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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 64B16-28.2021, 28.450, 28.503, 28.605, 28.606, 28.607, 28.702

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 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:

RULE NO.:
64B16-28.2021
64B16-28.450
64B16-28.503
64B16-28.605
64B16-28.606
64B16-28.607
64B16-28.702

Change of Ownership.
Centralized Prescription Filling, Delivering and Returning.
Transmission of Starter Dose Prescriptions for Patients in Class I
Institutional or Modified II B Facilities.
Class II Institutional Pharmacies – Automated Distribution and Packaging.
Remote Medication Order Processing for Class II Institutional Pharmacies.
Automated Pharmacy System – Long Term Care, Hospice, and Prison.
Modified Class II Institutional Pharmacies.

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DEPARTMENT OF HEALTH
BOARD OF PHARMACY

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, 465.0155, 465.022, 465.0265 FS.

LAW IMPLEMENTED: 465.003(11)(a), (16), 465.018, 465.019, 465.0193, 465.0196, 465.022, 465.0235, 465.026, 465.0265 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:

64B16-28.2021 Change of Ownership.

(1) No change.

(2) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an "opening inventory" for DEA purposes. Both the new permit and the old permit must keep appropriate records for four (4) ~~two (2)~~ years for the transfer of legend drugs and controlled substances.

(3) No change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History—New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05, _____.

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) through (5) No change.

(6) The supplying and receiving pharmacy shall each be identified on the prescription container label. The receiving pharmacy shall be identified with pharmacy name and address. The supplying pharmacy may be identified by a code available at the receiving pharmacy. Prescription and labeling requirements for pharmacies participating

in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. through 3. No change.

4. Maintain the original prescription for a period of four (4) two years from the date the prescription was last refilled.

5. No change.

(b) No change.

Rulemaking Authority 465.005, 465.0265 FS. Law Implemented 465.003(16), 465.022, 465.0265 FS. History–New 9-23-03, Amended 7-27-04, 4-28-08; _____.

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.

(1) through (5) No change.

(6) A record of each starter dose prescription shall be:

(a) No change.

(b) Maintained for four (4) two years.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.019, 465.022 FS. History–New 11-29-04, Amended _____.

64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.

(1) through (6) No change.

(7) Record Keeping.

(a) through (b) No change.

(c) The following records shall be maintained for at least four (4) two (2) years:

1. through 3. No change.

(8) through (9) No change.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History–New 4-22-07, Amended 1-1-10; _____.

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.

(1) through (3) No change.

(4) Records.

(a) through (b) No change.

(c) The record shall be readily retrievable for at least the past four (4) two (2) years.

(d) No change.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.026 FS. History–New 11-29-04, Amended _____.

64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.

(1) through (6) No change.

(7) Record Keeping Requirements.

(a) through (b) No change.

(c) The record shall include:

1. through 9. No change.

(d) A record of every transaction with the automated pharmacy system shall be maintained for four (4) two (2) years.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History–New 4-22-07, Amended 1-1-10; _____.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) through (5) No change.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type “A” and Type “B” as provided herein, shall be those drugs generally utilized in the treatment modalities

encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. through 6. No change.

7. Provisions for maintaining the records of consultations for not less than four (4) ~~two (2)~~ years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. through 5. No change.

6. Provisions for maintaining the records of consultations for not less than four (4) ~~two (2)~~ years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. through 5. No change.

6. Provisions for maintaining the records of consultations for not less than four (4) ~~two (2)~~ years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) through (8) No change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c), 465.022 FS. History--New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01; _____.

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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REGULATORY COMMITTEE