicant may:

   - Submit a current and satisfactory inspection report from an entity approved by the board. Approved entities can be found on the Board's website at www.floridaspharmacy.gov; or

- Request the Department to perform an onsite inspection in which all costs are borne by the applicant.

**c.** A copy of the applicant's existing policies and procedures for sterile compounding. The policies and procedures must comply with pharmaceutical standards in chapters 797, 71, 85 and 731 of the United States Pharmacopoeia.

**d.** Any and all other documentation requested or mandated within this application.

**3.** Once an application is complete and approved, the Department will issue a permit which you will receive within 7 days.

**All pharmacies must answer the following questions.** The questions will assist in the Board's review of your application to determine your pharmacy's compliance the applicable chapters of the United States Pharmacopeia. 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 of 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: |
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| |

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: |
|---|
| |
| 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) during your pharmacy's daily cleaning routine.

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

| 1. |
|---|
| 2. |

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

6. USP Chapter 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.

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 an environmental 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: |
| --- |
| Describe briefly: |
| |

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

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 compounded sterile product (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 describe your use of lyophilization in your 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: |
|---|
| |

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# NONRESIDENT STERILE COMPOUNDING APPLICATION FOR NONRESIDENT PHARMACIES

**Please submit the application fee and unlicensed activity fee totaling $255 with your application.**

_____Existing Nonresident Pharmacy Permit Number (If you do not have this permit, you must also submit an application for a Nonresident Pharmacy Registration.)

_____Existing Nonresident Sterile Compounding Permit Number (if applicable)

**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) or equivalent**

Name | License No. | Start Date

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

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

**8. Do you have 24-hour access to patient records?____Yes____No**
(If no, please provide an explanation on a separate sheet of paper)

**9. Date of last inspection: Day_____Month _____Year _____**

**Inspecting Authority_____**

**10. Was this inspection structured to ensure compliance with Chapters 797, 71, 85, and 731 of the United States Pharmacopeia? (Attach a copy of the inspection report, the floor plan and your policies and procedures manual).**

_____Yes _____No

**11. Prescription Department Operating Hours**

Monday-Friday: Open_____Close: Open

Saturday: _____Close: Open

Sunday: _____Close: _____

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

(_____)_____-_____

**13. Ownership Information**

**a. Type of Ownership**

_____Individual_____Corporation_____Partnership_____Other:_____

**CORPORATIONS & LIMITED PARTNERSHIPS: INCLUDE A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE STATE WHERE THE FACILITY IS LOCATED.**

**b. List each principal, officer, agent, managing employee or affiliated person of the applicant.**

***Attach a separate sheet if necessary.***

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

**Questions 14 through 18 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. Supporting documentation must include at a minimum the official charging document and the official judgment and sentence.**

**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, Florida Statutes or a similar felony offense committed in another state or jurisdiction? (If "no", skip to question 15.)**

Yes_____ No _____

**If "yes", for the felonies of the first or second degree (or the equivalent level of felony in another state or jurisdiction), has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?**

Yes_____ No _____

**If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction), has it been 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 or a similar felony offense committed in another state or jurisdiction.**

Yes_____ No_____

**If "yes", for the felonies of the third degree (or the equivalent level of felony in another state or jurisdiction) under Section 893.13(6)(a), Florida Statutes or a similar felony offense committed in another state or jurisdiction has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?**

Yes_____ No_____

**If "yes", 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?**

Yes_____ No _____

**15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If "no", skip to question 16.)**

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

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

Yes_____ No_____

16. **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", skip to question 17.)**

Yes_____ No _____

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

Yes_____ No _____

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 from any other state Medicaid program? (If "no", skip to question 18)**

Yes_____ No _____

**If "yes", has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been in good standing with a state Medicaid program for the most recent five years?**

Yes_____ No _____

**If "yes", did the termination occur at least 20 years prior to the date of this application?**

Yes_____ No _____

18. **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_____

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 or any principal, officer, agent, managing employee, or affiliated person 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.**

Yes_____ No_____(If yes, please list them below, you may provide additional sheet)

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

**21. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant 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)

**22. Has any principal, officer, agent, managing employee, affiliated person of the applicant ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?**

Yes_____ No_____(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.)

**23. 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)

**24. Does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have any outstanding fines, liens or overpayments assessed by a final order of the department?**

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

***If "yes", does the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant have a repayment plan approved by the department?***

Yes_____ No _____

**25. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 3 years?**

Yes_____ No_____(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.)

# APPLICANT SIGNATURE PAGE

**Florida law requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application that 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 of board.**

**********

I, the undersigned, 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. I do authorize the Florida Board of Pharmacy and the Department to make any investigations that they deem appropriate and to secure any additional information concerning the applicant or me. 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. I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be denied, 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.

I, the undersigned, hereby acknowledge that providing false information in relation to this application, may result in denial of licensure, discipline, and/ or criminal penalties pursuant to sections 456.067, 465.015 (5), 775.082, 775.083, and 775.084, *Florida Statutes*.

I, the undersigned, have completely reviewed and read the foregoing document and state that the facts stated in it are true.

SIGNATURE _____ TITLE_____DATE_____
Owner/Officer

**********

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# ATTESTATION

Section 465.0158(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 hereby attest 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.*

I declare that I have read the foregoing Attestation and that the facts stated in it are true.

SIGNATURE_____ TITLE_____ DATE_____
**(Owner/Officer)**

SIGNATURE_____ TITLE_____ DATE_____
**(PDM/PIC of Sterile Compounding)**