

June 9, 2016

**SENT VIA ELECTRONIC MAIL**

*James.A.Arnold@usdoj.gov*

Mr. James Arnold  
Acting Chief  
Liaison & Policy Section  
Office of Diversion Control  
DEA Headquarters  
600 Army-Navy Drive  
Arlington, Virginia 22202

Re: Electronic Emergency Kit Guidance

Dear Mr. Arnold:

As we have discussed, there has been some confusion with some of the local Drug Enforcement Administration (“DEA”) Offices, state boards of pharmacy, and state departments of health about whether electronic emergency kits (automated cabinets or electronic systems which store emergency medications) at long term care facilities require a separate registration with DEA. Therefore, I am writing you to seek confirmation of this issue so that I can share it with our membership.

Pharmacies have traditionally maintained an emergency supply of medications at a long term care facility in order to meet the needs of the residents and ensure the availability of necessary medications for their care. These emergency medications, which are typically packaged in single unit dose containers, remain the property of the pharmacy until they have been dispensed or released per a physician order or prescription. These emergency supplies, commonly called emergency kits, or e-kits, are stored in a secure area, in a tamper resistant container. Use of medications from an emergency kit must be properly documented by the long term care facility as required by state boards of pharmacy, state health department regulations, or the regulations of other state agencies.

The DEA has long recognized the use of emergency kits in long term care facilities, which federally are non-registered locations with DEA. On April 8, 1980 the agency published a Statement of Policy titled, *Controlled Substances in Emergency Kits for Long Term Care Facilities*, which was in response to various inquiries about the use and handling of controlled substances in emergency kits for patients in long term care facilities (“Statement of Policy on E-kits”). The Statement of Policy on E-kits provides:

[www.ascp.com](http://www.ascp.com)

A pharmacy may place an emergency kit with controlled substances in a non-DEA registered Long Term Care Facility (LTCF), if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate:

1. The source from which the LTCF may obtain controlled substances for emergency kits and that the source of supply is a DEA-registered hospital/clinic, pharmacy, or practitioner.
2. The security safeguards for each emergency kit stored at the LTCF, including who may have access to the emergency kit, and specific limitation of the type and quantity of controlled substances permitted in the kit.
3. The responsibility for proper control and accountability of the emergency kit within the LTCF, including the requirement that the LTCF and the supplying registrant maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of the controlled substances, and the requirement to take and maintain periodic physical inventories.
4. The emergency medical conditions under which the controlled substances may be administered to LTCF patients, including the requirement that controlled substances be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 C.F.R. §§ 1306.11 and 1306.21.
5. The prohibited activities that if violated could result in state revocation, denial, or suspension of the privilege to supply or possess emergency kits containing controlled substances.

As previously mentioned, these emergency kits are generally kept in a tamper resistant container which resembles that of a tackle box. Traditionally, the emergency kit, or tackle box, will be sealed with some type of break-away tie to ensure proper control and accountability of the contents in accordance with the guidance above. Technological advances, however, are changing the way in which pharmacies store emergency supplies at the long term care facility. Automated cabinets and electronic systems have been designed and developed to act as storage containers for onsite emergency medications. These automated cabinets and electronic systems, also referred to as “electronic emergency kits,” provide the supplying pharmacy with a more secure way to control, account for, and track the use of emergency medications. These systems have numerous advantages and are becoming more prevalent in the industry, however there is some confusion as to whether they require a separate registration with DEA.

We have reviewed the Controlled Substances Act and DEA’s regulations, and it is our understanding that where a pharmacy utilizes an automated cabinet or electronic system solely for the storage of emergency medications at a long term care facility (just as they do today with a tackle box), a separate registration with DEA is not required for the placement of this electronic emergency kit. Rather, these systems, like a traditional tackle box-style emergency kit, are required to comply with DEA’s Statement of Policy on E-kits. Additionally, this approach is consistent with good policy as the DEA would want to encourage pharmacy providers to utilize a

more secure storage container that helps safeguard against diversion. If a separate registration was required for an electronic emergency kit, but not for a traditional tackle box emergency kit, it would serve as an obvious disincentive for pharmacies to use a more secure solution which provides for better control and accountability of controlled substances that are stored at the long term care facility.

It is also worth noting how electronic emergency kits vastly differ from automated dispensing systems<sup>1</sup> (“ADS”). Simply stated, an ADS is utilized by a pharmacy to dispense single dosage units each day to prevent the accumulation of controlled substances at the long term care facility. Unlike an electronic emergency kit which has only a few doses of each medications and is used solely for emergent situations, an ADS typically stores hundreds of doses, which may or may not be unit dosed, and provides *routine* prescriptions on an ongoing basis. The installation and operation of an ADS requires a registration with DEA pursuant to 21 CFR §1301.27. The DEA acknowledged in the ADS Final Rule<sup>2</sup> that it would be foreseeable for a pharmacy to provide an emergency supply of controlled substance medications through an ADS, however, such ADS would still require a separate registration because the activity of the system involves both routine and emergency medications. The same, however, is not true for an electronic emergency kit, as it cannot provide both routine and emergency medications. Rather by definition it can only provide emergency medications and thus does not require a registration. Therefore, the need for a registration is dependent on the activity of the device or system.

State boards of pharmacy have also drawn a distinction between automated dispensing systems and electronic emergency kits; whereas electronic emergency kits based on their limited activity are treated differently than automated dispensing systems. For example, in Maryland the regulations expressly provide that an interim box (another name for emergency kit) is not a ‘remote automated medication system’.<sup>3</sup> Additionally, in California the regulations make a distinction between activities as an emergency pharmaceutical supplies container (an emergency kit) and when used to provide routine pharmacy services.<sup>4</sup> While these distinctions made by the states have no bearing on the DEA’s interpretation of its guidelines and regulations, it illustrates that there is a recognized difference between the two in the industry and by regulators.

Based on the foregoing, we would like confirm with the DEA that where an automated cabinet or electronic system is used solely for the storage of emergency medications, and is no way utilized for the dispensation of routine or non-emergent medications, a separate registration with the DEA is not required.

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<sup>1</sup> An *automated dispensing system* is defined as “...a mechanical system that performs operations or activities, other compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.” 21 CFR §1300.01(b).

<sup>2</sup> Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities, 70 Fed. Reg. 92, 25462 (May 13, 2005).

<sup>3</sup> MD. CODE REGS. 10.34.28.02(B)(7)(b).

<sup>4</sup> CAL. HEALTH & SAFETY CODE §1261.6.

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Again, we would greatly appreciate your input on this issue. Should you require any additional information or have any questions related to this matter, please do not hesitate to contact me. Thank you in advance for your assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Arnold Clayman", with a long horizontal line extending to the right.

Arnold E. Clayman, PD, FASCP  
Vice President of Pharmacy Practice & Government Affairs