



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

NOV 30 2016

Arnold E. Clayman, PD, FASCP
Vice President of Pharmacy Practice & Government Affairs
American Society of Consultant Pharmacists
1321 Duke Street
Alexandria, Virginia 22314-3563

Dear Mr. Clayman:

This responds to your letter dated June 9, 2016, to the Drug Enforcement Administration (DEA), which was submitted as a follow-up to a meeting between the DEA and the American Society of Consultant Pharmacists (ASCP) on May 25, 2016, regarding the use of electronic emergency kits in Long Term Care Facilities (LTCFs). In your letter, you ask whether electronic emergency kits at LTCFs require a separate registration. The DEA appreciates the opportunity to address your inquiry.

As your letter points out, DEA issued a policy statement in 1980 addressing the use of emergency kits in LTCFs. 70 FR 24128 (April 9, 1980). In that document, DEA took the position that an emergency kit containing controlled substances may be placed in a "non-federal registered" LTCF if certain conditions were met. As DEA has not issued any Federal Register document rescinding that policy statement, it remains effective.

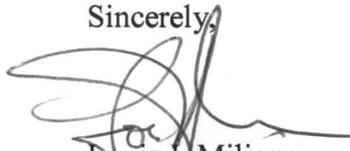
Your letter also refers to the DEA regulations relating to an Automated Dispensing System (ADS). As set forth in 21 CFR § 1301.27, a retail pharmacy that installs and operates an ADS at an LTCF must maintain a separate registration at that location.

All emergency kits – whether or not they are electronic – remain subject to the 1980 policy statement (and thus need not be separately registered), *provided they satisfy the criteria of the 1980 policy statement at all times*. Among other things, it is crucial to bear in mind that an emergency kit is only an emergency kit if it is used *exclusively for emergencies*. It also bears emphasis that, in accordance with the CSA and DEA regulations, a controlled substance may only be dispensed for emergency purposes (or otherwise) pursuant to a valid prescription. Thus, where, as in the scenario described in your letter, the kit is maintained at the LTCF by a pharmacy, controlled substances may not be dispensed from the kit for emergencies prior to receipt by the pharmacist of a valid prescription in accordance with the requirements of in 21 CFR §§ 1306.11 and 1306.21. As these sections of the regulations indicate, such prescription may, depending on the circumstances, be issued in writing (paper or electronic in accordance with part 1311), orally, or by fax. In addition, as you know, to be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice, and the pharmacist bears a corresponding responsibility therefor. 21 CFR § 1306.04(a).

If, at any time, a kit is used to administer or dispense controlled substances for a purpose other than an emergency, the kit thereafter ceases to be an emergency kit and, as a result, the separate registration requirement applies.

We trust this letter adequately addresses your inquiry. For information regarding the DEA Diversion Control Division, please visit www.DEAdiversion.usdoj.gov. If you have any additional questions on this issue, please contact the Diversion Control Division Liaison and Policy Section at (202) 307-7297.

Sincerely,

A handwritten signature in black ink, appearing to read "Louis J. Milione", with a stylized flourish extending to the right.

Louis J. Milione
Assistant Administrator
Diversion Control Division