



TO: The Honorable the Members of the Board of Regents

FROM: Johanna Duncan-Poitier
Johanna Duncan-Poitier

COMMITTEE: Professional Practice

TITLE OF ITEM: Proposed Amendment to the Rules of the Board of Regents and the Regulations of the Commissioner of Education Relating to Pharmacy and the Registration of New York Pharmacies and Nonresident Establishments

DATE OF SUBMISSION: January 14, 2003

PROPOSED HANDLING: Approval

RATIONALE FOR ITEM: To Implement Statute and Policy

STRATEGIC GOAL: Goal 3

AUTHORIZATION(S): *[Signature]* *[Signature]*

SUMMARY:

Attached for action is a proposed promulgation of section 29.7(c) of the Rules of the Board of Regents and section 63.8 of the Regulations of the Commissioner of Education, and amendment to section 63.6 of the Regulations of the Commissioner of Education, relating to pharmacy and the registration of New York pharmacies and nonresident establishments. Supporting materials for the proposed amendment are available upon request from the Secretary to the Board of Regents.

The purpose of the proposed amendment is to establish requirements for the registration of nonresident establishments that ship, mail, or deliver prescription drugs and/or devices into New York State, remove unnecessary requirements for faxing a prescription to a New York pharmacy that is under contract with a hospital or nursing home, and delete outdated references to registered stores in the regulations.

The proposed amendment was discussed at the December 2002 meeting of the Board of Regents. A Notice of Proposed Rule Making concerning the proposed amendment was published in the State Register on December 4, 2002.

I recommend that the Board of Regents take the following action:

VOTED: That subdivision (c) of section 29.7 of the Rules of the Board of Regents be added, section 63.6 of the Regulations of the Commissioner of Education be amended, and section 63.8 of the Regulations of the Commissioner of Education be added, as submitted, effective March 19, 2003.

Attachment

AMENDMENT TO THE RULES OF THE BOARD OF REGENTS AND THE
REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 6509, 6801,
6808, 6808-b of the Education Law

1. Subdivision (c) of section 29.7 of the Rules of the
Board of Regents is added, effective March 19, 2003, as follows:

(c) The requirements of this section and sections 29.1 and
29.2 of this Part shall be applicable to nonresident
establishments, as defined in section 6808-b of the Education
Law, to the extent prescribed in section 63.8 of this Title.

2. Section 63.6 of the Regulations of the Commissioner of
Education is amended, effective March 19, 2003, as follows:

63.6 Registration and operation of New York establishments.

(a) General provisions. (1) The requirements of this
section shall apply to establishments located in New York State.
Section 63.8 of this Part sets forth requirements for the
registration of nonresident establishments.

[(1)] (2) A certificate of registration issued for the
operation of a pharmacy, manufacturer, or wholesaler [or
registered store] shall be valid only for that address stated on
the certificate. Endorsement of the certificate to another
address may be made by the State Board of Pharmacy upon
application to the board, the payment of the fee set forth in
Education Law, section 6808, and a finding by the board that the

new location meets the requirements of the applicable subdivisions of this section. An application for endorsement to another address shall be made not less than 30 days prior to the expected date of relocation.

[(2)] (3) . . .

[(3)] (4) No certificate of registration shall be issued or continued for the conduct of a pharmacy, manufacturer, or wholesaler [or registered store] unless the premises occupied by such registered establishment shall be equipped with proper sanitary appliances and kept in a clean and orderly manner.

[(4)] (5) . . .

[(5)] . . .]

(6) . . .

(7) . . .

(8) . . .

(9) . . .

(b) . . .

(c) . . .

[(d)] . . .]

[(e)] d . . .

3. Section 63.8 of the Regulations of the Commissioner of Education is added, effective March 19, 2003, as follows:

63.8 Registration of nonresident establishments.

(a) Definitions. For purposes of this section and section 6808-b of the Education Law:

(1) Nonresident establishment means any pharmacy, manufacturer, or wholesaler located outside of New York State that ships, mails, or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in New York State. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.

