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RULE ADOPTION

LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

**DUTIES OF REGISTERED PHARMACIST-IN-CHARGE; PROCEDURES FOR CENTRALIZED
PRESCRIPTION HANDLING; LABELING REQUIREMENTS**

Adopted Amendments: N.J.A.C. 13:39-3.18 and 5.9

Adopted New Rule: N.J.A.C. 13:39-5.10

Proposed: January 5, 2004 at 36 N.J.R. 11(a).

Adopted: May 12, 2004 by the Board of Pharmacy, Edward McGinley, R.P., President.

Filed: September 10, 2004 as R.2004 d.380, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-32, 45:14-33, 45:14-36 and 45:14-36.1.

Effective Date: October 4, 2004.

Operative Date: For amendments to N.J.A.C. 13:39-5.9, April 2, 2005.

Expiration Date: December 13, 2004.

Federal Standards Statement

A Federal standards analysis is not required because the adopted new rule and amendments are governed by N.J.S.A. 45:14-1 et seq., and, therefore, are not subject to any Federal requirements or standards. The Board notes, however, that pharmacies wishing to handle controlled substance prescriptions in a centralized manner must do so consistent with the Federal Drug Enforcement Administration standards articulated at 21 C.F.R. § § 1300 et seq.M

Full text of the adoption follows :

<< NJ ADC 13:39-3.18 >>

13:39-3.18 Registered pharmacist-in-charge

(a)-(d) (No change.)

(e) A registered pharmacist-in-charge shall be physically present in the pharmacy or pharmacy department for that amount of time necessary to ensure the fulfilling of the following responsibilities:

1.-7. (No change.)

Recodify existing 9.-14. as 8.-13. (No change in text.)

<< NJ ADC 13:39-5.9 >>

13:39-5.9 Labeling

(a) The dispensed container for any product shall bear a permanently affixed label with at least the following

information:

Recodify existing 2.-3. as 1.-2. (No change in text.)

3. The brand name of generic name and if generic, the name of the manufacturer;

4. The strength of medication, where applicable;

5. The quantity dispensed;

6. (No change in text.)

7. A CDS cautionary label, where applicable;

8. (No change in text.)

9. Initials of the dispensing pharmacist;

10. The prescriber name;

11. (No change in text.)

12. Directions for use; and

13. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging.

i. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container.

(b) The patient name, the brand or generic name of the medication, and the directions for use shall appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (a) above.

(c) In addition to the requirements set forth in (a) and (b) above, the dispensed container for any product shall bear all auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist.

<< NJ ADC 13:39-5.10 >>

13:39-5.10 Procedures for centralized prescription handling

(a) The four component functions of handling a prescription are intake, processing, fulfillment and dispensing.

(b) Central prescription handling entails two or more licensed pharmacies sharing responsibility for performing the four component functions of handling a prescription.

(c) The following pharmacies may engage in central prescription handling: an intake or originating pharmacy; a central processing pharmacy; a central fill pharmacy; and a dispensing pharmacy. The four component functions of handling a prescription shall be performed by the following pharmacies:

1. An intake or originating pharmacy, which is a licensed pharmacy that received the patient's or prescribing practitioner's request to fill or refill a prescription. A central processing pharmacy or a central fill pharmacy, as delineated in (c)2 and 3 below, may be considered the intake or originating pharmacy if the prescription was transmitted by the prescribing practitioner directly to the centralized pharmacy as provided in N.J.A.C. 13:39-5.8A and 5.8B or if the patient requested the refill from that pharmacy;

2. A central processing pharmacy, which is a licensed pharmacy that engages in prescription review by performing functions that may include, but are not limited to, data entry, prospective drug review, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication;

3. A central fill pharmacy, which is a licensed pharmacy engaging in central prescription handling by filling and/or refilling prescriptions which includes the preparation and packaging of the medication; and

4. A dispensing pharmacy, which is a licensed pharmacy that receives the processed prescription and/or the filled or refilled prescription for dispensing to the patient or to the patient's authorized representative.

(d) Two or more of the licensed pharmacies delineated in (c) above may engage in central prescription handling provided:

1. Any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner;

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. The pharmacies shall make a single application to the Board, delineating the scope of practice of each pharmacy and the specific rules in this chapter with which each pharmacy shall comply;

3. An audit trail is maintained that records and documents the name(s) <<+ or other personal identifier(s)+ >> of the <<-individual(s)- >> <<+ pharmacist(s) or pharmacy technician(s)+ >> and the component function(s) performed by each, at the time the functions are performed, for each step of prescription handling. The audit trail shall be maintained for not less than five years from the date the prescription is filled or refilled. The oldest four years of information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of information shall be <<-immediately- >> retrievable and readable <<+ within one business day+ >>;

4. The dispensed prescription for any product bears a permanently affixed label with at least the following information:

i. The brand name or generic name, and if generic, the name of the manufacturer;

ii. The strength of medication, where applicable;

iii. The quantity dispensed;

iv. The date upon which prescription medication is dispensed;

v. A CDS cautionary label, where applicable and when permitted by law;

vi. The patient name;

vii. The prescriber name;

viii. The prescription number;

ix. Directions for use;

x. The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging. For purposes of this paragraph, "use by date" means the earlier of one year from the date of dispensing or the expiration date on the manufacturer's container;

xi. All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional

judgment of the dispensing pharmacist; and

xii. The name, address and telephone number of any or all of the following:

(1) The intake pharmacy;

(2) The central processing pharmacy;

(3) The central fill pharmacy; and/or

(4) The dispensing pharmacy;

5. The patient name, the brand or generic name of the medication, and the directions for use appear in larger type, in a different color type, or in bolded type, in comparison to the other information required to appear on the label of the dispensed container pursuant to (d)4 above;

6. The patient is provided with written information, either on the prescription label or with the prescription container, that indicates which pharmacy to contact if the patient has any questions about the prescription or the medication. The written information provided to the patient shall be in bold print, easily read, and shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service shall be available at no cost to the pharmacy's primary patient population;

7. All pharmacies that are to engage in central prescription handling maintain a common policies and procedures manual which designates who shall be responsible for each of the component functions of handling the prescription and for ensuring compliance with the Board rules set forth in this chapter. The policies and procedures manual shall also include maintenance of the audit trail required by (d)3 above. The policies and procedures manual shall be made available to the Board upon request;

8. All pharmacies that are to engage in central prescription handling share a common electronic file; and

9. All pharmacies that are to engage in central prescription handling are responsible for ensuring that the prescription has been properly filled.

(e) A prescription for a controlled substance may be filled or refilled by pharmacies engaging in central prescription handling when permitted by law, consistent with Federal requirements set forth at 21 C.F.R. § § 1300 et seq.