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

Pursuant to sections 207, 212, 215, 6504, 6507, 6509, 6802, 6808, 6808-b, 6811, 6811-a, 6812, 6817 and 6831 of the Education Law and Part D of Chapter 60 of the Laws of 2014.

1. Subdivision (a) of section 29.2 of the Rules of the Board of Regents is amended, effective October 1, 2014, to read as follows:

(a) Unprofessional conduct shall also include, in the professions of: acupuncture, athletic training, audiology, certified dental assisting, chiropractic, creative arts therapy, dental hygiene, dentistry, dietetics/nutrition, licensed practice nursing, marriage and family therapy, massage therapy, medicine, mental health counseling, midwifery, occupational therapy, ophthalmic dispensing, optometry, pharmacy, physical therapist assistant, physical therapy, physician assistant, podiatry, psychoanalysis, psychology, registered professional nursing, respiratory therapy, respiratory therapy technician, social work, special assist, occupational therapy assistant, speech-language pathology (except for cases involving those professions licensed, certified or registered pursuant to the provisions of Article 131 or 131-B of the Education Law in which a statement of charges of professional misconduct was not served on or before July 26, 1991, the effective date of Chapter 606 of the Laws of 1991):

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(12) issuing prescriptions for drugs and devices which do not contain the following information: the date written, the prescriber's name, address, telephone number, profession and registration number, the patient's name, address and age, the name, strength and quantity of the prescribed drug or device, as well as the directions for use by the patient. In addition, all prescriptions for controlled substances shall meet the requirements of article 33 of the Public Health Law; [and]

(13) failing to use scientifically accepted infection prevention techniques appropriate to each profession for the cleaning and sterilization or disinfection of instruments, devices, materials and work surfaces, utilization of protective garb, use of covers for contamination-prone equipment and the handling of sharp instruments. Such techniques shall include but not be limited to:

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(xiii) placing all specimens of blood and body fluids in well-constructed containers with secure lids to prevent leaking; and cleaning any spill of blood or other body fluid with an appropriate detergent and appropriate chemical germicide; and

(14) failing to adhere to applicable practice guidelines, as determined by the Commissioner, for the compounding of sterile drugs and products.

2. Paragraph (17) of subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended, effective October 1, 2014, to read as follows:

(17) Holding for sale, offering for sale, or selling:

(i) any drug later than the date, if any, marked upon the label as indicative of the date beyond which the contents cannot be expected beyond reasonable doubt to be

safe and effective[;] and/or the beyond use date, which shall mean the expiration date of the drug; provided, however, that when such drug is identified as an outdated drug by segregation from regular stock or by other means, the holding of such drug beyond its expiration date shall not be deemed a violation of this paragraph. When the expiration date is expressed by month and year, the expiration date shall be the last day of the month indicated; or

(ii) …

3. Paragraphs (2) and (4) of subdivision (a) of section 63.6 of the Regulations of the Commissioner of Education are amended, effective October 1, 2014, to read as follows:

(2) A certificate of registration issued for the operation of a pharmacy, manufacturer, outsourcing facility or wholesaler shall be valid for only 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 subdivision 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.

(3) ….

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

4. Subdivision (c) of section 63.6 of the Regulations of the Commissioner of Education is amended, effective October 1, 2014, as follows:

(c) Manufacturers, outsourcing facilities and wholesalers:

(1) Except as provided in paragraph (2) of this subdivision, no manufacturer or wholesaler shall be registered pursuant to the provisions of subdivision 4 of section 6808 of the Education Law and no outsourcing facility shall be registered pursuant to the provisions of subdivision 5 of section 6808 of the Education Law unless a registered pharmacist is present at all times when the establishment is open for business; provided, however, that establishments registered as a manufacturer or wholesaler under this section may be under the supervision of an individual who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs satisfactory to the department and is either: [a chemist who holds a bachelor's degree in chemistry and who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs]:

(i) a chemist who holds a bachelor's degree in chemistry; or

(ii) an individual who holds a bachelor's degree in pharmaceutical manufacturing, biochemistry, microbiology or other bachelor's degree deemed satisfactory to the department.

(2) …

(3) …

(4) …

(5) Manufacturers, outsourcing facilities or wholesalers shall sell drugs and/or devices only to those purchasers authorized by law. Records of the receipt and disposition of all drugs/devices shall be maintained for a period of five years and shall be available to the department for review and copying upon request.

(6) . . .

(7) Additional requirements for outsourcing facilities.

(i) Upon initially registering as an outsourcing facility and every six months thereafter, each outsourcing facility shall submit to the executive secretary of the state board of pharmacy a report, on a form prescribed by the Commissioner, which shall include, but not be limited to:

(a) identification of the drugs compounded by such outsourcing facility during the previous six-month period; and

(b) with respect to each such identified drug, provide the active ingredient; the source of such active ingredient; the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individuals units produced; and the national drug code number of the final product, if assigned.

