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ATTORNEY GENERAL
STATE OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL
Administrative Law

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DEC 17 2013

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Florida Board of Pharmacy

MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist 

RE: Rule 64B16-28.901

DATE: December 16, 2013

We are pleased to inform you that the above-referenced rule was filed for adoption on December 11, 2013, and will become effective December 31, 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.

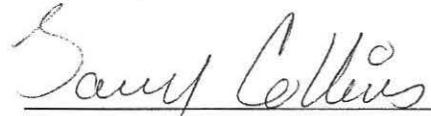
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.901

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

Acting Executive Director
Title

Number of Pages Certified

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

**Rick Scott**

Governor

John H. Armstrong, MD, FACS

State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation**MEMORANDUM**

Date: November 21, 2013

To: Lucy C. Gee, M.S., Division Director
Division of Medical Quality Assurance

From: Cassandra G. Pasley, BSN, JD, Chief
Bureau of Health Care Practitioner Regulation

Subject: Delegation of Authority

This is to advise you that until further notice, the following have delegated authority serve as Acting Executive Director for the Board of Pharmacy:

Daisy King, Program Operations Administrator, for EMT/Paramedic/Rad Tech. Daisy may be reached at 245-4549.

Tammy Collins, Program Operations Administrator, for Pharmacy. Tammy may be reached at 245-4614.

/vc

cc: Susan Love
Lola Pouncey
Lisa Eaton
Executive Directors

Florida Department of Health

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DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE NO.:
64B16-28.901
Requirements.

RULE TITLE:
Nuclear Pharmacy - General

SUMMARY: The proposed rule amendments will update and correct the terminology and labeling requirements for nuclear 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 update and correct the terminology and labeling requirements for nuclear pharmacies.

64B16-28.901 Nuclear Pharmacy – General Requirements.

(1) through (7) No Change.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) No Change.

(b) The date of distribution and the time of calibration ~~administration~~ of the radiopharmaceutical;

(c) through (e) No Change.

~~(f) The serial number assigned to the prescription order for the radiopharmaceutical;~~

~~(f)~~ (g) Any specific instructions; and

~~(g)~~ (h) The initials of the person who received the prescription order.

~~(h)~~ (i) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) through (m) No Change.

(n) Molybdenum 99 content to USP limits, applies only to Tc 99m ~~TC-99M~~ products; and

(o) The name of the patient for therapeutic or blood-product radiopharmaceuticals or the words "Physician's Use Only" for diagnostic radiopharmaceuticals ~~in the absence of a patient name~~. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(p) No Change.

(10) No Change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a)3, (14), (15), 465.0126, 465.014 FS. History—New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10, _____.