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## MEMORANDUM

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

**FROM:** Michele Bass, Paralegal Specialist 

**RE:** Rule 64B16-28.800

**DATE:** June 18, 2013

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We are pleased to inform you that the above-referenced rule was filed for adoption on June 12, 2013, and will become effective July 2, 2013. Attached is a copy of the rule for your records.

Enclosure

cc: Jennifer Tschetter, General Counsel

RECEIVED

JUN 20 2013

Florida Board of Pharmacy

CERTIFICATION OF  
BOARD OF PHARMACY ADMINISTRATIVE RULES  
FILED WITH THE DEPARTMENT OF STATE

I hereby certify:

(1) That all statutory rulemaking requirements of Chapter 120, F.S., and all rulemaking requirements of the Department of State have been complied with; and

(2) There is no administrative determination under subsection 120.56(2), F.S., pending on any rule covered by this certification; and

(3) All rules covered by this certification are filed within the prescribed time limitations of paragraph 120.54(3)(e), F.S. They are filed not less than 28 days after the notice required by paragraph 120.54(3)(a), F.S., and;

(a) Are filed not more than 90 days after the notice; or

(b) Are filed not more than 90 days after the notice, but not more than 60 days after the administrative law judge files the final order with the clerk or until 60 days after the subsequent judicial review is complete; or

(c) Are filed more than 90 days after the notice, but not less than 21 days nor more than 45 days from the date of publication of the notice of change; or

(d) Are filed more than 90 days after the notice, but not less than 14 nor more than 45 days after the adjournment of the final public hearing on the rule; or

(e) Are filed more than 90 days after the notice, but within 21 days after the date of receipt of all material authorized to be submitted at the hearing; or

(f) Are filed more than 90 days after the notice, but within 21 days after the date the transcript was received by this agency; or

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TALLAHASSEE, FLORIDA  
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[ ] (g) Are filed not more than 90 days after the notice, not including the days the adoption of the rule was postponed following notification from the Joint Administrative Procedures Committee that an objection to the rule was being considered; or

[ ] (h) Are filed more than 90 days after the notice, but within 21 days after a good faith written proposal for a lower cost regulatory alternative to a proposed rule is submitted which substantially accomplishes the objectives of the law being implemented; or

[ ] (i) Are filed more than 90 days after the notice, but within 21 days after a regulatory alternative is offered by the small business regulatory advisory committee.

Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.800

Under the provision of subparagraph 120.54(3)(e)6., F.S., the rules take effect 20 days from the date filed with the Department of State or a later date as set out below:

Effective: \_\_\_\_\_  
(Month) (Day) (Year)



Signature, Person Authorized  
To Certify Rules

Executive Director  
Title

Number of Pages Certified

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE NO.:  
64B16-28.800

RULE TITLE:  
Special Pharmacies.

SUMMARY: The board proposed to review the necessity of adding additional categories of special pharmacies. This review will include the topic and category of compounding.

SUMMARY OF THE HEARING ON THE RULE:

No timely request for a hearing was received and no hearing was held.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

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

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.

(h) Special Sterile Compounding.

~~(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with an application (Form DOH\PH105 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.~~

(2) ~~(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, 456.022 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, \_\_\_\_\_.