TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Proposed Amendment to Sections 29.2 and 29.7 of the Rules of the Board of Regents and Sections 63.6 and 63.8 of the Regulations of the Commissioner of Education to Implement Part D of Chapter 60 of the Laws of 2014, Relating to the Registration and Regulation of Outsourcing Facilities.

DATE: September 8, 2014

AUTHORIZATION(S):

SUMMARY

Issue for Decision

Should the Board of Regents amend sections 29.2 and 29.7 of the Rules of the Board of Regents and sections 63.6 and 63.8 of the Regulations of the Commissioner of Education to implement Part D of Chapter 60 of the Laws of 2014, relating to the registration and regulation of outsourcing facilities?

Reason(s) for Consideration

Required by State statute and review of policy.

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for recommendation to the full Board for adoption as a permanent rule at the September 2014 meeting of the Board of Regents. In addition, a second emergency action is necessary to ensure that the emergency rule adopted at the June 2014 Regents meeting remains continuously in effect until October 1, 2014, which is the effective date of the adoption of the permanent rule. A copy of the permanent rule, the emergency rule, and a Statement of Facts and Circumstances Which Necessitate

Emergency Action are attached. Supporting materials are available upon request from the Secretary to the Board of Regents.

Procedural History

The proposed amendment was adopted as an emergency rule at the June 2014 Regents meeting, effective June 29, 2014. A Notice of Emergency Action and Proposed Rule Making was published in the State Register on July 9, 2014 for a 45-day public comment period. Because the June emergency rule will expire on September 22, 2014, a second emergency action is necessary to ensure that the emergency rule remains continuously in effect until the permanent rule takes effect on October 1, 2014. Additionally, following the above-referenced publication of the Notice of Proposed Rule Making, the Department received no comments on the proposed amendment. Therefore, an Assessment of Public Comment is not required and no changes to the proposed amendment are needed.

Background Information

For more than a century, the Department has regulated entities and professionals who engage in the manufacture, repackaging, distribution and dispensing of prescription drugs. Unlike most states, however, New York never allowed practices often referred to as "compounding for office use" or other exceptions to the strict manufacturing requirements for prescription drug products, including sterile drugs.

Due to increasing numbers of drug shortages, a temporary shortage of pharmacists and significant and unexpected price increases from traditional manufacturers, a category of facilities that called themselves "outsourcing pharmacies" began to operate across the nation. A series of outbreaks of illnesses and deaths occurred due to contaminated products compounded at these facilities. Then, in the fall of 2012, a fungal contamination at the New England Compounding Center of a supposedly sterile product became the latest and most severe case in history. This "outsourcing pharmacy" prepared approximately 17,000 vials of a steroidal injectable product. This product was ultimately determined to be contaminated with a fungus. This contamination resulted in a need to monitor approximately 13,000 patients. Ultimately, 751 patients were confirmed to be infected, 64 of which died as a result of this contaminated product.

Following the discovery of this tragedy, the FDA invited the Boards of Pharmacy from all 50 states and the District of Columbia to a meeting at the FDA headquarters in Maryland. This meeting provided stakeholders an opportunity to suggest a means by which such tragedies could be avoided in the future. There was agreement that new federal legislation was needed to resolve the long-standing challenges to the FDA's authority over these facilities.

On November 27, 2013, the President signed the Drug Quality and Security Act of 2013 (DQSA), in an effort to ensure the safety of compounded drugs and our nation's pharmaceutical supply chain to prevent a future public health crisis like the 2012 meningitis outbreak tied to the New England Compounding Center. Title I of DQSA provides for the comprehensive oversight of firms which seek to compound and

distribute sterile drugs and products without first obtaining patient-specific prescriptions. Title II of DQSA outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

On March 29, 2014, the Governor signed Part D of Chapter 60 of the Laws of 2014 ("the Budget Bill"). Part D of Chapter 60 of the Laws of 2014 included amendments to the Education Law to implement Title I of DQSA, which provide for the registration and regulation of outsourcing facilities by the Department and became effective on June 29, 2014.

The proposed amendment implements the requirements of the new State law. First, the proposed amendment sets forth the registration requirements for both resident and non-resident outsourcing facilities, which includes a requirement that the facility be registered by the FDA as an outsourcing facility. It also requires that outsourcing facilities submit, upon initial registration and at least annually thereafter, the results of an inspection by either representatives of the FDA, the Department or a third party acceptable to the Department.

The proposed amendment further requires that a New York registered pharmacist be present at all times when an outsourcing facility is open for business and that outsourcing facilities submit a report, on a form prescribed by the Commissioner, to the Executive Secretary to the State Board upon initial registration and every six months thereafter, identifying the drugs compounded by the facility during the 6-month period and providing certain information relating to such drugs. It requires outsourcing facilities to maintain quality control records for determining beyond use dating and stability for five years and to make such records available to the Department for review and copying upon request and requires all outsourcing facilities to comply with the special provisions relating to outsourcing facilities set forth in Education Law §6831 and to comply with good manufacturing practices as defined by the FDA for such facilities. The proposed amendment also requires non-resident outsourcing facilities to notify the Department on forms prescribed by the Department at least 30 days prior to the expected date of relocation.

