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**ATTORNEY GENERAL**  
**STATE OF FLORIDA**

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Administrative Law

RECEIVED  
APR 23 2013  
Florida Board of Pharmacy

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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 64B16-28.800

**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.:  
64B16-28.800

RULE TITLE:  
Special Pharmacies.

RECEIVED  
2013 APR 16 PM 2:38  
JOINT ADMINISTRATIVE  
PROCEDURES COMMITTEE

PURPOSE AND EFFECT: To review the necessity of adding additional categories of special pharmacies. This review will include the topic and category of compounding.

SUMMARY: The proposed rule amendments are necessary to update requirements of special pharmacies regarding compounding.

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: 64B16-28.800 Special Pharmacies.

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

(a) through (g) No Change.

(f) Special Sterile Compounding.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with ~~an application (Form DOHAPH105 Revised 7/23/98, effective 11/11/98, which is hereby incorporated by reference and which can be obtained from the Department of Health) and a~~ Policy and Procedure Manual which sets forth a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. The Policy and Procedure Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in this chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893, F.S., and Chapter 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

Rulemaking Specific Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01, \_\_\_\_\_.

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 9, 2013