

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part LIII: Pharmacists

Chapter 11. Pharmacies

Subchapter D. Off-Site Services

§1139. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise.

Centralized Prescription Dispensing—the fulfillment by one permitted pharmacy of a request from another permitted pharmacy to fill or refill a prescription drug order. ~~The fulfillment necessarily includes return of the labeled and filled prescription to the on site pharmacy for delivery to the patient.~~

On-Site Pharmacy—a permitted pharmacy which utilizes centralized prescription dispensing services from a remote dispenser or remote processing services from a remote processor.

Remote Dispenser—a Louisiana permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.

Remote Processing Services—the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

- a. receipt, interpretation, or clarification of an order;
- b. data entry and information transfer;
- c. interpretation of clinical data;
- d. performance of drug utilization review; and
- e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.

Remote Processor—a Louisiana-permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR 39:313 (February 2013).

§1141. Centralized Prescription Dispensing

A. General Requirements

1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote dispenser provided the pharmacies:

- a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
- b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.

2. Labeling. The remote dispenser shall label the container in compliance with Section 2527 of this Part, using the on-site pharmacy's information. The label shall also include the remote dispenser's name and either its Louisiana pharmacy permit number or DEA registration number, indicating that the prescription was filled at the remote dispenser. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

3. Audit Trail Information. The remote dispenser and on-site pharmacy shall maintain a complete audit trail identifying pharmacy personnel involved in the dispensing process.

4. Delivery Between Remote Dispenser and On-Site Pharmacy. Delivery of prepared prescriptions between the remote dispenser and the on-site pharmacy is permissible using a common carrier, contract carrier, or pharmacy employee. Proper safeguards shall be in place to ensure the integrity of the medication — preserving its safety, identity, strength, quality, and purity throughout the delivery process.

a. Standards. The pharmacy shall ensure that all prescription drugs are delivered in compliance with nationally recognized standards, including those established by the manufacturer or the United States Pharmacopeia (USP).

b. Packaging. Prescription drugs delivered by a common or contract carrier shall be enclosed in tamper-evident packaging.

c. Temperature Control. Throughout the delivery process, prescription drugs shall be maintained within the temperature range specified by the United States Pharmacopeia (USP) or as recommended by the manufacturer, with allowances for permitted excursions.

d. Possession and Control. When a pharmacy relinquishes physical possession and control of a prescription drug during delivery, the drug shall not be returned to the pharmacy for reuse.

i. Common or Contract Carrier. In the absence of a formal agreement with a common or contract carrier granting the pharmacy control during transit, the prescription drug shall not be returned to the pharmacy for reuse.

ii. Pharmacy Employee. When a pharmacy employee delivers a prescription drug, the pharmacy retains physical possession and control of the medication throughout the delivery process.

f. Compromised Product. If a pharmacist determines a prescription drug is in any way compromised during delivery, it shall not be dispensed.

5. The on-site pharmacy shall return to the remote dispenser prepared prescriptions not dispensed to the patient, if the pharmacies do not have the same owner.

6. Centralized prescription dispensing of controlled substances shall comply with all applicable provisions of 21 CFR Parts 1300 - 1399.

B. Policies and Procedures

1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized dispensing services shall maintain a policy and procedure manual for reference by all personnel; it shall be made available for inspection and copying by the board.

2. At a minimum, the manual shall include policies for:

- 75 a. a description of how the parties will comply with federal and state laws and regulations;
- 76 b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and
- 77 counseling processes;
- 78 c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing
- 79 process;
- 80 d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the
- 81 dispensing the prescription drug order; and
- 82 e. the provision of adequate security to protect the confidentiality and integrity of patient information and to
- 83 prevent its illegal use or disclosure.

84 AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

85 HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007),

86 amended LR