



## **AGENDA**

### **Florida Board of Pharmacy Compounding Committee Meeting August 14, 2017 – 1:00 p.m.**

Embassy Suites Fort Lauderdale \* 1100 SE 17<sup>th</sup> Street  
Fort Lauderdale, FL 33316 \* (954)315-1326

#### **Committee Members:**

Michele Weizer, PharmD – Chair  
Debra Glass, BPharm  
Mark Mikhael, PharmD  
Jeenu Philip, BPharm

#### **Board Staff**

C. Erica White, MBA, JD - Executive Director  
Savada Knight, Regulatory Supervisor  
Jessica Hollingsworth – Gov. Analyst II

#### **Board Counsel:**

David Flynn, Assistant Attorney General  
Lawrence Harris, Assistant Attorney General

*Note: Participants in this public meeting should be aware that these proceedings are being recorded.*

1. **Nonresident Sterile Compounding Mandatory Inspections**
2. **Special Sterile Compounding Permits - Dispensing For Outpatient Use versus Inpatient Use**
3. **Assignment of Prescription Department Managers or Consultant Pharmacist of Record for Special Sterile Compounding Permits**
4. **Old Business**
  - A. **Rule 64B16-27.797, F.A.C.**
    - This rule has been OPENED for Development
    - There was very good discussion on this rule at our last meeting
    - The rule states there is a copyrighted version of the 26th revision of the chapters below effective December 1, 2013. The rule says the copy is located at DOH, 4052 Bald Cypress Way, Tallahassee, FL 32399-3254 and at the Department of State, Administrative Code and Register Section, Room 701, the Capitol, Tallahassee, FL 32399-0250.
    - The Board Members must have a copy of the USP 797 chapter effective December 1, 2013 for the upcoming meeting.

- The Board Office has an OFFICIAL COPY that should travel to every committee meeting.
- We got permission to PUBLISH in our agenda materials --- EFFECTIVE December 2013 (compounding committee)
- <http://www.floridaspharmacy.gov/Meetings/Agendas/2013/12-December/120213-compounding-rules-agenda.pdf>
- It was accessed by Board Staff September 2013. USP 797 starts on Page 47 of the agenda materials and goes to page 88.
- USP 71 Sterility Tests starts page 138 through 145
- USP 85 (Bacterial Endotoxins test Starts page 145- 150
- USP 731 Loss on Drying Page 214
- SAME ACCESSED VERSION IS PUBLISHED FEBRUARY 2014 COMPOUNDING RULES AGENDA <http://floridaspharmacy.gov/Meetings/Agendas/2014/02-february/021014-comp-rules-agenda.pdf>

B. Rule 64B16-28.802, F.A.C.

- Received minor JAPC comments from last board amendment

5. **New Business**

- A. PDMs and Consultant of Records for SSCPs discussion topic
- B. Nonresident sterile compounding mandatory inspections
- C. SSCP permit- dispensing for Outpatient verses Inpatient use
  - 1. Explanation of Special P/E for hospital use

5. **Public Comment**

6. **Adjourn**

JOE NEGRON  
President



Representative George R. Moraitis, Jr., Chair  
Senator Kevin Rader, Vice Chair  
Senator Daphne Campbell  
Senator George B. Gainer  
Senator Keith Perry  
Representative Jason Fischer  
Representative Michael Grant  
Representative Sam H. Killebrew  
Representative Amy Mercado  
Representative Barrington A. "Barry" Russell

RICHARD CORCORAN  
Speaker



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THE FLORIDA LEGISLATURE  
**JOINT ADMINISTRATIVE  
PROCEDURES COMMITTEE**

May 17, 2017

Mr. David Flynn  
Assistant Attorney General  
Department of Legal Affairs  
PL-01, The Capitol  
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy  
Rule 64B16-28.802, F.A.C.**

Dear Mr. Flynn:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on May 12, 2017. I have the following comments.

- 64B16-28.802(6):** It appears that "institutional Modified II B Pharmacy" should be "Type B Modified Class II Institutional Pharmacy." See Fla. Admin. Code R. 64B16-28.702(2)(c).
- 64B16-28.802(6)(a) and (b):** Please explain why these rule paragraphs refer to "low-risk sterile products." It appears the United States Pharmacopeia, incorporated by reference in rule 64B16-27.797, refers to "low-risk level compounded sterile preparations."

Please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

A handwritten signature in blue ink that reads "Marjorie C. Holladay".

Marjorie C. Holladay  
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief  
Mr. Lawrence Harris, Assistant Attorney General

64B16-28.802 Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities.

(1) through (5) No change.

(6) The SSCP is not required for an Type B Modified Class Institutional Pharmacy under the following conditions:

(a) The pharmacy only compounds low-risk level compounded sterile preparations; and

(b) The pharmacy only compounds those low-risk level compounded sterile preparations for immediate use pursuant to the provisions the United States Pharmacopeia adopted and incorporated in rule 64B16-27.797, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 6-18-13, Amended 10-20-13, 5-8-16, 12-18-16,\_\_\_\_\_.