

4729:5-9-02.13

Institutional central fill pharmacies.

(A) As used in this section:

- (1) "Central fill pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs acting as an agent of an originating pharmacy to fill or refill a medication order. A central fill pharmacy may be used to replenish automated drug storage systems and automated pharmacy systems.
- (2) "Originating pharmacy" means an institutional pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill medication order. A central fill pharmacy may be used to replenish automated drug storage systems and automated pharmacy systems.

(B) A central fill pharmacy and originating pharmacy may process a request for the filling or refilling of a medication order received by an originating pharmacy pursuant to the following requirements:

- (1) The central fill pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law, rules and regulations.
- (2) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a medication order received by the originating pharmacy. The record shall be made readily retrievable and maintained for a period of three years.
- (3) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the medication order.
- (4) The originating pharmacy shall comply with the minimum required information for a patient profile pursuant to rule 4729:5-9-02.5 of the Administrative Code prior to sending a medication order to the central fill pharmacy.
- (5) The originating pharmacy shall remain responsible for compliance with the dangerous drug dispensing requirements of this chapter and the compounding requirements of chapter 4729:7-2 of the Administrative Code that are not assumed in writing by the central fill pharmacy.

- (6) The prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order.
- (7) The originating pharmacy shall maintain the original of all medication orders received for purposes of filing and record keeping as required by state and federal law, rules, and regulations.
- (8) The central fill pharmacy shall maintain all original fill and refill requests received from the originating pharmacy and shall treat them as original and refill medication orders for purposes of filing and record keeping as required by state and federal law, rules, and regulations.
- (9) The central fill pharmacy and originating pharmacy shall each maintain records to capture the positive identification of the licensed or registered individuals responsible for performing respective activities in accordance with rule 4729:5-9-02.3 of the Administrative Code.
- (10) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.
- (C) Dangerous drugs may be returned by the originating pharmacy to the central fill pharmacy for the purpose of being returned to the central fill pharmacy's stock shelves in accordance with the following:

 - (1) The central fill pharmacy complies with the requirements of rule 4729:5-3-16 of the Administrative Code; and
 - (2) The originating and central fill pharmacy are under common ownership and control.
- (D) An originating pharmacy may return dangerous drugs received by a central fill pharmacy to stock shelves in accordance with rule 4729:5-3-16 of the Administrative Code.
- (E) All written documentation required by this rule shall be maintained for three years from the date of execution or review and shall be made readily retrievable.

(F) An institutional pharmacy may utilize a central fill pharmacy to dispense outpatient prescriptions in accordance with rule 4729:5-5-19 of the Administrative Code.

(G) Drugs that are repackaged or relabeled by a central fill pharmacy shall comply with the requirements of rule 4729:5-9-02.12 of the Administrative Code.

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Certification

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Date

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