

4729-5-28

Central fill pharmacies.**(A) As used in this rule:**

(1) "Central fill pharmacy" means a pharmacy or central filling operation licensed as a terminal distributor of dangerous drugs acting as an agent of or under contract with an originating pharmacy to fill or refill a prescription. A central fill pharmacy may also be the originating pharmacy pursuant to paragraph (L) of this rule.

(2) "Originating pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription order and pursuant to paragraph (O) of rule 4729-5-01 of the Administrative Code.

(B) An originating pharmacy may outsource prescription filling or refilling to a central fill pharmacy provided the pharmacies have the same owner or the pharmacies have entered into a written contract or agreement. The contract or agreement shall outline the services to be provided and the responsibilities and accountability of each pharmacy to comply with federal and state laws, rules and regulations.

(C) A central fill pharmacy and originating pharmacy shall comply with all applicable federal laws and regulations, including those specified in Federal Register Citation 68 FR 37405 (July 24, 2003.)

(D) The originating and central fill pharmacies must 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 prescription.

(E) An originating pharmacy using a central fill pharmacy is responsible for maintaining records of the processing of all prescriptions entered into its information system including prescriptions filled or refilled at a central fill pharmacy. The pharmacist at the originating pharmacy must comply with the minimum required information for a patient profile pursuant to rule 4729-5-18 of the Administration Code prior to sending a prescription to the central fill pharmacy. The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

(F) The prescription label of a centrally filled prescription shall display the name and address of the originating pharmacy, pursuant to paragraphs (A)(1) and (A)(10) of rule 4729-5-16 of the Administrative Code. The label shall also display the name of the central fill pharmacy.

(G) The serial number used by the central fill pharmacy shall be the same as the originating pharmacy if in accordance with paragraph (D) of rule 4729-5-19 of the Administrative Code.

(H) Unless the central fill pharmacy operates pursuant to paragraph (L) of this rule, the originating pharmacy shall designate staff members to be responsible for signing for the receipt of prescriptions delivered from the central fill pharmacy. The receipt must be maintained as part of the prescription records.

(I) All central fill pharmacies providing central prescription filling processing services to pharmacies in Ohio shall be licensed as a terminal distributor of dangerous drugs.

(J) The originating pharmacy and central fill pharmacy shall maintain a policy and procedure manual, which shall be available for inspection by a state board of pharmacy designated agent. The manual shall include all of the following:

(1) Outline the responsibilities of each of the pharmacies;

(2) Include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies participating in the central fill prescription filling; and

(3) Include policies and procedures for:

(a) Protection of the confidentiality and integrity of patient information;

(b) Maintenance of appropriate records to identify the method(s) of positive identification used, as defined in paragraph (N) of rule 4729-5-01 of the Administrative Code, and specific activity(ies) of each pharmacist who performed any processing;

(c) Compliance with federal and state laws, rules and regulations;

(d) Operation of a continuous quality improvement 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, and resolve identified problems; and

(e) Annual review of the written policies and procedures and documentation of such review.

(K) No medication shall be returned to the central fill pharmacy by the originating pharmacy. This paragraph does not apply if a central fill pharmacy operates in accordance with paragraph (L) of this rule and the dangerous drugs have not left the custody of the central fill pharmacy.

(L) A central fill pharmacy may dispense a prescription directly to a patient pursuant to the following requirements:

- (1) A drug utilization review is conducted pursuant to a written contract or agreement in accordance with rule 4729-5-20 of the Administrative Code and is appropriately documented by a pharmacist using positive identification as defined in rule 4729-5-01 of the administrative code;
- (2) Patient counseling is provided pursuant to a written contract or agreement in accordance with rule 4729-5-22 of the Administrative Code;
- (3) The dispensing software shall utilize positive identification as defined in rule 4729-5-01 of the administrative code to distinguish between the practice of pharmacy conducted at the central fill pharmacy, the originating pharmacy and any contracted location;
- (4) The dispensing is conducted in accordance with all applicable state and federal laws, regulations and rules.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

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