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MEMORANDUM

TO: Mark Whitten, Executive Director
Board of Pharmacy

FROM: Michele Bass, Paralegal Specialist

RE: Notice of Proposed Rulemaking
Rule 64B16-28.901

DATE: September 27, 2013

The above-referenced Notice was submitted to the BAC on September 23, 2013, for publication in the F.A.R. on September 24, 2013. Enclosed is a copy for your records.

If you have any questions or concerns, please feel free to contact me at 414-3766.

Enclosure

cc: Jennifer Tschetter, Assistant General Counsel

RECEIVED
SEP 30 2013
Florida Board of Pharmacy

DEPARTMENT OF HEALTH
Board of Pharmacy

RULE NO.:
64B16-28.901

RULE TITLE:
Nuclear Pharmacy - General Requirements.

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.

STATEMENT REGARDING FEDERAL STANDARDS: There is no ascertainable parallel federal rule or standard with which to make a comparison.

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HOSPITAL ADMINISTRATIVE
PROCEDURES COMMITTEE

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

RULE NO.:
64B16-28.901

RULE TITLE:
Nuclear Pharmacy - General Requirements.

PURPOSE AND EFFECT: The board proposes the rule development to update and correct the terminology and labeling requirements for nuclear pharmacies.

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

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COST AND LEGISLATIVE

RATIFICATION: The agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency. The agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: **During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.** Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 456.022 FS.
LAW IMPLEMENTED: 465.003(14), 465.0126, 465.014 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Mark Whitten, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE TEXT OF THE PROPOSED RULE IS:

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(14), 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, _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy.

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Board of Pharmacy.

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: August 13, 2013

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: September 6, 2013

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