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Florida Board of Pharmacy

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Angela Southwell, Paralegal Specialist

RE: Notice of Proposed Rulemaking
Rule 64B16-28.820

DATE: April 7, 2014

The above-referenced Notice was submitted to the Bureau of Administrative Code on March 24, 2014, for publication in the Florida Administrative Register on March 25, 2014. Enclosed is a copy for your records.

If you have any questions or concerns, please feel free to contact me.

Enclosure

cc: DOH General Counsel

NOTICE OF PROPOSED RULE

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULE TITLE:

RULE NO.:
64B16-28.820

Sterile Products and Special Parenteral/Enteral Compounding.

PURPOSE AND EFFECT: The Board proposes the rule amendment to delete out-of-date language.

SUMMARY: Language regarding past deadlines will be deleted.

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, 465.007, 465.022 FS.

LAW IMPLEMENTED: 465.007, 465.018, 456.0196 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: Tammy Collins, Acting Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.

(1) through (5) No Change

~~(6) A community pharmacy permittee may perform parenteral/enteral compounding or prepare sterile products without obtaining an additional permit under this section, so long as prior to entering into such activities, the community pharmacy meets the requirements of subsections (1)-(5) above and is inspected for compliance by the Department of Health. A community pharmacy permittee that was engaged in the preparation of sterile products other than parenteral/enteral products as of June 1, 2002 shall have until June 1, 2003 to meet the requirements of subsections (1)-(5) above for the preparation of sterile products other than parenteral/enteral products.~~

Rulemaking Specific Authority 465.005, 465.007, 465.022 FS. Law Implemented 465.007, 465.018, 456.0196 FS. History--New 4-26-84, Formerly 21S-1.40, Amended 7-27-86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

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

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: February 13, 2014.

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: March 6, 2014.

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DEPARTMENT OF HEALTH
ADMINISTRATIVE
SERVICES COMMITTEE