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 FOR

Outsourcing Facilities

FEBRUARY 2015

DH5004-MQA-02/15
Rule 64B16-28.100

Dear Florida Pharmacy 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 Statutes* is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into Florida.

We welcome all 503b Outsourcing Facilities seeking a mandatory Nonresident Sterile Compounding Permit. 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 Statutes require the Board to receive a completed application and all applicable fees before reviewing an application. So please read this application carefully and fully before submission. Keep a copy of the completed application for your records. When mailing the completed application and fees, use the address noted in the instructions and on the application form.

Fees will be deposited upon of the receipt of your application. Board staff will notify you of the receipt and deposit at this time. If you need to contact the Board, email us at info@floridaspharmacy.gov, or 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 SUBMISSION; PROCESSING; AND PERMITING

Failure to attach any required documentation or a failure to submit a completed application with the required application fee is considered an incomplete application. A submitted application will expire after one year.

1) Mail completed applications 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

2) Along with the application, **Outsourcing Facilities** must submit the following:

a. Proof of registration as an outsourcing facility with the Secretary of the United States Department of Health and Human Services;

b. 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; or a current inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act. The current inspection must demonstrate compliance with section 465.015, *Florida Statutes* and compliance with Federal Current Good Manufacturing Practices. A current inspection is an inspection that was conducted within 6 months before the date of submitting the application for an initial permit.

c. Existing policy and procedures for sterile compounding. The policy and procedures and any supporting documentation must demonstrate compliance with the standards of Current Good Manufacturing Practices; and

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

3) Once an application is completed and 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.

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

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR OUTSOURCING FACILITIES

Application Type:

☐ **New Establishment $255 fee (1020)**

☐ **Change of Location $100 fee (3012)** _____ **Nonresident Sterile Compounding Permit No.**

☐ **Change of Ownership* $255 fee (1023 create new file)** _____ **Nonresident Sterile Compounding Permit No.**

***New permit number will be issued**

Federal Employer Identification Number (FEIN)	

1. Corporate and Registered Outsourcing Facility 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. Supervising Pharmacist

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

Day _____ **Month** _____ **Year** _____ **Inspecting Authority** _____

10. Was this inspection structured to ensure compliance with Current Good Manufacturing Practices - cGMP? (Attach a copy of the inspection report, the floor plan and policies and procedures manual).

_____Yes _____No

11. Toll-Free Telephone Contact Number

(_____) _____- _____

12. 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. 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 20 are required pursuant to Section 456.0635(2) *Florida Statutes*. Please explain any "yes" answers 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 ? (If yes, provide court documents.)

Yes_____ No _____

If yes to 13: For felonies of the second and first degree, is the date of application more than 15 years from the date of plea, sentence, and completion of any subsequent probation? Yes _____ No _____

If yes to 13: For 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_____

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_____

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?

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_____

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 Supervising Pharmacist 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 Supervising Pharmacist 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, affiliated persons, partners, officer, directors, or supervising pharmacist 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 address on listed 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 Supervising Pharmacist 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 to 26*:* Does the applicant, affiliated person, partner, officer, director or Supervising Pharmacist have a repayment plan approved by the department?

Yes _____ No _____

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.

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

APPLICANT ATTESTATION FOR OUTSOURCING FACILITIES

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 Supervising Pharmacist.

I hereby by attest and affirm 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.

Under Penalties of Perjury, I declare that I have read the foregoing Attestation Form and that the facts stated in it are true.

SIGNATURE _____ TITLE _____DATE_____
(Owner/Officer)

SIGNATURE _____ TITLE _____DATE_____
(Supervising Pharmacist)

If the owner or office who executed this attestation is no longer an owner or officer, another or new owner or officer shall execute a new attestation within 10 days of the change.

If there is a change in the supervising pharmacist who executed this attestation, the new supervising pharmacist shall execute a new attestation within 10 days of the change.