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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  
Rules 64B16-27.210, 64B16-27.300, 64B16-27.800, 64B16-27.851

**DATE:** April 7, 2014

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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 26, 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:

General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

Standards of Practice – Continuous Quality Improvement Program.

Requirement for Patient Records.

Record-Keeping for Orthotics and Pedorthics.

RULE NO.:

64B16-27.210

64B16-27.300

64B16-27.800

64B16-27.851

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: 465.022, 465.0155, 465.186(2), 468.802, 468.812(3) FS.

LAW IMPLEMENTED: 456.057(16), 465.0155, 465.022, 465.186, 468.802, 468.812(3)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:

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:

(1) through (6) No change.

(7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of four (4) two (2) years.

(8) through (11) No change.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.022, 465.186 FS. History—New 5-1-86, Formerly 21S-18.002, 21S-27.210, 61F10-27.210, 59X-27.210, Amended 11-18-07; \_\_\_\_\_.

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

(1) through (4) No change.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for four (4) two (2) years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

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Rulemaking Authority 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History--New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10; \_\_\_\_\_.

64B16-27.800 Requirement for Patient Records.

(1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:

(a) through (d) No change.

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the four (4) twø years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

(f) No change.

(2) No change.

(3) A patient record shall be maintained for a period of not less than four (4) twø years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) No change.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155, 465.022 FS. History--New 8-18-93, Formerly 21S-27.800, 61F10-27.800, 59X-27.800, Amended 6-15-98, \_\_\_\_\_.

64B16-27.851 Record-Keeping for Orthotics and Pedorthics.

(1) through (2) No change.

(3) The licensee shall retain the patient record for at least four (4) twø years from the date of last entry, unless otherwise provided by law.

Rulemaking Authority 468.802, 468.812(3) FS. Law Implemented 456.057(16), 465.0155, 465.022, 468.802, 468.812(3) FS. History--New 5-2-07, \_\_\_\_\_.

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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