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## **MEMORANDUM**

**TO:** Tammy Collins, Acting Executive Director  
Board of Pharmacy

**FROM:** Angela Southwell, Paralegal Specialist

**RE:** Rule 64B16-28.140

**DATE:** April 2, 2014

RECEIVED

APR 03 2014

Florida Board of Pharmacy

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We are pleased to inform you that the above-referenced rule was filed for adoption on March 4, 2014, and became effective March 24, 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

2014 MAR -4 PM 2:16  
DEPARTMENT OF STATE  
TALLAHASSEE, FLORIDA  
**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.

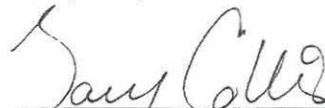
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.140

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:

Record Maintenance Systems for Community,  
Special-Limited Community, Special Closed  
Systems, Special-Parenteral/Enteral, and Nuclear Permits.

64B16-28.140

SUMMARY: The proposed rule amendments are necessary to delete an outdated citation to a repealed rule and insert the correct rule citation, update general record maintenance requirements to four instead of two years to be compatible with statutory requirements and biennial inspections, and make the rule applicable to all pharmacies. All similar pharmacy rules will be updated to be consistent with this record maintenance change.

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 amendments in order to delete an outdated citation to a repealed rule and insert the correct rule citation, update general record maintenance requirements to four instead of two years to be compatible with statutory requirements and biennial inspections, and make the rule applicable to all pharmacies. All similar pharmacy rules will be updated to be consistent with this record maintenance change.

64B16-28.140 Record Maintenance Systems for All Pharmacy Community, ~~Special-Limited Community,~~  
~~Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.~~

(1) Requirements for records maintained in a data processing system.

(a) through (c) No Change.

(d) Original prescriptions, including prescriptions received as provided for in Rule ~~64B16-27.1003~~ ~~64B16-28.130~~, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than four (4) ~~two~~ years from date of last filling. To the extent authorized by 21 C.F.R. Section 1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than four (4) ~~two~~ years from the date of last filling.

(e) No Change.

(f) Requirements for back-up systems.

1. No Change.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) ~~two~~ years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. through 2. No Change.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) ~~two~~ years from the date of initial entry into the data processing system.

(h) No Change.

(2) No Change.

(3) Records of dispensing.

(a) through (d) No Change.

(e) In lieu of producing the printout described in paragraphs (b) and (c) of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such

a system for a period of four (4) ~~two~~ years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) through (h) No Change.

(4) through (6) No Change.

Rulemaking Specific Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 465.035, 893.07 FS. History—New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-29-97, 6-15-98, 11-11-98, 10-15-01, \_\_\_\_\_.