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Florida Board of Pharmacy

OCT 02 2013

RECEIVED

MEMORANDUM

TO: Mark Whitten, Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist

MJB

RE: Notice of Proposed Rulemaking
Rule 64B16-28.450

DATE: October 1, 2013

The above-referenced Notice was submitted to the BAC on September 23, 2013, for publication in the F.A.R. on September 24, 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.:
64B16-28.450

RULE TITLE:
Centralized Prescription
Filling, Delivering, and Returning.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING RULE PROPOSAL:

The proposed rule amendments are necessary to reorganize the existing language, remove duplicative language, use consistent terms for central fill pharmacies; refers to Class II institutional pharmacies in addition to community pharmacies as it pertains to centralized prescription filling, delivering and returning.

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

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2019 SEP 23 PM 2:58
JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE NO.:
64B16-28.450

RULE TITLE:
Centralized Prescription
Filling, Delivering, and Returning.

PURPOSE AND EFFECT: The board proposed the rule amendment to reorganize the existing language, remove duplicative language, use consistent terms for central fill pharmacies, and refers to Class II institutional pharmacies in addition to community pharmacies.

SUMMARY: The proposed rule amendments are necessary to reorganize the existing language, remove duplicative language, use consistent terms for central fill pharmacies; refers to Class II institutional pharmacies in addition to community pharmacies as it pertains to centralized prescription filling, delivering and returning.

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, 465.0265 FS.
LAW IMPLEMENTED: 465.003(16), 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: Mark Whitten, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

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

(1) As used herein:

(a) The term "originating pharmacy" means a permitted community or Class II institutional pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and

(b) The term "central fill pharmacy" means a permitted community or Class II institutional pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must: ~~be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto.~~

(a) Be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto, and;

(b) Have the same owner as the originating pharmacy or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

~~(3) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:~~

- (a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;
- (b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and
- (c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

(3) (4) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

- (a) No Change.
- (b) Include the information required by ~~in subsections~~ Sections 465.0265(2)(a)-(f), F.S.;
- (c) Designate the types of medications that may and may not be filled by the central fill pharmacy;
- (d) Set forth procedures for communicating orders from the originating pharmacy to the central fill pharmacy;
- (e) Set forth procedures for securely transporting the filled prescriptions from the central fill pharmacy to the originating pharmacy; and
- (f) Designate the specific services provided and the duties and responsibilities of the central fill and originating pharmacies.

~~(c) Each pharmacist that performs a specific function within the processing of the prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.~~

(4)(6) The central fill supplying and originating receiving pharmacy shall each be identified on the prescription container label. The originating receiving pharmacy shall be identified with pharmacy name and address. The central fill supplying pharmacy may be identified by a code available at the originating receiving pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering, and returning:

- (a) No Change.
- (b) The central fill pharmacy receiving the transmitted prescription must:
 1. through 3. No Change.

4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the originating receiving pharmacy's name and address, a unique identifier (e.g., i.e. the central fill supplying pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

(5) Delivery of medications. All deliveries ~~Delivery of medications from the central fill pharmacy to the originating pharmacy or to the ultimate consumer~~ must be made in a timely manner. ~~The originating and central fill pharmacies shall each be identified on the prescription container.~~

(a) ~~Delivery by central fill pharmacy to ultimate consumer.~~ A community central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following additional conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, including delivery services to the ultimate consumer or the consumer's agent ~~the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with federal and state laws, rules and regulations.~~

2. through 3. No Change.

4. ~~The pharmacies shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy.~~

~~45.~~ The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.

~~56.~~ The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a community central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.

(c) A Class II institutional central fill pharmacy may only deliver medications to the originating pharmacy.

(6)(e) Each pharmacist that performs a specific function within the processing of a central fill the prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(7) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

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

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: August 14, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 6, 2013