

Final Rule

Department of Health and Hospitals Board of Pharmacy

Controlled Dangerous Substances in Emergency Drug Kits

In accordance with the provisions of the Administrative Procedure Act (La. R.S. 49:950 *et seq.*) and the Pharmacy Practice Act (La. R.S. 37:1161 *et seq.*), the Louisiana Board of Pharmacy has amended its rules to authorize pharmacies utilizing emergency drug kits at long term care facilities to place a portion of its inventory of controlled dangerous substances within such kits.

Malcolm J Broussard
Executive Director
Louisiana Board of Pharmacy

Louisiana Administrative Code

Title 46 – Professional and Occupational Standards

Part LIII: Pharmacists

Chapter 17. Institutional Pharmacy

...

Subchapter B. Emergency Drug Kits

...

§1713. Emergency Drug Kit Requirements

A.– I. ...

J. The placement of controlled dangerous substances in an EDK in non-federally registered long term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:

1. Controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;
2. The source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the Board in possession of a valid DEA registration and Louisiana CDS license.
3. The number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight (8) separate drug entities with not more than eight (8) single-use containers of each drug entity.
4. The EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet.
5. Access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty.
6. Controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors.
7. A usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK.
8. The pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years.
9. When the EDK is opened:
 - a. The pharmacist shall be notified by the facility within 24 hours; and
 - b. Shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
10. Shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed.
11. The pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

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

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended LR 39:312 (February 2013).

...

Chapter 27. Controlled Dangerous Substances

...

Subchapter F. Production, Distribution and Utilization

...

§2743. Procurement Requirements

- A. ...
- B. ...
- C. Acquisition of Controlled Dangerous Substances by Institutional Facilities
 - 1. A Louisiana licensed pharmacy in possession of a valid Louisiana CDS license and DEA registration may include a portion of its controlled dangerous substance inventory within an emergency drug kit (EDK) placed in a non-federally registered institutional facility, but only under the following conditions:
 - a. The EDK bears a valid EDK permit issued by the board; and
 - b. The inclusion and management of controlled dangerous substances in such EDK shall comply with the provisions of Section 1713.J of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2148 (October 2008), amended LR 39:313 (February 2013).