In addition, it provides that an outsourcing facility's failure to adhere to applicable practice guidelines for the compounding of sterile drugs and products is unprofessional misconduct and clarifies that holding for sale, offering for sale, or selling any drug later than the beyond use date, which means the expiration date of the drug, constitutes unprofessional misconduct.

The proposed amendment also modifies certain regulatory provisions relating to supervision for resident manufacturers and wholesalers in section 63.6 of the Regulations of the Commissioner of Education, as these provisions required clarification.

Recommendation

It is recommended that the Board of Regents take the following action:

VOTED: That subdivision (a) of section 29.2 and paragraph (17) of subdivision (a) of section 29.7 of the Rules of the Board of Regents and paragraphs (2) and (4) of subdivision (a) and subdivision (c) of section 63.6 and section 63.8 of the Regulations of the Commissioner of Education are amended, as submitted, effective October 1, 2014; it is further

VOTED: That subdivision (a) of section 29.2 and paragraph (17) of subdivision (a) of section 29.7 of the Rules of the Board of Regents and paragraphs (2) and (4) of subdivision (a) and subdivision (c) of section 63.6 and section 63.8 of the Regulations of the Commissioner of Education are amended, as submitted, effective September 22, 2014, as an emergency action upon a finding by the Board of Regents that such action is necessary for the preservation of the public health and general wealth to ensure that the emergency rule adopted at the June 2014 Regents meeting to implement the requirements of Part D of Chapter 60 of the Laws of 2014 remains continuously in effect until the proposed amendment is adopted as a permanent rule, so that outsourcing facilities seeking to prepare and/or distribute compounded sterile drugs and products in New York will be on notice of the compliance and registration requirements for such facilities in this State.

Timetable for Implementation

The proposed amendment was adopted as an emergency rule at the June 2014 Regents meeting, effective June 29, 2014 and will expire on September 22, 2014. If adopted at the September 2014 Regents meeting, the permanent rule will take effect on October 1, 2014 and the emergency rule will take effect on September 22, 2014.

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):

(1) …

(2) …

(3) …

(4) …

(5) …

(6) …

(7) …

(8) …

(9) …

(10) …

(11) …

(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:

(i) . . .

(ii) . . .

(iii) . . .

(iv) . . .

(v) . . .

(vi) . . .

(vii) . . .

(viii) . . .

(ix) . . .

(x) . . .

(xi) . . .

(xii) . . .

(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.

8 NYCRR §§29.2, 29.7, 63.6 and 63.8

STATEMENT OF FACTS AND CIRCUMSTANCES

WHICH NECESSITATE EMERGENCY ACTION

The purpose of this amendment is to implement Part D of Chapter 60 of the Laws of 2014, effective June 29, 2014. This amendment to the Education Law provides for the registration and regulation of outsourcing facilities, a new category of establishment recognized by the Federal Food and Drug Administration pursuant to the Drug Quality and Security Act (DQSA) of 2013. DQSA's provisions are designed to ensure the safety of compounded drugs and our nation's pharmaceutical supply chain in order to prevent a future public health crisis like the 2012 meningitis outbreak tied to the New England Compounding Center. DQSA, inter alia, provides for comprehensive oversight of outsourcing facilities, which seek to compound and distribute sterile drugs and products to hospitals and medical practices without first obtaining patient-specific prescriptions. Part D of Chapter 60 of the Laws of 2014 conforms the Education Law to the requirements of DQSA.

The proposed amendment was adopted as an emergency action at the June 23-24, 2014 Regents meeting, effective June 29, 2014, and has now been adopted as a permanent rule at the September 15-16, 2014 Regents meeting. Pursuant to SAPA section 203(1), the earliest effective date of the proposed amendment is October 1, 2014, the date a Notice of Adoption will be published in the State Register. However, the emergency rule will expire on September 22, 2014. If the rule were to lapse, some outsourcing facilities seeking to prepare and/or distribute compounded sterile drugs and products in New York may not be on notice of the compliance and registration requirements for such facilities in this State, which may put the safety of compounded

drugs in this State's pharmaceutical supply chain at risk. To avoid the adverse effects of a lapse in the emergency rule, a second emergency action at the September 2014 Regents meeting is necessary for the preservation of the public health and general welfare to ensure that the proposed rule adopted by emergency action at the June Regents meeting to implement Part D of Chapter 60 of the Laws of 2014 remains continuously in effect until the effective date of its permanent adoption, so that outsourcing facilities seeking to prepare and/or distribute compounded sterile drugs and products in New York will be on notice of the compliance and registration requirements for such facilities in this State.

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 September 22, 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):

(1) …

(2) …

(3) …

(4) …

(5) …

(6) …

(7) …

(8) …

(9) …

(10) …

(11) …

(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:

(i) . . .

(ii) . . .

(iii) . . .

(iv) . . .

(v) . . .

(vi) . . .

(vii) . . .

(viii) . . .

(ix) . . .

(x) . . .

(xi) . . .

(xii) . . .

(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 September 22, 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 September 22, 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 September 22, 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 September 22, 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.