(2) Isolated transaction means for pharmacies, 600 or fewer prescriptions per calendar year for drugs and/or other devices delivered into New York State, and for manufacturers and wholesalers, sales that total less than \$10,000 in value, at wholesale per calendar year, for drugs and/or devices delivered into New York State, except that upon application by a nonresident establishment, the department may deem a transaction to be an isolated transaction, when such transaction is necessary to protect the public health by addressing a temporary emergency shortage of a prescription drug and/or device in New York State.

(b) Registration requirements.

(1) All nonresident establishments that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into New

York State shall be registered with the department in accordance with this section and section 6808-b of the Education Law, except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control, and except that such registration shall not apply to nonresident establishments that have been granted an exception under subdivision (e) of this section.

(2) Application. Nonresident establishments shall apply to the department for registration upon forms prescribed by the department. The application for nonresident manufacturers or wholesalers of prescription drugs and/or devices shall be accompanied by a fee of \$825. The application for nonresident pharmacies shall be accompanied by a fee of \$345.

(3) Renewal of registration. All registrations for nonresident establishments shall be renewed on dates set by the department. The triennial registration fee for the renewal of a registration of a nonresident manufacturer or wholesaler shall be \$520 or a prorated share thereof, as determined by the department. The triennial registration fee for the renewal of a registration of a nonresident pharmacy shall be \$260 or a prorated share thereof, as determined by the department.

(4) Failure to register shall subject the nonresident establishment to the late fee set forth in section 6502(3) of the Education Law.

(5) In order to be registered, nonresident establishments shall:

(i) be licensed and/or registered in good standing with the state of residence;

(ii) maintain, in readily retrievable form, records of drugs and/or devices shipped into New York State;

(iii) supply, upon request, all information needed by the department to carry out the department's responsibilities under law;

(iv) comply with all statutory and regulatory requirements of the state where the nonresident establishment is located, for prescription drugs or devices shipped, mailed, or delivered into New York State, except for controlled substances shipped, mailed, or delivered into New York State, the nonresident pharmacy shall follow Federal law and New York State law;

(v) designate a resident agent in New York State for service of process pursuant to Rule 318 of the Civil Practice Law and Rules; and

(vi) meet the following requirements of the Education Law to the extent that they pertain to the delivery of prescription drugs and devices into New York State: Education Law, sections

6802, 6810, 6811, 6811-b, 6813, 6814, 6815, 6816, 6816-a, 6817, 6822, 6824, and 6825.

(6) Additional requirements for nonresident establishments that are pharmacies. In order to be registered, nonresident establishments that are pharmacies shall provide a toll-free telephone number that is available during normal business hours at least 40 hours per week, to enable communication between a patient in New York State and a pharmacist at the pharmacy who has access to the patient's records, and shall place such toll free number on a label affixed to each drug or device container.

(c) Disciplinary action.

(1) Nonresident establishments shall be subject to disciplinary action in accordance with the requirements of subdivision (6) of section 6808-b of the Education Law, section 6510 of the Education Law and implementing regulations, including but not limited to section 3.3 and Part 17 of this Title.

(2) A nonresident establishment shall be subject to disciplinary action for:

(i) professional misconduct, as defined in section 6509 of the Education Law;

(ii) unprofessional conduct, as defined in paragraphs (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12) (i) (a), (13), and (14) of subdivision (b) of section 29.1 of this Title;

(iii) unprofessional conduct, as defined in paragraphs (1), (2), (4), (5), (6), (8), and (10) of subdivision (a) of section 29.2 of this Title;

(iv) unprofessional conduct, as defined in paragraphs (16), (17), and (19) of subdivision (a) of section 29.7 of this Title;
and

(v) failure to meet the registration requirements prescribed in subdivision (b) of this section, any other requirements of this section, and the requirements of section 6808-b of the Education Law.

(3) In a disciplinary action, a nonresident establishment shall be subject to revocation or suspension of its registration and other applicable penalties in accordance with Article 130 of the Education Law.

(d) Notification of change of address or discontinuance. A registered nonresident establishment shall notify the department on forms prescribed by the department of a change of address of the establishment or the discontinuance of the establishment within 10 days after such change of address or discontinuance.

(e) Exception to registration requirements. Upon application by a nonresident establishment, the department may grant an exception to the registration requirements of this section to a nonresident establishment that restricts its sale or dispensing of prescription drugs and/or devices to residents

of New York State to isolated transactions, as defined in
subdivision (a) of this section.