

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION

Pursuant to sections 207, 6504, 6506, 6507, 6808, 6809 and 6810 of the Education Law.

1. Subdivision (b) of section 63.6 is amended by adding paragraph (10) to read as follows:

(10) Central fill pharmacies.

(i) For the purposes of this section:

(a) An *originating pharmacy* means a pharmacy that receives prescriptions and utilizes the services of a central fill pharmacy to prepare and fill those prescriptions prior to dispensing to the patient.

(b) A *central fill pharmacy* means a pharmacy registered for the sole purposes of preparing and filling prescriptions for an originating pharmacy and subsequently delivering such filled prescriptions to the originating pharmacy for dispensing to the patient.

(ii) General requirements.

(a) A pharmacy operated as a central fill pharmacy shall be registered in accordance with this section and:

(1) shall provide services only to originating pharmacies of the same ownership, or to other originating pharmacies for which there is a written contract that outlines the services provided and shared responsibilities of each pharmacy participating in central fill;

(2) shall only prepare and fill prescriptions sent from an originating pharmacy;

(3) shall not be open to the public;

(4) shall not deliver or dispense filled prescriptions directly to patients;

(5) shall not prepare compounded medications; and

(6) shall not prepare controlled substances as defined in Article 33 of the Public Health Law.

(iii) Operations. A central fill pharmacy together with each originating pharmacy for which it provides services shall:

(a) be jointly responsible for properly processed and filled prescriptions;

(b) share a common electronic file or technology that allows access to information necessary or required to perform central fill processes in conformance with all applicable state and federal statutory and regulatory requirements;

(c) maintain a system that adequately protects the confidentiality and integrity of patient information;

(d) maintain a mechanism for tracking the prescription order during each step of the process including, but not limited to, the names of each individual, and license or registration numbers if applicable, taking part in each step of the process;

(e) ensure that the originating pharmacy obtains the consent of the patient, or the patient's authorized representative, in writing that a prescription may be prepared by a central fill pharmacy on behalf of the originating pharmacy. Such consent must be obtained prior to the dispensing of a prescription for the first time to a new patient of the originating pharmacy or a prescription for a new medication for an existing patient of the originating pharmacy and/or a change in the dose, strength, route of administration or directions for use of an existing prescription previously dispensed for an existing patient

of the originating pharmacy. Nothing in this clause shall prohibit a patient from opting-out of having their prescriptions filled via a central fill pharmacy at any time.

**Question: Is a blanket waiver appropriate or should consent be obtained for each applicable prescription?**

(f) ensure that patients are made aware that part or all of their prescription may be filled off-premises using signage conspicuously posted at or adjacent to the place in the originating pharmacy where prescriptions are presented for compounding and dispensing, in the waiting area for customers, or in the area where prescribed drugs are dispensed;

**Questions: Should the sign be required to have print of a certain font / imprint? Should the sign include the address of the Central Fill facility that is being utilized?**

(g) ensure that all prescription labels, in addition to the standardized patient-centered data elements for the originating pharmacy as set forth in section 63.12 of this Part, also identify that the prescription was filled by and include the address of the central fill pharmacy.

**Question: What are the Board's thoughts on this amendment that would include both the central fill pharmacy's address and advise that the prescription was filled at the central fill pharmacy?**

(h) ensure that drugs stored at central fill pharmacies are only accessible to authorized personnel;

(i) ensure that drugs are stored and transported in a secure manner and in compliance with all applicable state and federal requirements;

(j) ensure that the originating pharmacy is responsible for the requirements for the patient profile and counseling provisions set forth in paragraphs (7) and (8) of this subdivision;

(k) maintain a mechanism that allows the originating pharmacy to prepare and dispense a prescription to a patient when the filled prescription has not been received from the central fill pharmacy or if the patient seeks to pick-up the prescription at the originating pharmacy before the originating pharmacy has received the prescription from the central fill pharmacy for dispensing.

(l) maintain all records for a period of five years following the date of most recent entry and shall make such records available to the department for review and copying upon request; and

(m) jointly develop and implement written policies and procedures for central fill processing that shall include, but not be limited to:

(1) a description of the roles and responsibilities of each central fill pharmacy and originating pharmacy;

(2) an accurate and up to date listing of the name, address, telephone numbers, and all registration numbers of all the pharmacies involved in the preparation and processing of prescriptions; and

(3) policies and procedures for meeting each of the requirements set forth in clauses (a) through (l) of this subparagraph.

(iv) A pharmacy engaging in activities that fit within the definition of a central fill pharmacy set forth in this subdivision that was registered prior to the effective date of this paragraph, on the basis of meeting requirements different from those specified in this paragraph shall be required to meet the requirements of this paragraph no later than twelve months after the effective date.

2. Paragraphs (22) and (23) of subdivision (a) of section 29.7 of the Regulations of the Commissioner of Education are added, to read as follows:

(22) Failure of a pharmacy operating as central fill pharmacy or originating pharmacy as defined in paragraph (10) of subdivision (b) of section 63.6 to adhere to the requirements set forth in such paragraph.

(23) Failure of a pharmacy operating as central fill pharmacy or originating pharmacy as defined in paragraph (10) of subdivision (b) of section 63.6 to maintain adequate records and policies in accordance with the requirements set forth such paragraph.

**Additional Questions:**

- **Does the Board have any other recommendations/comments regarding these draft regulations?**
- **Are there any elements regarding Central Fill that are missing from the current draft but that should be given consideration?**
- **Are there any other issues or considerations regarding Central Fill that should be noted or flagged for review by the State Education Department?**