AGENDA

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING

September 26, 2014 – 2:00p.m.

Conference Call
Meet Me # 1(888) 670-3525
Conference Code – 513 489 6685

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

Board Members
Jeffrey J. Mesaros, PharmD, Chair, Orlando
Michele Weizer, PharmD, Vice-Chair, Boca Raton
Win Adams, CSE, Consumer Member, Fern Park
Goar Alvarez, PharmD, Ft. Lauderdale
Lee Fallon, BPharm, PhD, The Villages
Debra B. Glass, BPharm, Tallahassee
Gavin Meshad, Consumer Member, Sarasota
Mark Mikhael, PharmD, Orlando
Jeenu Philip, BPharm, Jacksonville

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 and that an audio file of the meeting will be posted to the board's website.

Friday, September 26, 2014 – 2:00p.m.

1. The Non-Resident Sterile Compounding Permit

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 PERMIT APPLICATION

& SUPPORTING INFORMATION

OCTOBER 2014

DH-MQA XXXX, 10/14
Rule 64B16-28.100 F.A.C.

Dear Florida Permit Applicant,

Thank you for applying for a permit in the State of Florida. The information in this packet has been designed to provide the essential information required to process your application in a timely manner. Your assistance in providing all required information will enable the Florida Board of Pharmacy (the board) staff to process your application as soon as possible. You are encouraged to apply as early as possible, to avoid delays due to a large volume of applicants.

Florida Statutes require a completed application and fees before your application can be reviewed. Please read these instructions carefully and fully before submitting the application. You should keep a copy of the completed application and all other materials sent to the board office for your records. When you mail the completed application and fees, use the address noted in the instructions and on the application form.

When your application arrives, your fees will be deposited and verified before the staff review can begin. You will receive a letter acknowledging receipt of your application. The staff will notify you in approximately 7-14 days if any materials are incomplete.

If you need to communicate with the board staff, 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 are responded to within 48 hours during normal business hours. Our staff is committed to providing prompt and reliable information to our customers. Many procedures have been streamlined to expedite the processing of applications; we certainly welcome your comments on how our services may be improved.

Sincerely,

The Board of Pharmacy

NON-RESIDENT SPECIAL COMPOUNDING PERMIT APPLICATION INFORMATION

Non-Resident Sterile Compounding registration as authorized by Section 465.0158, F.S. is required in order to ship, mail, deliver, or dispense in any manner, a compounded sterile product into this state, a nonresident pharmacy registered under s. 465.0156, or an outsourcing facility must hold a nonresident sterile compounding permit.

APPLICATION PROCESSING

Please read all application instructions before completing your application.

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 6320
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

Within 7-14 days of receipt of your application and fees, the board office will notify you of the receipt of your application, any required documents, and your status. If your application is incomplete, you will be notified in writing of what is required to make your application complete.

2) Non-Resident Pharmacies must submit a letter of licensure verification for the facility as well as for the Pharmacy Manager from the state, territory or district board of pharmacy where you are located. The letter must include:

a. Original Licensure Date
b. Expiration Date; and
c. Licensure Status

Outsourcing Facilities must submit proof of registration as an outsourcing facility with the United States Department of Health and Human Services if you are eligible for such registration pursuant to the federal Drug Quality and Security Act.

3) Non-Resident Pharmacies must submit a copy of your most recent inspection by the state, territory, or district board of pharmacy or the entity responsible for conducting inspections in the state where you are physically located which demonstrates compliance with USP Chapter <797>.

Outsourcing facilities must submit a copy of their most recent inspection report conducted by the U.S. Food and Drug Administration (FDA) which demonstrates compliance with current good manufacturing practices,.

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 by the regulatory or licensing agency of the state, territory, or district in which the facility is located, due to acceptable circumstances, as established by rule, or if an inspection has not 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, as determined by rule, from an entity approved by the board.

ALL APPLICANTS MUST COMPLETE THE FOLLOWING QUESTIONS

Applicants must complete and submit answers to the policy and procedure questions. The Pharmacist in Charge or Prescription Department Manager 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.

An applicant must submit existing policies and procedures for sterile compounding, which 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:

The questions below 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. (This section is not applicable to outsourcing facilities).

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:

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:

LICENSURE PROCESS

Once the application is deemed complete, and if the license is approved, the board staff will issue the new license number. The actual copy of your license should arrive within 7 days of the issue date.

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) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

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

NONRESIDENT STERILE COMPOUNDING PERMIT APPLICATION

Application Type – Please choose one of the following:

____ New Establishment $255 fee (1020)
(A new non-resident pharmacy applicant must also apply for the Special Non-Resident Pharmacy Permit)

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

____ Change of Ownership (a new permit number will be issued) $255 fee (1023 create new file)

_____ Existing Non-Resident Permit Number (If applicable)

Please list your Federal Employer Identification Number_____

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. List 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-hour 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. Operating Hours

Prescription Department Hours

Monday-Friday: Open _____ Close: _____

Saturday: Open: _____ Close: _____

Sunday: Open: _____ Close: _____

11a. Provide Toll-Free Telephone Number Available six 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. List each person 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 being asked pursuant to Section 456.0635(2) *Florida Statutes*. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of 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 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 signed**

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

_____ **Prescription Department Manager/Pharmacist in Charge 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**

_____ **Attach copies of your inspection report, policy & procedures manual, and floor plan.**

KEEP A COPY OF THE COMPLETED APPLICATION FOR YOUR RECORDS