(ii) Outsourcing facilities shall maintain quality control records for determining beyond use dating and stability for five years and shall make such records available to the department for review and copying upon request.

(iii) Outsourcing facilities shall comply with the special provisions relating to outsourcing facilities set forth in Education Law section 6831.

(iv) Outsourcing facilities shall comply with current good manufacturing practices as specified in parts 210 and 211 of title 21, Code of Federal Regulations (2013 edition, Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402; 2013, available at New York State Board of Pharmacy, 2nd Floor, Education Building, 89 Washington Avenue, Albany, New York 12234).

(v) At all times such facilities shall be under the supervision of a pharmacist licensed and registered to practice pharmacy in New York State.

(vi) Upon initial registration and at each renewal, such facilities shall submit to the department documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

(vii) Upon initial registration and at least annually thereafter, such facilities shall submit to the department the results of an inspection by either: representatives of the Federal Food and Drug Administration, this department or a third party acceptable to the department.

(viii) No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also a New York State registered pharmacy and meets all other applicable requirements of federal and State law.

(ix) Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act shall not meet the requirements for renewal of registration.

5. Section 63.8 of the Regulations of the Commissioner of Education is amended, effective October 1, 2014, to read as follows:

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

(1) Nonresident establishments means any pharmacy, manufacturer [or], outsourcing facility 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 transactions means for pharmacies[,] only, 600 or fewer prescriptions per calendar for drugs and/or 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, a nonresident [establishment] pharmacy, manufacturer or wholesaler, 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 in 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 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. The intra-company transfer exemption shall not apply to outsourcing facilities.

(2) Application. Nonresident establishments shall apply to the department for registration upon forms prescribed by the department. The application for nonresident manufacturers, outsourcing facilities or wholesalers of prescription drugs and/or devices shall be accompanied by a fee of $825. The application fee 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, outsourcing facility 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. Nonresident establishments that fail to demonstrate that they are licensed and/or registered in good standing with their state of residence shall not meet the requirements for renewal of registration. Additionally, non-resident outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act shall not meet the requirements for renewal of registration.

(4) …

(5) . . .

(6) …

(7) Additional requirements for nonresident establishments that are outsourcing facilities.

(i) Upon initially registering as an outsourcing facility and every six months thereafter, each outsourcing facility shall submit to the executive secretary of the state board of pharmacy a report, on a form prescribed by the Commissioner, which shall include, but not be limited to:

(a) identification of the drugs compounded by such outsourcing facility during the previous six-month period; and

(b) with respect to each such identified drug, provide the active ingredient; the source of such active ingredient; the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individuals units produced; and the national drug code number of the final product, if assigned.

(ii) Outsourcing facilities shall maintain quality control records for determining beyond use dating and stability for five years and shall make such records available to the department for review and copying upon request.

(iii) Outsourcing facilities shall comply with the special provisions relating to outsourcing facilities set forth in Education Law section 6831.

(iv) Outsourcing facilities shall comply with current good manufacturing practices as specified in parts 210 and 211 of title 21, Code of Federal Regulations (2014 edition, Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402; 2014, available at New York State Board of Pharmacy, 2nd Floor, 89 Washington Avenue, Albany, New York 12234) .

(v) At all times such facilities shall be under the supervision of a pharmacist licensed and registered to practice pharmacy in New York State.

(vi) Upon initial registration and at each renewal, such facilities shall submit to the department documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

(vii) Upon initial registration and at least annually thereafter, such facilities shall submit to the department the results of an inspection by either: representatives of the Federal Food and Drug Administration, this department or a third party acceptable to the department.

(viii) No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also a New York registered pharmacy and meets all other applicable requirements of federal and State law.

(c) Disciplinary action.

(1) . . .

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

(i) . . .

(ii) . . .

(iii) unprofessional conduct, as defined in section 29.2(a)(1)-(2), (4)-(6), (8), [and] (10) and (14) of this Title;

(iv) . . .

(v) . . .

(d) Notification of change of address or discontinuance. A registered nonresident manufacturer or wholesaler [establishment] shall notify the department on forms prescribed by the department within 10 days of such change of address or discontinuance. A registered nonresident outsourcing facility shall notify the department on forms prescribed by the department not less than 30 days prior to the expected date of relocation or discontinuance.

(e) Exception to registration requirements. Upon application by a nonresident pharmacy, manufacturer or wholesaler, 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. The isolated transactions exception shall not apply to nonresident outsourcing facilities.

(f) Reporting requirements for registered nonresident establishments that are outsourcing facilities. Registered nonresident outsourcing facilities shall provide any information and/or submit reports to the department at the Commissioner's request.