Requirements for Manufacturers and Distributors Regarding Controlled Substances

Effective date: 8/10/16

Pursuant to the authority vested in the Commissioner by Public Health Law Section 3308(2), section 80.11 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, is amended to read as follows, effective upon publication of a Notice of Adoption in the New York State Register:

80.11 Additional requirements for manufacturers and distributors. In addition to the requirements set forth in article 33 of the Public Health Law, holders of licenses shall comply with the following requirements:

(a) [Except as hereinafter provided, no person shall obtain a class 1 or 2 license for controlled substances unless he or she employs a full-time pharmacist and, except as hereinafter provided, no licensed activity shall be conducted by a holder of a class 1 or 2 license unless such activity is under the personal supervision of a chemist or pharmacist.] A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is intended for human or animal consumption and presents a potential for abuse, must employ a full-time pharmacist and the licensed controlled substance activity must be under the personal supervision of a pharmacist or a chemist. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health. A chemist is a person who meets the following requirements:

(1) possess a bachelor of science or a bachelor of arts degree in chemistry, pharmacology or equivalent specialization and have had not less than four years of experience in the manufacture of drug products;

(2) be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States;

(3) be of the age of 21 years or older;

(4) be of good moral character and, if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no person shall be deemed not to be a chemist on account of having been previously convicted of one or more criminal offense unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the position or (ii) deeming the person a chemist would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In addressing these questions, the Department shall evaluate all factors listed under New York State Correction Law Section 753; and

(5) not be, and not have been, a habitual user of narcotics or any other habit-forming drugs.

(b) [A manufacturer who produces a final product that by its composition or combination with other ingredients is not intended for human or animal consumption and does not present a potential for abuse, may employ either a full-time pharmacist or a person who meets the following requirements:

(1) possess a bachelor of science or a bachelor of arts degree in chemistry, pharmacology or equivalent specialization and have had not less than four years of experience in the manufacture of drug products;

(2) be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States;

(3) be of the age of 21 years or over;

(4) be of good moral character as attested to by affidavits signed by either the sheriff of the county of residence, local police officials, or other such persons acceptable to the department;

(5) not have been convicted of a misdemeanor or felony by any court of the State of New York, or by any court of the United States or of any other state; and

(6) not be, and not have been, a habitual user of narcotics or any other habit-forming drugs.]

A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is not intended for human or animal consumption and does not present a potential for abuse, must employ either a full-time pharmacist or a full-time chemist and the licensed activity in which he or she is engaged must be under the supervision of either a pharmacist, or a chemist, as defined in subdivision (a) of this section. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health.

(c) [A distributor who does not bottle or rebottle, pack or repack, label or relabel, controlled substances may obtain a class 2 license, provided that the licensed activity in which he is engaged is conducted under the supervision of a pharmacist or person approved by the department. A person not a pharmacist shall meet the following requirements:] An applicant for licensure who is a registered outsourcing facility pursuant to Title 8 of the Education Law and who compounds controlled substances not pursuant to a patient specific prescription shall be deemed as conducting manufacturing activities of controlled substances. Manufacturing

activities shall be conducted under the personal supervision of a licensed pharmacist. An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who bottles or rebottles, packs or repacks, labels or relabels, controlled substances shall be deemed as conducting class 1 manufacturing activities of controlled substances and subject to the requirements of subdivision (a) of this section. An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who does not bottle or rebottle, pack or repack, label or relabel, controlled substances may obtain a class 2 distributor license, provided that the licensed activity in which he or she is engaged is conducted under the personal supervision of a pharmacist or a person approved by the department. The supervisor shall not be at the same time a supervisor of any other establishment registered by the New York State Board of Pharmacy. A person not a pharmacist shall meet the following requirements:

(1) possess a high school diploma, or the equivalent thereof;

(2) be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States;

(3) be of the age of 21 years or over;

(4) [be of good moral character as attested to by affidavits signed by either the sheriff of the county of residence, local police officials, or other such persons acceptable to the department;

(5) not have been convicted of a misdemeanor or felony by any court of the State of New York, or by any court of the United States or of any other state] be of good moral character and if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no distributor license shall be denied by reason of the applicable employee having been previously convicted of one or more criminal offenses unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the

license or (ii) licensing the applicant would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In determining these questions, the agency will look at all factors listed under New York State Correction Law Section 753;

[(6)] (5) not be, and not have been, an habitual user of narcotics or other habit-forming drugs; and

[(7)] (6) have had not less than eight years of experience in the wholesaling of controlled substances, or such other experience determined by the department to be the equivalent thereof.

(d) Persons conducting manufacturing activities of controlled substances within the State of New York shall obtain a class 1 license from the department.

