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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

39 N.J.R. 4935(a)

Adopted Amendments: N.J.A.C. 13:39-1.3, 4.2 and 4.18

Adopted New Rules: N.J.A.C. 13:39-1.6 and 4.19

Fee Schedule; Waiver; Issuance of Permits; Permit Renewals; Procedures for Centralized Prescription Handling; Out-of-State Pharmacy Registration

Proposed: November 6, 2006 at 38 N.J.R. 4630(a).

Adopted: August 8, 2007 by the Board of Pharmacy, Edward G. McGinley, R.P., President.

Filed: October 18, 2007 as R.2007 d.351, with technical changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-47 and 45:14-73.

Effective Date: November 19, 2007.

Expiration Date: December 10, 2009.

Summary of Agency-Initiated Changes

The Board is making a technical change to N.J.A.C. 13:39-4.19(e) and (f) on adoption in order to correct cross references contained in the subsections. As proposed, subsection (e) provides, in part, that an out-of-State pharmacy registered with the Board must submit an annual renewal application, which must contain the information set forth in paragraphs (c)1 through 6 of the rule, as well as a renewal fee. Paragraph (c)6, however, refers to an initial application fee, which applicants for registration renewal do not have to submit. Subsection (e), therefore, is being changed on adoption, to require applicants for registration renewal to submit a renewal application containing the information set forth in paragraphs (c)1 through 5 of the rule. Similarly, subsection (f) provides that an out-of-State pharmacy registered with the Board must submit the information set forth in paragraphs (c)1 through 6, and the applicable fee, if there are any changes in ownership, registered agents or officers of the pharmacy, or in the pharmacy's location, name or registered pharmacist-in-charge. The Board did not intend these registrants to resubmit the initial registration fee referenced in paragraph (c)6. Therefore, subsection (f) is being changed on adoption to require registrants to submit the information set forth in paragraphs (c)1 through 5 of the rule when any of the referenced changes occur.

Federal Standards Statement

A Federal Standards analysis is not required because the adopted amendments and new rules are governed by N.J.S.A. 45:14-40 et seq., and are not subject to any Federal requirements or standards.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks *thus*; deletions from proposal indicated in brackets with asterisks *[thus]*):

13:39-1.3 Fee schedule

(a) The following fees shall be charged by the Board:

1. (No change.)

2. For in-State pharmacies as follows:

i.-iv. (No change.)

3. (No change.)

4. For out-of-State pharmacies as follows:

i. Pharmacy permits

- (1) Application for permit..... 175.00
- (2) Annual permit renewal..... 175.00
- (3) Change of ownership/name..... 175.00
- (4) Change of location..... 175.00
- ii. Replacement of annual permit..... 25.00
- iii. Late renewal fee..... 100.00
- iv. Verification of permit..... 25.00

13:39-1.6 Waiver

(a) The rules in this chapter may be relaxed by the Board upon a showing of undue hardship, economic or otherwise, on an applicant; that the waiver of the rule would not unduly burden any affected parties; and that the waiver is consistent with the underlying purposes of the Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq. and the implementing rules of this chapter.

(b) Waiver requests shall be submitted to the Board in writing and shall include the following:

- 1. The specific rule(s) or part(s) of the rule(s) for which the waiver is requested;
- 2. The reasons for requesting the waiver, including a statement detailing the hardship that would result to the applicant if the waiver is not approved; and
- 3. Documentation which supports the applicant's request for the waiver, if applicable.

(c) Absent a request for a waiver, the Board may waive the rules in this chapter if full compliance with the rules, or parts of the rules, would endanger the health, safety and welfare of the general public.

13:39-4.2 Issuance of permits; permit renewals

(a) All permits shall be issued by the Board in the name of the pharmacy or other licensed establishment for the operation of which the permit is issued.

(b) A permit holder shall submit to the Board, on an annual basis, within 30 days after the permit expiration, a renewal application and the renewal fee set forth in N.J.A.C. 13:39-1.3(a)2. A permit holder that fails to submit the renewal application within 30 days after the permit expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3(a)2 in addition to the renewal fee. A permit holder that continues to engage in the practice of pharmacy with an expired permit shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(c) The Board shall send a notice of renewal to each permit holder, at least 60 days prior to the expiration of the permit. If the notice to renew is not sent 60 days prior to the expiration date, no monetary penalty or fines shall apply to the permit holder for any unauthorized practice during the period following the permit expiration, not to exceed the number of days short of 60 before the renewal was issued.

13:39-4.18 Procedures for centralized prescription handling

(a)-(c) (No change.)

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

1. (No change.)

2. Prior to engaging in central prescription handling, all pharmacies that are parties to the central prescription handling obtain Board approval. If a participating pharmacy is located outside the State of New Jersey, the pharmacy shall have registered with the Board pursuant to N.J.A.C. 13:39-4.19. 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.-9. (No change.)

(e) (No change.)

13:39-4.19 Out-of-State pharmacy registration

(a) Any pharmacy located in a state other than New Jersey (hereinafter "out-of-State pharmacy") that ships, mails, distributes or delivers in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State, or which participates in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, shall be registered with the Board pursuant to this section.

