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MEMORANDUM

RECEIVED

APR 03 2014

Florida Board of Pharmacy

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Angela Southwell, Paralegal Specialist

RE: Rule 64B16-28.303

DATE: April 2, 2014

We are pleased to inform you that the above-referenced rule was filed for adoption on March 31, 2014, and will become effective April 20, 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

DEPARTMENT OF STATE
TALLAHASSEE, FLORIDA
2014 MAR 31 PM 2:51

FILED

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

[] (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.

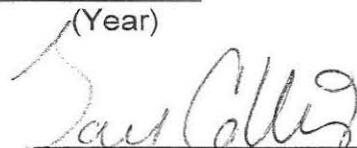
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.303

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 TITLE:

RULE NUMBER:

Destruction of Controlled Substances All Permittees
(excluding Nursing Homes.

64B16-28.303

SUMMARY: The proposed rule amendment is necessary to amend the destruction of controlled substances procedure for Class II institutional pharmacies, requiring one of the two signatures to be the prescription department manager or the consultant pharmacist of record, and to clarify that a copy of the destruction documents be mailed to the DEA within one business day.

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 amend the destruction of controlled substances procedure for Class II institutional pharmacies, requiring one of the two signatures to be the prescription department manager or the consultant pharmacist of record, and to clarify that a copy of the destruction documents be mailed to the DEA within one business day.

64B16-28.303 Destruction of Controlled Substances All Permittees (~~E~~excluding Institutional Class I Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form DEA-41 "Registrants Inventory of Drugs Surrendered" (effective 8/31/2014), herein incorporated by reference, available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-03998> or http://www.dea diversion.usdoj.gov/21cfr_reports/surrend/. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction ~~does not require prior approval from D.E.A., but does require~~ that a copy of the completed and witnessed Form DEA-41 ~~Form 41~~ be mailed to the D.E.A. office in his/her area within one (1) business day after the destruction. ~~D.E.A. immediately after destruction.~~

(3) Another method of destruction shall be conducted by at least two persons: One will be the prescription department manager or the consultant pharmacist of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the Form DEA-41 and the destruction. This method of destruction requires that a copy of the completed and witnessed Form DEA-41 be mailed to the D.E.A. office in the permittee's area within one (1) business day after destruction. ~~who are either a licensed pharmacist, physician or nurse, or a sworn law enforcement officer or any combination thereof, to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.~~

(4) In lieu of destruction on the premises as outlined in (2) and (3) above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

(5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B pharmacy, the destruction method in subsection 64B16-28.301(2) must be followed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History—New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12, _____.

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:

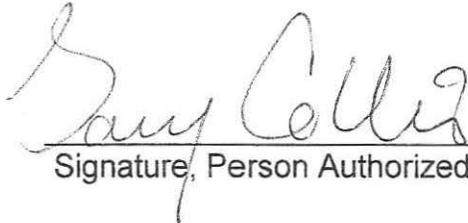
(1) That materials incorporated by reference in Rule 64B16-28.303, F.A.C., have been electronically filed with the Department of State.

(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 DEA-41 "Registrants Inventory of Drugs Surrendered" effective 08/31/2014

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