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Florida Board of Pharmacy

JAN 30 2014

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist 

RE: Rule 64B16-28.450

DATE: January 26, 2014

We are pleased to inform you that the above-referenced rule was filed for adoption on January 21, 2014, and will become effective February 10, 2014. Attached is a copy of the rule for your records.

Enclosure

cc: Jennifer Tschetter, General Counsel

CERTIFICATION OF
BOARD OF PHARMACY ADMINISTRATIVE RULES
FILED WITH THE DEPARTMENT OF STATE

I hereby certify:

(1) That all statutory rulemaking requirements of Chapter 120, F.S., and all rulemaking requirements of the Department of State have been complied with; and

(2) There is no administrative determination under subsection 120.56(2), F.S., pending on any rule covered by this certification; and

(3) All rules covered by this certification are filed within the prescribed time limitations of paragraph 120.54(3)(e), F.S. They are filed not less than 28 days after the notice required by paragraph 120.54(3)(a), F.S., and;

(a) Are filed not more than 90 days after the notice; or

(b) Are filed not more than 90 days after the notice, but not more than 60 days after the administrative law judge files the final order with the clerk or until 60 days after the subsequent judicial review is complete; or

(c) Are filed more than 90 days after the notice, but not less than 21 days nor more than 45 days from the date of publication of the notice of change; or

(d) Are filed more than 90 days after the notice, but not less than 14 nor more than 45 days after the adjournment of the final public hearing on the rule; or

(e) Are filed more than 90 days after the notice, but within 21 days after the date of receipt of all material authorized to be submitted at the hearing; or

(f) Are filed more than 90 days after the notice, but within 21 days after the date the transcript was received by this agency; or

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[] (g) Are filed not more than 90 days after the notice, not including the days the adoption of the rule was postponed following notification from the Joint Administrative Procedures Committee that an objection to the rule was being considered; or

[] (h) Are filed more than 90 days after the notice, but within 21 days after a good faith written proposal for a lower cost regulatory alternative to a proposed rule is submitted which substantially accomplishes the objectives of the law being implemented; or

[] (i) Are filed more than 90 days after the notice, but within 21 days after a regulatory alternative is offered by the small business regulatory advisory committee.

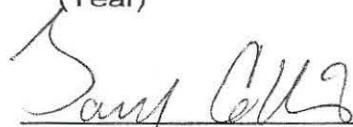
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.810

Under the provision of subparagraph 120.54(3)(e)6., F.S., the rules take effect 20 days from the date filed with the Department of State or a later date as set out below:

Effective: _____
(Month) (Day) (Year)



Signature, Person Authorized
To Certify Rules

Executive Director

Title

2

Number of Pages Certified

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE NO.:
64B16-28.810

RULE TITLE:
Special Pharmacy - Limited
Community Permit.

SUMMARY: 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 OF THE HEARING ON THE RULE:

No timely request for a hearing was received and no hearing was held.

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.

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, _____.