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MEMORANDUM

TO: Tammy Collins, Acting Executive Director
Board of Pharmacy

FROM: Angela Southwell, Paralegal Specialist

RE: Rule 64B16-28.608

DATE: April 2, 2014

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 2:44
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.

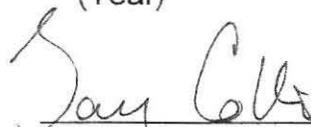
Attached are the original and two copies of each rule covered by this certification. The rules are hereby adopted by the undersigned agency by and upon their filing with the Department of State.

Rule No(s).

64B16-28.608

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

3

Number of Pages Certified

DEPARTMENT OF HEALTH

BOARD OF PHARMACY

ADDITIONAL STATEMENT TO THE SECRETARY OF STATE

RULE TITLE:

RULE NUMBER:

Automated Filling Systems within a Pharmacy.

64B16-28.608

SUMMARY: The rule will define the process of automated fill and set forth the procedures for using automated fill equipment within a pharmacy.

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 define the process of automated fill and set forth the procedures for using automated fill equipment within a pharmacy.

64B16-28.608 Automated Filling Systems within a Pharmacy.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(a) "Automated filling system" means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or systems governed by Rule 64B16-28.606 or 64B16-28.607, F.A.C.

(b) "Electronic verification process" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

(c) "Manufacturer Unit of Use Package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

(d) "Repackager" means a repackager registered with the United States Food and Drug Administration (FDA), as defined by Section 499.003(50), F.S.

(e) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA Repackager and is placed in a container for use in an automated filling system, as referenced by Section 499.003(42), F.S.

(f) "Load" means assigning new medications for new NDC numbers to the system, which must be completed by an onsite pharmacist.

(2) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or restocked by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C.

(3) Medication Loading. System must be loaded by an onsite pharmacist.

(4) Verification. Except as provided herein, a licensed pharmacist must verify the accuracy of the final contents of any medication filled or packaged by a system, and any label affixed thereto, prior to dispensing, as defined by subsection 64B16-27.1001(3), F.A.C.

(5) The pharmacist verification requirements of subsection (4) shall be deemed satisfied if:

(a) The pharmacy establishes and follows a policy and procedure manual that complies with subsection (6) of this rule:

(b) The system is fully automated from the time the medication is loaded into the machine until a completed, labeled and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication may occur after the medication is loaded into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage:

(c) A pharmacist must perform a prospective drug review and verify the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automatic fill process. The name, initials or identification codes(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing, or longer if required by applicable law:

(d) All medication Repacked by the pharmacy must be verified by a pharmacist pursuant to subsection 64B16-27.1001(3), F.A.C.

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly stocked, filled and loaded in the system. Alternatively, an electronic verification process may be used to verify a manufacturer unit of use package, repackaged, or prepacked containers:

(f) The medication to be dispensed is selected, filled, labeled, or sealed in the prescription container by the system or dispensed by the system in a manufacturer's unit of use package, repacked, or prepacked container:

(g) An electronic verification process is used to verify the proper prescription label has been affixed to the correct medication, prepackaged medication or manufacturer unit of use package for the correct patient: and

(h) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintain for four (4) years.

(6) Policies and Procedures. Pharmacies verifying prescriptions pursuant to subsection (5) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the prescription department manager or consultant pharmacist of record and shall be maintained in the pharmacy's records for a minimum of four (4) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for:

(a) Maintaining the system and any accompanying electronic verification system in good working order:

(b) Ensuring accurate filling, loading, and stocking of the system;

(c) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(d) Testing the accuracy of the system and any accompanying electronic verification system. At a minimum, the system and electronic verification process shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification process that changes or alters the filling or electronic verification process;

(e) Training persons authorized to access, stock, restock, or load the system in equipment use and operations;

(f) Conducting routine and preventive maintenance and, if applicable, calibration;

(g) Removing expired, adulterated, misbranded or recalled drugs;

(h) Preventing unauthorized access to the system, including assigning, discontinuing or changing security access;

(i) Identifying and recording persons responsible for stocking, loading and filling the system;

(j) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(k) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification process to ensure proper and accurate functioning, including tracking and documenting of automated filling system errors that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for four (4) years and produced to the Board upon request.

(7) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of four (4) years, or longer if required under applicable law. If the verification requirements of paragraph (5)(d) of this rule are completed by a pharmacist, the name, initials or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing. Records shall be made available for inspection and produced to the Board or the Board's authorized designee upon request.