§ 6808-b. Registration of nonresident establishments. 1. Definition. The term "nonresident establishment" shall mean any pharmacy located outside of the state that participates in shared pharmacy services for registered pharmacies and/or patients residing in this state or pharmacy, manufacturer, wholesaler, or outsourcing facility located outside of the state that ships, mails or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in this state. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.

2. Registration. All nonresident establishments that participate in shared pharmacy services for registered pharmacies and/or patients residing in this state or that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into this state shall be registered with the department; 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. The provisions of this subdivision shall apply solely to nonresident establishments and shall not affect any other provision of this article.

3. Agent of record. Each nonresident establishment that participates in shared pharmacy services or ships, mails or delivers drugs and/or devices into this state shall designate a resident agent in this state for service of process pursuant to rule three hundred eighteen of the civil practice law and rules.

4. Conditions of registration. As a condition of registration, a nonresident establishment shall comply with the following requirements:

a. Be licensed and/or registered and in good standing with the state of residence;

b. Maintain, in readily retrievable form, records of drugs and/or devices shipped into this state;

c. Supply, upon request, all information needed by the department to carry out the department's responsibilities under the laws and rules and regulations pertaining to nonresident establishments;

d. 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 this state, except that for controlled substances shipped, mailed or delivered into this state, the nonresident pharmacy shall follow federal law and New York law relating to controlled substances;

e. The application shall be made in the manner and form prescribed by the department;

f. The application of establishments to be registered as a manufacturer, wholesaler or outsourcing facility of drugs and/or devices shall be accompanied by a fee as provided in section sixty-eight hundred eight of this article; and

g. The application of establishments to be registered as a nonresident pharmacy shall be accompanied by a fee of three hundred forty-five dollars and shall be renewed triennially at a fee of two hundred sixty dollars.

5. Additional requirements. Nonresident pharmacies registered pursuant to this section shall:

a. Provide a toll-free telephone number that is available during normal business hours and at least forty hours per week, to enable communication between a patient in this state and a pharmacist at the pharmacy who has access to the patient's records; and

b. Place such toll-free telephone number on a label affixed to each drug or device container.

6. Disciplinary action. Except in emergencies that constitute an immediate threat to public health, the department shall not prosecute a

complaint or otherwise take formal action against a nonresident establishment based upon delivery of a drug into this state or a violation of law, rule, or regulation of this state if the agency having jurisdiction in the state where the nonresident establishment is based commences action on the violation complained of within one hundred twenty days from the date that the violation was reported; provided however, that the department may prosecute a complaint or take formal action against a nonresident establishment if it determines that the agency having jurisdiction in the state where the nonresident establishment is based has unreasonably delayed or otherwise failed to take prompt and appropriate action on a reported violation.

7. Revocation or suspension. A nonresident establishment that fails to comply with the requirements of this section shall be subject to revocation or suspension of its registration and other applicable penalties in accordance with the provisions of article one hundred thirty of this chapter.

8. Exception. The department may grant an exception from the registration requirements of this section on the application of a nonresident establishment that restricts its sale or dispensing of drugs and/or devices to residents of this state to isolated transactions.

9. Rules and regulations. The department shall promulgate rules and regulations to implement the provisions of this section.