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ATTORNEY GENERAL
STATE OF FLORIDA

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Florida Board of Pharmacy

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

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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 24, 2013

We are pleased to inform you that the above-referenced rule was filed for adoption on January 16, 2014, and will become effective February 5, 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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TALLAHASSEE, FLORIDA

[] (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.

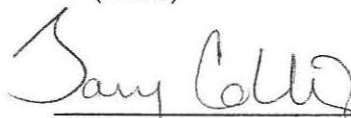
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.450

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

3

Number of Pages Certified

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE NO.:
64B16-28.450

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

SUMMARY: 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 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 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.

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

(1) As used herein:

(a) The term “originating pharmacy” means a 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 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 paragraphs 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, 465.0155, 465.0265 FS. Law Implemented 465.003(16), 465.019, 465.0265 FS.

History—New 9-23-03, Amended 7-27-04, 4-28-08, _____.