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Florida Board of Pharmacy

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

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MEMORANDUM

TO: Mark Whitten, Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist 

RE: Notice of Proposed Rulemaking
Rule 64B16-28.810

DATE: November 18, 2013

The above-referenced Notice was submitted to the BAC on October 17, 2013, for publication in the F.A.R. on October 18, 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.:
64B16-28.810

RULE TITLE:
Special Pharmacy - Limited
Community Permit.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The proposed rule amendment is necessary to allow a class II institutional pharmacy to obtain a limited community permit to dispense multi-dose medicinal drugs under a doctor's order to patients being discharged from the hospital. This allows for continued use of the multi-dose medicine originally prescribed while the patient was in the hospital.

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

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PROCEDURES COMMITTEE

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE NO.:
64B16-28.810

RULE TITLE:
Special Pharmacy - Limited
Community Permit.

PURPOSE AND EFFECT: The board proposes the rule amendment to allow a class II institutional pharmacy to obtain a limited community permit to dispense multi-dose medicinal drugs under a doctor's order to patients being discharged from the hospital. This allows for continued use of the multi-dose medicine originally prescribed while the patient was in the hospital.

SUMMARY: The proposed rule amendment is necessary to allow a class II institutional pharmacy to obtain a limited community permit to dispense multi-dose medicinal drugs under a doctor's order to patients being discharged from the hospital. This allows for continued use of the multi-dose medicine originally prescribed while the patient was in the hospital.

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, 465.022 FS.
LAW IMPLEMENTED: 465.0196 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: Mark Whitten, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

64B16-28.810 Special Pharmacy - Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances, to:

- (1) through (2) No Change.
- (3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual, and-
- (4) Discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs if the following requirements are met:
 - (a) The label affixed to a container used in dispensing multi-dose medicinal drugs contains at least the following information:
 1. The name of and contact information of the pharmacy;

2. The name of the prescriber;
3. The name of the patient;
4. The date of the original filling and any applicable expiration date;
5. The prescription number or other prescription identification adequate to readily identify the prescription;
6. The directions for use;
7. The name, strength, and size of the medicinal drug dispensed; and
8. The quantity of the drug in the container.

(b) The patient is deemed competent to handle and administer the multi-dose medicinal drug.

(c) A specific order is written by the patient's physician to authorize that the multi-dose medicinal drug is appropriate to dispense upon discharge.

(d) Before the hospital dispenses a multi-dose medicinal drug as specified in paragraph (4) of this section, the hospital shall establish protocols to ensure the following:

1. Infection control during transport and handling of multi-dose medicinal drug containers that have been in contact with a patient;

2. Patient or caregiver education on administration of the multi-dose medicinal drug if necessary on an individual basis.

(e) A "multi-dose medicinal drug" as used in this rule means, but is not limited to, commercially available multi-dose packages such as inhalers, ocular products, insulin vials or pens, otic products, bulk antibiotic suspensions, topical agents, and methylprednisolone dose packets dispensed to inpatients, provided in containers that may exceed a three (3) day supply, and are intended to be continued by the patient on an outpatient basis but not to be re-filled by the hospital. Controlled substances are not considered multi-dose medicinal drugs as defined in this rule.

Rulemaking Specific Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History—New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05, _____.

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: October 9, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: October 18, 2013

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