(e) Persons conducting manufacturing activities of controlled substances outside of the State of New York and doing business within the State of New York shall obtain a class 1a license from the department. A class 1a license applicant shall meet the following requirements:

(1) the out-of-state manufacturer possesses a valid New York State Board of Pharmacy registration or exemption; and

(2) the out-of-state manufacturer possesses a valid U.S. Drug Enforcement Administration registration; and

(3) based on the application, the commissioner is satisfied that the out-of-state manufacturer will be able to maintain effective control against diversion of controlled substances.

(f) Persons conducting distributing activities of controlled substances within the State of New York shall obtain a class 2 license from the department, except that;

(1) Except in an adult care facility subject to provisions of Title 18 NYCRR Parts 487, 488 and 490, a pharmacy may distribute a controlled substance to a practitioner in a Class 3a institutional dispenser limited solely for stocking in sealed emergency medication kits. Such distribution shall be pursuant only to a written request by the Class 3a facility indicating the name and address of the facility, the name and address of the pharmacy, the date of the request, the type and quantity of the drug requested and the signature of the authorized person making the request. With each distribution, the pharmacy shall provide the Class 3a facility with an itemized list indicating the name and address of the pharmacy, the name and address of the Class 3a facility, the date of the distribution, the type and quantity of the drug distributed, and the signature of the pharmacist.

(g) Out-of-State persons conducting distributing activities of controlled substance to persons within the State of New York shall obtain a class 2a license from the department. A class 2a license applicant shall meet the following requirements:

(1) the out-of-state distributor possesses a valid New York State Board of Pharmacy registration or exemption; and

(2) the out-of-state distributor possesses a valid U.S. Drug Enforcement Administration registration; and

(3) based on the application, the commissioner is satisfied that the out-of-state distributor will be able to maintain effective control against diversion of controlled substances.

(h) All persons authorized to manufacture or distribute controlled substances shall accept returns of such controlled substances manufactured or distributed by them, and either destroy them or provide for the return, disposition, and disposal of such controlled substances in a manner approved by the Department pursuant to section 80.51(c)(2).

(i) An individual who is designated as the supervisor of controlled substance activity pursuant to subdivisions (a), (b) or (c) of this section shall be responsible for the following non-delegable tasks:

(1) maintaining all required records relating to the purchase and distribution of all controlled substances manufactured or repacked at that facility;

(2) providing for the proper storage of controlled substances in order to prevent loss or theft;

(3) assuring security and limiting access to all areas holding controlled substances;

(4) insuring against all unauthorized sales or distribution of controlled substances to establishments or professionals not authorized to receive such items;

(5) issuing verbal and written notice to each of his or her subordinates concerning the applicable state and federal laws, regulations and rules to ensure full compliance;

(6) for manufacturers, assuring that all Good Manufacturing Procedures as outlined by the FDA are followed; and

(7) for manufacturers engaged in compounding of controlled substances, assuring that all controlled substances are compounded under the personal supervision of a licensed pharmacist.

REGULATORY IMPACT STATEMENT

Statutory Authority:

PHL 3308 authorizes the Commissioner to promulgate regulations which are necessary and proper to supplement the provisions of Article 33 to effectuate its purposes and intent. Additionally, PHL 3390 authorizes the Commissioner to revoke a license or certificate issued under Article 33 in whole or in part upon a finding that the licensee or certificate holder has been convicted in any jurisdiction relating to a substance listed as a controlled substance in Article 33. PHL 3312 contains the licensure requirements for manufacturers and distributors of controlled substances. It requires applicants to demonstrate that they are of good moral character and to report whether they have any convictions relating to or arising out of the manufacture or distribution of drugs.

Legislative Objectives:

The purpose of PHL Article 33 is to prevent the illegal use of and trade in controlled substances and to provide for the legitimate use of controlled substances in health care.

Needs and Benefits:

The current section 80.11is amended to ensure consistency with Correction Law Article 23-A's balancing test that is used when reviewing application forms for applicants and existing providers who have criminal convictions.

The proposed regulations also clarify when a chemist and/or pharmacist is required to be

employed, on-site, or in a supervisory position. Language is also updated to provide consistency with the State Education Department State Board of Pharmacy registration requirements.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

The proposed rule does not impose any new costs on the regulated parties.

Cost to State and Local Government:

There will be no costs to the general public, state and local government.

Cost to the Department of Health:

The Department of Health will not incur any additional costs.

Local Government Mandates:

These provisions do not add any additional mandates to local governments

Paperwork:

The regulation proposes no new reporting or filing requirements.

Duplication:

This measure does not duplicate, overlap or conflict with a State or federal statute or rule.

Alternative Approaches:

There are no other viable alternative approaches.

Federal Requirements:

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

This proposal will go into effect upon publication of a Notice of Adoption in the New York *State Register*.

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STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.