



TO: Professional Practice Committee
FROM: Sarah S. Benson *Sarah S. Benson*
SUBJECT: Proposed Amendment of Section 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 Relating to the Registration and Operation of Central Fill Pharmacies
DATE: June 1, 2023
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SUMMARY

Issue for Discussion

Should the Board of Regents amend section 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 relating to the registration and operation of central fill pharmacies?

Reason for Consideration

Review of policy.

Proposed Handling

The proposed amendment will be presented to the Professional Practice Committee for discussion at the June 2023 meeting of the Board of Regents. A copy of the proposed amendment is attached (Attachment A).

Procedural History

A Notice of Proposed Rulemaking will be published in the State Register on June 28, 2023, for a 60-day public comment period. Supporting materials are available upon request from the Secretary to the Board of Regents.

Background Information

The practice of pharmacy, including the registration and operation requirements for pharmacy establishments, are set forth in Article 137 of the New York State Education Law, Part 29 of the Regents Rules and Part 63 of the Commissioner's regulations.

Over the past several years, the practice of pharmacy has evolved to include increased direct patient care responsibilities, such as administering immunizations and medications. At the same time, the methods by which pharmacies operate to provide patient services have also evolved to incorporate new technologies and new business models. Utilizing the services of a "central fill pharmacy" to prepare and fill prescriptions prior to the pharmacy dispensing them to a patient is one such model.

In a central fill model, a pharmacy that receives an original prescription from an authorized prescriber (sometimes referred to as the "originating pharmacy"), would be responsible for prescription intake processes, such as data entry, drug utilization review, prescription data verification, etc., and would then transmit the prescription information to the central fill pharmacy. The central fill pharmacy would then prepare (fill, label, verify the medication, and package the prescription) the prescribed medication for distribution back to the originating pharmacy where the prescription would be dispensed to the patient.

Establishing clear parameters for the central fill pharmacy model through regulation will allow New York State registered pharmacies the ability to access this model, if they so choose. In addition, regulation of this model would assist in maintaining sound public health, safety, and consumer protections. Thus, the Department, with assistance from the New York State Board of Pharmacy, has developed the proposed amendments to Part 29 of the Regents Rules and Part 63 of the Commissioner's regulations.

Proposed Amendments

The proposed amendments to Part 63.6 of the Commissioner's regulations:

- Establish the following definitions for originating and central fill pharmacies to clearly delineate their respective roles and responsibilities:

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.

Central fill pharmacy means a pharmacy registered for the 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.

- Establish general requirements for the registration and operation of central fill pharmacies.

- Establish operational requirements for which originating and central fill pharmacies are jointly responsible for their respective roles in the preparation and dispensing of prescriptions.
- Require originating pharmacies that are currently utilizing central fill pharmacies, and pharmacies that are currently operating as central fill pharmacies, to provide notice to the Department of such activities within thirty days of the regulations effective date.
- Provide for a twelve-month phase-in period for originating pharmacies that are utilizing central fill pharmacies and central fill pharmacies to come into compliance with the requirements of the regulations.
- Establish that originating or central fill pharmacies that fail to meet the requirements of section 63.6 after the twelve-month phase-in period may be denied registration renewal.

The proposed amendments to Part 63.8 of the Commissioner's regulations:

- Require non-resident pharmacies that provide central fill activities on behalf of registered pharmacies located in New York State to meet the same operational requirements as central fill pharmacies located in New York State, including, but not limited to, the notice to the Department requirements and possible denial of registration renewal for failure to meet the operational requirements set forth in section 63.6(b)(10)(iii).

The proposed amendments to Part 29 of the Rules of the Board of Regents:

- Establish that it is professional misconduct for a resident or non-resident pharmacy operating as a central fill pharmacy or an originating pharmacy engaged in central fill activity with a central fill pharmacy to fail to adhere to the requirements set forth in section 63.6 of the Commissioner's regulations.

Recommendation

Not Applicable.

Timetable for Implementation

It is anticipated that the proposed amendment will be presented for adoption at the October 2023 Regents meeting, after publication of the proposed amendment in the State Register and expiration of the 60-day public comment period required under the State Administrative Procedure Act. If adopted at the October meeting, the proposed amendment will become effective as a permanent rule on November 1, 2023.

Attachment A

AMENDMENT TO THE REGULATIONS OF THE COMMISSIONER OF EDUCATION
Pursuant to sections 207, 6504, 6506, 6507, 6509, 6801, 6808, 6808-b, and 6810 of the
Education Law

1. Paragraph (10) is added to subdivision (b) of section 63.6 of the Regulations of
the Commissioner of Education 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 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 pharmacy operated as a central fill pharmacy shall
be registered in accordance with this section and shall:

(a) 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;

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

(c) not be open to the public;

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

(e) not prepare medications that require compounding; and

(f) 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 shall 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;

(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. Such sign shall state in bold, block letters at least one inch in height that pending a patient's consent a prescription may be filled offsite by a central fill pharmacy and shall include the central fill pharmacy's registered name and registration number;

(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 the central fill pharmacy at which the prescription was filled, including its registered name and registration number;

(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 statutory and regulatory 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 originating and central fill 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 paragraph that was registered prior to the effective date of this paragraph, shall provide notice to the department of such activities no later than 30 days from the effective date of this paragraph, and shall be required to meet the requirements of this paragraph no later than twelve months after such effective date. Failure to meet the requirements of this paragraph within twelve months of the effective date may result in a denial of renewal of registration.

(v) After twelve months from the effective date of this paragraph, no establishment registered under this Part shall engage in central fill services unless they have met all the requirements of this paragraph and are registered with the department for such purpose.

2. Paragraph (6) of subdivision (b) of section 63.8 is amended by adding subparagraph (iii) to read as follows:

(iii) Central fill pharmacies. Nonresident establishments that are pharmacies and are operated as central fill pharmacies that prepare and fill prescriptions on behalf of in-state pharmacies registered pursuant to 63.6 of this Part, shall comply with the requirements set forth in subparagraphs (iii), (iv), and (v) of paragraph (10) of section 63.6 of this Part.

3. Subdivision (a) of section 29.7 of the Rules of the Board of Regents is amended by adding a new paragraph (22) 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.