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## **MEMORANDUM**

**TO:** Mark Whitten, Executive Director  
Board of Pharmacy

**FROM:** Angela Southwell, Paralegal Specialist

**RE:** Rule 64B16-28.100

**DATE:** February 7, 2013

Board of  
FEB 12 REC'D  
Pharmacy

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We are pleased to inform you that the above-referenced rule was filed for adoption on February 1, 2013, and will become effective February 21, 2013. 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).

64B16-28.100

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

5  
\_\_\_\_\_  
Number of Pages Certified

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE TITLE:

RULE NUMBER:

Pharmacy Permits – Applications and Permitting.

64B16-28.100

SUMMARY: A new rule will be created to provide a single rule for permitting of pharmacies.

SUMMARY ON THE HEARING ON THE RULE: No timely request for a hearing was received and no hearing was held.

STATEMENT OF FACTS AND CIRCUMSTANCES JUSTIFYING PROPOSED RULE:

The Board proposes the rule promulgation in order to combine the permitting rules into a single rule and to incorporate new applications.

64B16-28.100 Pharmacy Permits- Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at <http://www.doh.state.fl.us/mqa/pharmacy> or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at <http://www.FLHealthsource.com>. The application must be accompanied with a \$250 initial permit fee, payable to the Board.

(1) All Permits: A permit is valid only for the name and address to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

(a) A permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

1. A contiguous area under the control of the permit holder. For purposes of this rule, a public thoroughfare will be considered to have not broken the area of contiguity, and

2. An area not more than one half (1/2) mile from the central location of the permit.

(b) The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02297> or on the web at <http://www.doh.state.fl.us/mqa/pharmacy>.

(c) Each applicant must file with the board a legible set of fingerprint cards and a \$48 fee for each person who submits an application meeting the requirements in Section 465.022(3), F.S. An applicant may register demographic information and purchase fingerprint cards (FD-258) at <http://http://www.fldoh.sofn.net/>. If an applicant chooses not to purchase a fingerprint card, the applicant must make sure the police or agency that rolls the fingerprints uses a FD-258 fingerprint card. A Non-Resident Pharmacy Registration applicant is not required to submit a legible set of fingerprints upon application.

(d) Passing an on-site inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the on-site inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.

(e) Each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

(2) Community Pharmacy Permit as authorized by Section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," effective August 2012 which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02298>.

(a) Applicants for a Community Pharmacy Permit must:

1. Comply with all permitting requirement found in paragraph (1) of this rule; and
2. Designate a prescription department manager as required by Section 465.018, Florida Statutes;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02299>.

(c) The policy and procedure manual for Community Pharmacies shall contain the procedures implemented to minimize the dispensing of controlled substances based on fraudulent representations. The policy and procedural manual shall provide the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

(3) Institutional Pharmacy Permits as authorized by Section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for a Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215,

"Institutional Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02300>.

(a) Applicants for an Institutional Pharmacy Permit must:

1. Comply with all permitting requirement found in paragraph (1) of this rule; and
2. Designate a consultant pharmacist of record as required by Section 465.019, Florida Statutes; and

(b) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02301>.

(4) Nuclear Pharmacy Permit as authorized by Section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02302>.

(a) Applicants for an Nuclear Pharmacy Permit must:

1. Comply with all permitting requirement found in paragraph (1) of this rule; and
2. Designate a nuclear pharmacist of record as required by Section 465.0193, Florida Statutes; and

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special-Parenteral and Enteral, Special- Closed System Pharmacy, Special- End Stage Renal Disease (ESRD), Special-Parenteral/Enteral Extended Scope, and Special- Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02303>.

(a) Applicants for a Special Pharmacy Permit must:

1. Comply with all permitting requirement found in paragraph (1) of this rule; and

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, Florida Statutes;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.

(d) The Board recognized the following types of Special Pharmacy permits:

1. Special Limited Community Permit may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. Special Parenteral and Enteral Permit is required to provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special- Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special- Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. Special Closed System Pharmacy Permit is not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, ALF's, Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. Special Pharmacy- End Stage Renal Disease (ESRD) Permit is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. Special Pharmacy- Parenteral/Enteral Extended Scope Permit is required for pharmacies to compound patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.

6. Special- Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6) Internet Pharmacy Permit as authorized by Section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective August 2012.

(a) Applicants for an Internet Pharmacy Permit must:

1. Comply with all permitting requirement found in paragraph (1) of this rule; and
2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0197, Florida Statutes;

(b) As set forth in Section 465.0197, F.S., the permittee shall notify the board within 30 days of any change of location, corporate officers, and the pharmacist serving as the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(7) Non-Resident Pharmacy Registration as authorized by Section 465.0156, F.S., is required for those pharmacies located outside the state and which ships, mails, or delivers a dispensed medicinal drug into this state. Applicants for a Non-Resident Registration must complete an application for a registration using an original Form DH-MQA 1217, "Non-Resident Pharmacy Permit Application and Information," effective August 2012, which is incorporated by reference herein and is available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-02304>. Applicants for registration as a non-resident pharmacy must comply with all requirements found in Section 465.0156, F.S.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History—New, \_\_\_\_\_.

CERTIFICATION OF  
MATERIALS INCORPORATED BY REFERENCE  
IN RULES FILED WITH THE DEPARTMENT OF STATE

I hereby certify pursuant to Rule 1-1.013, Florida Administrative Code:

(1) That materials incorporated by reference in Rule 64B16-28.100, F.A.C., have been electronically filed with the Department of State.

(2) That because there would be a violation of federal copyright laws if the submitting agency filed the incorporated materials described below electronically, a true and complete paper copy of the incorporated materials are attached to this certification for filing. Paper copies of the incorporated materials below may be obtained at the agency by [include address/locations].

List form number(s) and form title(s) or title of document(s) below:

Form DH-MQA 1227 (eff. December 2010) "Pharmacy Permit Name Change Form"

Form DH-MQA 1214 (eff. August 2012) "Community Pharmacy Permit Application and Information"

Form DH-MQA PH10 (eff. December 2010) "Prescription Department Manager Change"

Form DH-MQA 1215 (eff. August 2012) "Institutional Pharmacy Permit Application and Information"

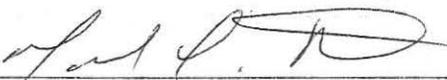
Form DH-MQA 1184 (eff. December 2010) "Change of Consultant Pharmacist of Record"

Form DH-MQA 1218 (eff. August 2012) "Nuclear Pharmacy Permit Application and Information"

Form DH-MQA 1220 (eff. August 2012) "Special Pharmacy Permit Application and Information"

Form DH-MQA 1217 (eff. August 2012) "Non-Resident Pharmacy Permit Application and Information"

Under the provisions of Section 120.54(3)(e)6.F.S., the attached materials take effect 20 days from the date filed with the Department of State, or a later date as specified in the rule.

  
\_\_\_\_\_  
Signature, Person Authorized To Certify Rules

Executive Director  
Title

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