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Florida Board of Pharmacy

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Administrative Law

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Angela Southwell, Paralegal Specialist

RE: Notice of Proposed Rulemaking
Rules 64B16-26.351, 64B16-26.601, 64B16-26.603

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:

Standards for Approval of Registered Pharmacy Technician Training Programs.

Standards for Approval of Courses and Providers.

Continuing Education Records Requirements.

RULE NO.:

64B16-26.351

64B16-26.601

64B16-26.603

PURPOSE AND EFFECT: The Board proposes the rule amendments to require consistent periods of record retention. Four years is compatible with the biennial inspection period by the Department of Health. Consistent periods of record retention increase efficiency.

SUMMARY: Period of time for record retention will be changed.

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, with input from the public, determined that there would not be an adverse effect on small business to maintain the records for 4 years, and that there would not be a regulatory cost of \$200,000 in the aggregate to any entity, because any additional economic impact that additional storage might have, would be more than offset by savings in employee time managing numerous kinds of records with different retention times. 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, 465.009, 465.014 FS.

LAW IMPLEMENTED: 456.025(7), 465.009, 465.014 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:

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.

(1) through (2) No change.

(3) All other training programs must be employer based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy or affiliated group of pharmacies under common ownership, must contain a minimum of 160 hours of training, that extends over a period not to exceed 6 months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010. The applicant must attach to the application copy of curriculum, catalog or other course description. All employer based programs must:

(a) through (h) No change.

(i) Maintain program records for a period not less than four (4) ~~three~~ years during which time the records must be available for inspection by the board or department.

(j) No change.

Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History—New 6-23-10, Amended 11-17-11.

64B16-26.601 Standards for Approval of Courses and Providers.

(1) No change.

(2) All offerings must meet the following standards:

(a) through (f) No change.

(g) Record Keeping.

1. through 2. No change.

3. Records shall be maintained by the provider for a minimum of four (4) ~~three (3)~~ years.

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BOARD OF PHARMACY
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(3) through (6) No change.

Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.009 FS. History--New 10-17-79, Amended 7-29-81, Formerly 21S-13.02, 21S-13.002, Amended 1-10-93, Formerly 21S-26.601, 61F10-26.601, 59X-26.601, Amended 1-29-03,

64B16-26.603 Continuing Education Records Requirements.

Each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than four (4) ~~two~~ years after the license is renewed for audit purposes if and when such audit is undertaken by the Department of Health and the Board of Pharmacy. Such documentation shall consist of statements of credit for lecture attendance, certification forms from instructors, or course completion slips from correspondence courses.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History--New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05,_____.

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 12, 2014.

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: March 5, 2014.

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