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MEMORANDUM

TO: Mark Whitten, Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist *(signature)*

RE: Notice of Proposed Rulemaking
Rule 64B16-29.005

DATE: March 13, 2013

Board of
MAR 15 2013
Pharmacy

The above-referenced Notice was submitted to the BAC on March 8, 2013, for publication in the F.A.R. on March 11, 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

DEPARTMENT OF HEALTH
Board of Pharmacy

RULE NO.:
64B16-29.005

RULE TITLE:
Storage.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The board proposes the rule amendments to update the medicinal drug storage pursuant to legislative changes.

STATEMENT REGARDING FEDERAL STANDARDS: There is no ascertainable parallel federal rule or standard with which to make a comparison.

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JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE NO.:
64B16-29.005

RULE TITLE:
Storage.

PURPOSE AND EFFECT: The board proposes the rule amendments to update the medicinal drug storage pursuant to legislative changes.

SUMMARY: The proposed rule amendments are necessary to update the medicinal drug storage pursuant to legislative changes.

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, 828.055 FS.

LAW IMPLEMENTED: 828.055 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:

64B16-29.005 Storage.

All controlled substances, medicinal drugs or legend drugs ~~Sodium pentobarbital and sodium pentobarbital with lidocaine~~ shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchases of sodium pentobarbital and sodium pentobarbital with lidocaine shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

Rulemaking Specific Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History—New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005. Amended _____.

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 6, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: February 22, 2013