



**PAM BONDI**  
**ATTORNEY GENERAL**  
**STATE OF FLORIDA**

OFFICE OF THE ATTORNEY GENERAL  
Administrative Law

Michele Bass  
Paralegal Specialist  
PL-01 The Capitol  
Tallahassee, FL 32399-1050  
Phone (850) 414-3766  
Fax (850) 922-6425  
michele.bass@myfloridalegal.com

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**MEMORANDUM**

**TO:** Mark Whitten, Executive Director  
Board of Pharmacy

**FROM:** Michele Bass, Paralegal Specialist 

**RE:** Notice of Revised Proposed Rulemaking  
Rule 64B16-28.802

**DATE:** April 18, 2013

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The above-referenced Notice was submitted to the BAC on April 15, 2013, for publication in the F.A.R. on April 16, 2013. Enclosed is a copy for your records.

If you have any questions or concerns, please feel free to contact me at 414-3766.

Enclosure

cc: Jennifer Tschetter, Assistant General Counsel

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH  
BOARD OF PHARMACY

RULE NO.:  
64B16-28.802

RULE TITLE:  
Special Sterile  
Compounding Permits.

RECEIVED  
2013 APR 16 PM 2:07  
FLORIDA ADMINISTRATIVE  
PROCEDURES COMMITTEE

PURPOSE AND EFFECT: To review the necessity of creating a new rule for classification or sub classification and permitting of special pharmacies. This includes the topic of compounding.

SUMMARY: The proposed rule promulgation is necessary to create a new rule in regard to special sterile compounding permits. The rule development title was previously titled special-parenteral, enteral and compounding pharmacies, as published in Vol. 39, No. 08, of the March 22, 2013, issue of the Florida Administrative Register.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST AND LEGISLATIVE

RATIFICATION: The agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency. The agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: **During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.** Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 465.0196 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Mark Whitten, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

64B16-28.802 Special Sterile Compounding Permits.

A special sterile compounding permit is a type of special permit, which is required before any permitted pharmacy may engage in the preparation of compounding sterile products. The compounding of sterile products must be in strict compliance with the standards set forth in rules 64B16-27.797 and 64B16-27.700.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History--New

NAME OF PERSON ORIGINATING PROPOSED RULE: Compounding Committee.

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Pharmacy.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 2, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: January 11, 2013