(b) It shall be unlawful for any out-of-State pharmacy not registered with the Board pursuant to this section to ship, mail, distribute or deliver in any manner, legend drugs or devices or controlled dangerous substances pursuant to a prescription into the State of New Jersey. Such conduct shall be deemed a violation of N.J.S.A. 45:14-73 and this section.

(c) An out-of-State pharmacy seeking to register with the Board shall submit a completed application for registration to the Board which shall include the following:

1. The name under which the pharmacy is to be operated, the type of practice in which the pharmacy will be engaging, the weekly hours of operation for the pharmacy, and a copy of the prescription label to be used by the pharmacy;

2. The location, names and titles of all principal corporate officers, if the applicant is a corporation, or the location, names and titles of any individuals in whom ownership is or will be vested, if the applicant is not a corporation;

3. The name of the pharmacist-in-charge and his or her license number in the state in which the pharmacy is located, and his or her weekly hours of employment;

4. A dated copy of the most recent inspection report resulting from an inspection of the out-of-State pharmacy conducted by the regulatory or licensing agency in the state in which the pharmacy is located;

5. A letter of good standing from the state licensing authority in the state in which the out-of-State pharmacy is licensed, permitted or registered; and

6. The application fee specified in N.J.A.C. 13:39-1.3(a)4.

(d) An out-of-State pharmacy registered with the Board shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws and regulations of the state in which it is located. The pharmacy shall notify the Board immediately upon the permanent closing of the pharmacy or upon the commencement of any action by the licensing authority in the state in which it is located concerning its license, permit or registration to conduct the pharmacy. Suspension or revocation of a pharmacy's license, permit or registration in the

state in which it is located shall result in the immediate commencement of proceedings by the Board to suspend or revoke the out-of-State pharmacy's registration in New Jersey.

(e) An out-of-State pharmacy registered with the Board shall submit on an annual basis, prior to the expiration of the registration, a renewal application which shall contain the information set forth in (c)1 through *[6]* *5* above, and the renewal fee set forth in N.J.A.C. 13:39-1.3(a)4. A registered out-of-State pharmacy that fails to submit the renewal application within 30 days after the registration expiration shall submit the late renewal fee set forth in N.J.A.C. 13:39-1.3(a)4 in addition to the renewal fee. An out-of-State pharmacy that continues to ship, mail, distribute or deliver legend drugs or devices or controlled dangerous substances into the State, or continues to participate in a central prescription handling arrangement pursuant to N.J.A.C. 13:39-4.18, with an expired registration shall be deemed to be engaging in the unauthorized practice of pharmacy and shall be subject to the penalties set forth in N.J.S.A. 45:1-25 et seq.

(f) An out-of-State pharmacy registered with the Board shall submit the information set forth in (c)1 though *[6]* *5* above and the fee set forth in N.J.A.C. 13:39-1.3(a)4, if applicable, within 30 days of the following:

1. Any change in ownership of the individual equity holder(s) or business entity holding the license, permit or registration to operate the pharmacy;
2. A change of registered agents or officers or a change of stock ownership involving 10 percent or more of the outstanding stock of a publicly traded corporation holding the license, permit or registration to operate the pharmacy;
3. A change in the location of the licensed, permitted or registered pharmacy;
4. A change in the name of the licensed, permitted or registered pharmacy; or
5. A change in the registered pharmacist-in-charge.

(g) An out-of-State pharmacy may obtain a replacement registration upon payment of the fee specified in N.J.A.C. 13:39-1.3(a)4 and upon submission of an affidavit describing the loss or destruction of the registration originally issued, or upon return of the damaged permit.

(h) An out-of-State pharmacy registered with the Board shall:

1. Inform the Board, upon request, of the results of any inspections or investigations conducted by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency, including the filing of any action against the pharmacy by the agency;
2. Inform the Board, upon request, of any directions to, and requests for information from, the pharmacy issued by the regulatory or licensing agency of the state in which the pharmacy is licensed, permitted or registered or by a Federal agency; and
3. Comply with directions concerning compliance with this section and any requests for information issued by the Board.

(i) An out-of-State pharmacy registered with the Board shall maintain its record of prescriptions for patients in the State of New Jersey for a period of not less than five years. The oldest four years of record information shall be maintained in such a manner so as to be retrievable and readable within two weeks. The most recent one year of record information shall be retrievable and readable within one business day.

(j) An out-of-State pharmacy registered with the Board shall, during its regular hours of operation, but not less than five days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the State of New Jersey and a pharmacist who has access to the patients' records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the State of New Jersey or the out-of-State pharmacy shall meet the requirements set forth in N.J.A.C. 13:39-4.18(d)6.

(k) The Board may forward a complaint against any out-of-State pharmacy registered with the Board for alleged violations of any New Jersey or Federal law or regulation, or any information concerning alleged violations of New Jersey or Federal law by the pharmacy, to the regulatory or licensing agency in the state in which the pharmacy is located, or the Board may institute disciplinary proceedings in New Jersey pursuant to N.J.S.A. 45:1-21 et seq., to resolve the complaint or alleged violation.