DIVISION OF MEDICAL QUALITY ASSURANCE
BOARD OF PHARMACY
4052 BALD CYPRESS WAY, BIN #C-04
TALLAHASSEE, FLORIDA 32399-3254
(850) 245-4474

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION FOR OUTSOURCING FACILITIES

JULY 2016

DH5004-MQA, 07/16
Rule 64B16-32.009, 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.

Definitions:

a. 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.

b. For the purposes of this application, the term “supervising pharmacist” shall be the equivalent to the terms “prescription department manager” or “pharmacist in charge”.

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, Outsourcing Facilities must submit the following:

a. Proof of registration as an outsourcing facility with the Secretary of the U.S. Department of Health and Human Services.

b. A letter of licensure verification for the Prescription Department Manager or Pharmacist in Charge or equivalent (ie. supervising pharmacist) 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.

c. 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 applicant is fully compliant with Current Good Manufacturing Practices that are adopted in Rule 64B16-27.797(3), Florida Administrative Code.

If you are unable to submit a current inspection report demonstrating compliance with Current Good Manufacturing Practices, 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 inspection report from the United States Food and Drug Administration conducted pursuant to the federal Drug Quality and Security Act;
- Submit a current and satisfactory inspection report from an entity approved by the board; or
- Request the Department to perform an onsite inspection in which all costs are borne by the applicant.

d. A copy of the applicant's existing policies and procedures for sterile compounding**.** The policies and procedures must comply with the standards for Current Good Manufacturing Practices.

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

3. Once an application is complete and approved, board staff will issue a permit which you will received within 7 days of the issue date.

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P.O. Box 6330 | Tallahassee, FL 32314
(850) 245-4474 | www.floridaspharmacy.gov

NONRESIDENT STERILE COMPOUNDING APPLICATION FOR OUTSOURCING FACILITIES

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

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

6. Contact Person	**Telephone Number**

7. DEA Registration Number (If applicable)

8. Do you have 24-hour access to patient records for those patients who receive a dispensed compounded product pursuant to a patient specific prescription.

___Yes_____No (If no, please provide an explanation on a separate sheet of paper)

____N/A Do not engage in patient specific compounding

9. Date of last inspection: Day______Month _____Year ________

Inspecting Authority____

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

_____Yes _____No

11. 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 12 through 16 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.

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a 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 13.)

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 _______

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 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 14.)

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_______

14. 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 15.)

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 __________

15. 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 16.)

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 __________

16. 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? (If "yes", please submit proof.)

Yes__________ No __________

If "yes", are you listed because you defaulted or are delinquent on a student loan?

Yes__________ No __________

If "yes", is the student loan default or delinquency the only reason you are listed on the LEIE?

Yes__________ No __________

17. 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

18. 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

19. 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)

20. Has any principal, officer, agent, managing employee, or 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.)

21. 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)

22. 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" to 26: **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 __________

23. Has the applicant received an FDA Form 483 or Warning Letter following an inspection conducted by the FDA within the last 5 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.

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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 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 supervising pharmacist.

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________________
(Supervising Pharmacist)